Equality Analysis

(Health Inequalities, Human Rights, Social Value)

Policy for the use of Image Guided Therapeutic Intra-Articular Joint Injections.

Before completing this equality analysis it is recommended that you:

- ✓ Contact your equality and diversity lead for advice and support
- ✓ Take time to read the accompanying policy and guidance document on how to complete an equality analysis

NHS Birmingham and Solihull Clinical Commissioning Group
NHS Sandwell and West Birmingham Clinical Commissioning Group

1. Background

EA Title	Image Guided Therapeutic Intra-Articular Joint Injections.		
EA Author	David King	**Team**	Equality & Diversity Team
Date Started	13/8/2019	**Date Completed**	04/12/2019
EA Version	4	**Reviewed by E&D**	

What are the intended outcomes of this work? Include outline of objectives and function aims

Arthritis refers to a clinical syndrome of joint pain accompanied by varying degrees of functional limitation and reduced quality of life. Arthritis is one of the leading causes of pain and disability worldwide. It is a chronic musculoskeletal disorder characterised by involvement of all joint structures including the synovial membrane, cartilage and bone. People with arthritis often have joint pain, reduced mobility, reduced participation in daily activities and poor quality of life [1].

The joints most commonly affected by arthritis are the knees, hips and small joints of the hand, although most joints can be affected. Pain, reduced function and effects on a person's ability to carry out their day-to-day activities can be important consequences of arthritis. Pain in itself is also a complex biopsychosocial issue, related in part to a person's expectations and self-efficacy (that is, their belief in their ability to complete tasks and reach goals), and is associated with changes in mood, sleep and coping abilities. There is often a poor link between changes visible on an X-ray and symptoms of arthritis: minimal changes can be associated with a lot of pain, or modest structural changes to joints can occur with minimal accompanying symptoms [2].

Contrary to popular belief, arthritis is not just caused by ageing and does not necessarily deteriorate. It is believed that a variety of traumas may trigger the need for a joint to repair itself which may result in a structurally altered but symptom-free joint. However, in some people, because of either overwhelming trauma or compromised repair, the process cannot fully compensate, resulting in eventual presentation with symptomatic arthritis; this might be thought of as 'joint failure'. This in part explains the extreme variability in clinical presentation and outcome that can be observed between people, and also at different joints in the same person [2].

Treatment options

A range of lifestyle, pharmacological, non-pharmacological, surgical and rehabilitation interventions are effective for controlling symptoms and improving function (NICE 2012). Conventional therapies include the use of simple analgesics, non-steroidal anti-inflammatory drugs, physical therapy and intra-articular (IA) corticosteroid administration [3].

NICE published Clinical Guideline (CG177) - Osteoarthritis: care and management in February 2014 [2]. The guidelines made the following recommendations regarding intra-articular injections;

- Intra-articular corticosteroid injections should be considered as an adjunct to core treatments for the relief of moderate to severe pain in people with osteoarthritis.

- Do not offer intra-articular hyaluronan injections for the management of osteoarthritis.

Intra-articular injections of corticosteroids have been used for several decades in the management of inflammatory and degenerative joint conditions when first line conservative therapies fail to provide adequate symptom relief [4].

Traditionally, intra-articular injections have been performed using anatomical landmarks to identify the correct trajectory for needle placement. However, different anatomical-guided injection techniques have yielded inconsistent intra-articular needle positioning due, in large part, to the fact that the physician cannot directly visualize the area of interest, and variations in anatomy are common. Incorrect needle placement has been partially associated with variable clinical outcomes.

Furthermore, inaccurate corticosteroid injections may result in complications such as post-injection pain, crystal synovitis, haemarthrosis, joint sepsis, necrosis, and steroid articular cartilage atrophy, as well as systemic effects, including fluid retention or exacerbation of hypertension or diabetes mellitus. Therefore, identification of methods and proper training to aid in correct needle placement during these procedures is warranted [4, 6].

The purpose of image guidance during corticosteroid joint injections is to allow visualisation, normally of the joint line typically in real time, so that the operator can achieve a more accurate and potentially safer and more effective injection [4, 5]. However clinical evidence demonstrates that visualisation of the joint line with image guidance only provides consistent improvement in injections techniques in the small joints of the hands and feet.

Who will be affected by this work? e.g. staff, patients, service users, partner organisations etc.

Therapeutic image guided intra-articular corticosteroid injections are **Restricted**.

Therapeutic image guided intra-articular corticosteroid injections should only be undertaken in the small joints (defined as joint of the hands & feet)

AND

Therapeutic image guided intra-articular corticosteroid injections should be offered ONLY to patients who have failed to respond to conventional pharmacological and non-pharmacological interventions due to the limited quality of evidence of the clinical and cost effectiveness of this intervention.

Pharmacological and non-pharmalogical interventions are defined as:

- Analgesics/nonsteroidal anti-inflammatory drugs (NSAIDs)
- Domestic exercise programme
- Supervised physiotherapy/manual therapy
- Non-image guided (palpated) steroid injections

N.B. Diagnostic image –guided injections are not within the remit of this policy.

This means **(for patients who DO NOT meet the above criteria)** the CCG will **only** fund the treatment if an Individual Funding Request (IFR) application proves exceptional clinical need and that is supported by the CCG.

Activity data:

Number of Procedures	BSOL	Sandwell
	1577	534

Due to limited data collection by the providers service activity data is available by headcount only not protected characteristic.
The Joint Strategic Needs Assessments for Birmingham, Solihull and Sandwell are available via the links below.

Sandwell

Birmingham

Solihull

2. Research

What evidence have you identified and considered? This can include national research, surveys, reports, NICE guidelines, focus groups, pilot activity evaluations, clinical experts or working groups, JSNA or other equality analyses.

Research/Publications	Working Groups	Clinical Experts
1. National Institute for Health and Clinical Excellence (NICE). Final Scope Osteoarthritis: the care and management of osteoarthritis. London, UK :NICE; 2012 https://www.nice.org.uk/guidance/cg177/documents/osteoarthritis-update-final-scope2 a. Last accessed 27 September 2018		

2. National Institute for Health and Clinical Excellence (NICE). Osteoarthritis: the care and management of osteoarthritis. Clinical Guideline 177. London, UK: NICE; 2014

3. Griesser MJ, Harris JD et al. Adhesive capsulitis of the shoulder: a systematic review of the effectiveness of intra-articular corticosteroid injections. J Bone Joint Surg Am 2011; 93: 1727-1733.

4. Berkoff DJ, Miller LE, Block JE. Clinical utility of ultrasound guidance for intra-articular knee injections: a review. Clin Interv Aging. 2012; 7:89-95.

5. Jüni P, Hari R et al. Intra-articular corticosteroid for knee osteoarthritis. Cochrane Database of Systematic Reviews 2015, Issue 10. Art. No.: CD005328

6. Nam SH, Kim J et al. Palpation versus ultrasound guided corticosteroid injections and short-term effect in the distal radioulnar joint disorder: A randomized, prospective single-blinded study. Clin Rheumatol 2013; 12:1807-1814.

7. Arthritis Research UK, Osteoarthritis in General Practice. 2013.

8. Wluka A, Lombard C, and Cicuttini F. Tackling obesity in knee osteoarthritis. Nature Reviews Rheumatology 2013; 9(4): 225-235.

9. Kearns K, Dee A et al. Chronic disease burden associated with overweight and obesity in Ireland: the effects of a small BMI reduction at population level. BMC Public Health 2014; 14(143)

10. Clemence P, Nguyen C et al. Risk factors and burden of osteoarthritis. Annals of Physical and Rehabilitation Medicine 2016 59 (3): 134–138.

11. Spector T and MacGregor A. Risk factors for osteoarthritis: genetics. Osteoarthritis and Cartilage 2004; 12: 39-44.

12. Berkoff DJ, Miller LE, Block JE. Clinical utility of ultrasound guidance for intra-articular knee injections: a review. Clin Interv Aging. 2012; 7:89-95

13. Jüni P, Hari R et al. Intra-articular corticosteroid for knee osteoarthritis. Cochrane Database of Systematic Reviews 2015, Issue 10. Art. No.: CD005328

14. Park KD, Kim TK et al. Palpation versus ultrasound-guided acromioclavicular joint intra-articular corticosteroid injections: a retrospective comparative clinical study. Pain Physician. 2015;18(4):333–341

15. Nam SH, Kim J et al. Palpation versus ultrasound guided corticosteroid injections and short-term effect in the distal radioulnar joint disorder: A randomized, prospective single-blinded study. Clin Rheumatol 2013; 12:1807-1814.

16. Sibbitt WL Jr, Band PA et al. A randomized controlled trial evaluating the costeffectiveness of sonographic guidance for intra-articular injection of the osteoarthritic knee. J Clin Rheumatol. 2011; 17(8):409–415.

17. Fraenkel L. Ultrasound (US)-Guided Versus Sham Ultrasound Corticosteroid (CS) Knee Injections. https://clinicaltrials.gov/ct2/show/NCT01032720

18. John Hopkins University. "Blind" vs. Fluoroscopy-Guided Steroid Injections for Knee Osteoarthritis. https://clinicaltrials.gov/ct2/show/NCT02104726

19. National Collaborating Centre for Chronic Conditions (UK). Osteoarthritis: National clinical guideline for care and management in adults. London: Royal College of Physicians (UK), 2008

20. Neogi T. The epidemiology and impact of pain in osteoarthritis. Osteoarthritis Cartilage 2013; 21: 1145-1153.

3. Impact and Evidence:

In the following boxes detail the findings and impact identified (positive or negative) within the research detailed above; this should also include any identified health inequalities which exist in relation to this work.

Age: Describe age related impact and evidence. This can include safeguarding, consent and welfare issues:

Age range data is not available for the profile of patients requesting the procedure. Some link may be identified between older patients and increased instances of joint pain, particularly in relation to arthritis.

As the treatment has been restricted, those who meet the criteria will be able to access treatment, who are the group who are deemed to benefit most. It is expected that patients not eligible would receive more suitable alternative treatment.

Disability: Describe disability related impact and evidence. This can include attitudinal, physical, communication and social barriers as well as mental health/ learning disabilities, cognitive impairments:

As with age, pain is itself a life limiting condition and is commonly found as a co morbidity with other conditions. It has not been shown the restricting this treatment will impact on this group negatively since those who would benefit can access it.

Gender reassignment (including transgender): Describe any impact and evidence on transgender people. This can include issues such as privacy of data and harassment:

No impact identified

Marriage and civil partnership: Describe any impact and evidence in relation to marriage and civil partnership. This can include working arrangements, part-time working, and caring responsibilities:

No impact identified

Pregnancy and maternity: Describe any impact and evidence on pregnancy and maternity. This can include working arrangements, part-time working, and caring responsibilities:

No impact identified on the basis of available data

3. Impact and Evidence:
Race: Describe race related impact and evidence**.** This can include information on different ethnic groups, Roma gypsies, Irish travellers, nationalities, cultures, and language barriers: No impact identified
Religion or belief: Describe any religion, belief or no belief impact and evidence. This can include dietary needs, consent and end of life issues: No impact identified
Sex: Describe any impact and evidence on men and women. This could include access to services and employment: No impact identified
Sexual orientation: Describe any impact and evidence on heterosexual people as well as lesbian, gay and bisexual people. This could include access to services and employment, attitudinal and social barriers: No impact identified
Carers: Describe any impact and evidence on part-time working, shift-patterns, general caring responsibilities: No impact identified
Other disadvantaged groups: Describe any impact and evidence on groups experiencing disadvantage and barriers to access and outcomes. This can include lower socio-economic status, resident status (migrants, asylum seekers), homeless, looked after children, single parent households, victims of domestic abuse, victims of drugs / alcohol abuse: (This list is not exhaustive) No impact identified

4. Health Inequalities	Yes/No	Evidence
Could health inequalities be created or persist by the proposals?	No	This condition is not linked to any identified health inequality
Is there any impact for groups or communities living in particular geographical areas?	No	No impact identified

Is there any impact for groups or communities affected by unemployment, lower educational attainment, low income, or poor access to green spaces?	No	No impact identified
How will you ensure the proposals reduce health inequalities?		

5. FREDA Principles/ Human Rights	Question	Response
Fairness – Fair and equal access to services	How will this respect a person's entitlement to access this service?	Yes, this decision has been made in line with clinical recommendation and NICE guidance
Respect – right to have private and family life respected	How will the person's right to respect for private and family life, confidentiality and consent be upheld?	No impact of evidence from this policy
Equality – right not to be discriminated against based on your protected characteristics	How will this process ensure that people are not discriminated against and have their needs met and identified?	No discrimination identified
	How will this affect a person's right to freedom of thought, conscience and religion?	N/A
Dignity – the right not to be treated in a degrading way	How will you ensure that individuals are not being treated in an inhuman or degrading way?	Policy will be applied with due regard to this consideration.
Autonomy – right to respect for private & family life; being able to make informed decisions and choices	How will individuals have the opportunity to be involved in discussions and decisions about their own healthcare?	An individual can discuss the impact with their GP and has the option for an IFR request to be made
Right to **Life**	Will or could it affect someone's right to life? How?	No impact of evidence from this policy
Right to **Liberty**	Will or could someone be deprived of their liberty? How?	No impact of evidence from this policy

6. Social Value
Consider how you might use the opportunity to improve health and reduce health inequalities and so achieve wider public benefits, through action on the social determinants of health.

Marmot Policy Objective	What actions are you able to build into the procurement activity and/or contract to achieve wider public benefits?
Enable all people to have control over their lives and maximise their capabilities	None
Create fair employment and good work for all	None
Create and develop health and sustainable places and communities	None
Strengthen the role and impact of ill-health prevention	None

7. Engagement, Involvement and Consultation

If relevant, please state what engagement activity has been undertaken and the date and with which protected groups:

Engagement Activity	Protected Characteristic/ Group/ Community	Date

For each engagement activity, please state the key feedback and how this will shape policy / service decisions (E.g. patient told us …. So we will …..):

As part of the process further targeted engagement is planned with representative groups from among Birmingham and Solihull Patients. In addition, it has been identified that patient and clinician information is key in ensuring that the harmonised treatment policies review delivers effective outcomes. To this end an information briefing sheet on each procedure will be developed to give more information on the procedure, eligibility criteria and signposting to further information sources, such as NHS Choices. These information sheets are also designed to help facilitate discussions between GPs and patients. Information briefing sheets have already been tested for the first and second phases of harmonised treatment policies for Birmingham and Solihull CCG. Due regard will be given to both the accessible information standard and the potential need to translate such leaflets into relevant local languages.

The engagement team used every possible route throughout the engagement period to encourage people to feedback on the proposed policy. Unfortunately, despite the wide communication undertaken through all communication and engagement channels available, 49 questionnaires were completed online and there was little interest from stakeholders, patients and the public to attend any of the five stakeholder events arranged. As a result, the events were cancelled, and the engagement team looked at other routes to encourage engagement with patients directly. A possible reason for the general lack of interest and feedback from stakeholders, patients and the public is most likely because this clinical treatment policy is either widening the scope of the current service provision, providing policies to protect the current service provision or the intervention is for somewhat rare conditions.

Also, in phase 3 of the harmonisation of policies programme clinicians had been integral to the development of the policies from the beginning of the process. It could therefore be argued the proposed policy shared for public engagement was to some extent already informed from a local patient experience and outcomes perspective.

The potential impact on patients was therefore minimal as the treatment is offered based on specific criteria. Feedback from healthcare professionals suggested that image guidance for certain areas such as the hip (which is outside the scope of this policy) or smaller joint areas such as the hands (which are already accommodated for within the policy) was essential, however generally, there were mixed responses supporting the use of image guided technology. Responses also suggest that the decision of making this treatment available should be made by the practitioner performing the procedure based upon the individual patients' condition. Discussions with physiotherapist revealed that although these injections may only be offered once conservative methods have failed, in certain cases, the pain relief provided by this procedure may help patients in pain and give them the rest period needed to start rehabilitation. The therapeutic injections themselves will not be restricted by the policy only the use of image-guidance to deliver the injections. The injections will still be available as palpated injections.

8. Summary of Analysis

Considering the evidence and engagement activity you listed above, please summarise the impact of your work:

The restriction of this policy will have limited impact on those who would wish to receive the treatments, as it is the use of image guidance to deliver the therapeutic injection, not the injections itself which is being restricted and this must be balanced against the need to adhere to NICE guidelines and the clinical effectiveness evidence. The opportunity for any exceptional cases to be considered via IFR remains and will ensure treatment is available in an exceptional case.

9. Mitigations and Changes :

Please give an outline of what you are going to do, based on the gaps, challenges and opportunities you have identified in the summary of analysis section. This might include action(s) to mitigate against any actual or potential adverse impacts, reduce health inequalities, or promote social value. Identify the **recommendations** and any **changes** to the proposal arising from the equality analysis.

None required

10. Contract Monitoring and Key Performance Indicators

Detail how and when the service will be monitored and what key equality performance indicators or reporting requirements will be included within the contract (refer to NHS Standard Contract SC12 and 13):

This policy is not linked to a contract however, prospective providers remain bound by their contracts with the CCG.

11. Procurement

Detail the key equality, health inequalities, human rights, and social value criteria that will be included as part of the procurement activity (to evaluate the providers ability to deliver the service in line with these areas):

N/A

12. Publication

How will you share the findings of the Equality Analysis?

This can include: reports into committee or Governing Body, feedback to stakeholders including patients and the public, publication on the web pages. All Equality Analysis should be recommended for publication unless they are deemed to contain sensitive information.

Publication on the CCG's website.

Following approval all finalised Equality Analysis should be sent to the Communications and Engagement team for publication: bsol.comms@nhs.net

13. Sign Off

The Equality Analysis will need to go through a process of **quality assurance** by the Senior Manager for Equality and Diversity, Senior Manager for Assurance and Compliance or Equality and Human Rights Manager **and** signed-off by a delegated committee

	Name	Date
Quality Assured By:		
Which Committee will be considering the findings and signing off the EA?		
Minute number (to be inserted following presentation to committee)		

Please send to Balvinder Everitt or Michelle Dunne, Equality, Diversity and Inclusion for Quality Assurance.

Once you have committee sign off, please send to Caroline Higgs, Communications & Engagement Team for publication: bsol.comms@nhs.net

Equality Analysis

(Health Inequalities, Human Rights, Social Value)

Policy for Adenoidectomy

Before completing this equality analysis it is recommended that you:

- ✓ Contact your equality and diversity lead for advice and support
- ✓ Take time to read the accompanying policy and guidance document on how to complete an equality analysis

NHS Birmingham and Solihull Clinical Commissioning Group
NHS Sandwell and West Birmingham Clinical Commissioning Group

1. Background

EA Title	Adenoidectomy		
EA Author	David King	**Team**	Equality and Diversity Team
Date Started	13/08/2019	**Date Completed**	4/12/2019
EA Version	4	**Reviewed by E&D**	

What are the intended outcomes of this work? Include outline of objectives and function aims

Adenoids

Adenoids are small lumps of tissue at the back of the nose, above the roof of the mouth. You can't see a person's adenoids by looking in their mouth.
Adenoids are part of the immune system, which helps fight infection and protects the body from bacteria and viruses.

In most cases only children have adenoids. They start to grow from birth and are at their largest when a child is around three to five years of age. However there is a small group of adults where adenoids remain and may become enlarged.
By age seven to eight, the adenoids start to shrink and by the late teens, they're barely visible. By adulthood, in most people they will have disappeared completely.
Adenoids can be helpful in young children, but they're not an essential part of an adult's immune system.

Adenoids can sometimes become swollen or enlarged. This can happen after a bacterial or viral infection, or after a substance triggers an allergic reaction.
In most cases, swollen adenoids only cause mild discomfort and treatment isn't needed. However, for some, it can cause severe discomfort and interfere with their daily life.

Adenoidectomy

The adenoids can be removed during an adenoidectomy. The operation is usually carried out by an ear, nose and throat (ENT) surgeon and takes around 30 minutes. Afterwards, the patient will need to stay in the recovery ward for up to an hour until the anaesthetic has worn off.

Adenoidectomies are sometimes day cases if carried out in the morning, in which case you / your child may be able to go home on the same day. However, if the procedure is carried out in the afternoon, you / your child may need to stay in hospital overnight.

Who will be affected by this work? e.g. staff, patients, service users, partner organisations etc.

Eligibility Criteria: Restricted

<u>Adenoids may only be removed in the following clinical circumstances:</u>

- Documented medical problems caused by obstruction of the airway by enlarged adenoids **AND** all conservative treatments have been exhausted.

For the purposes of this eligibility criteria, a medical problem is defined as a medical problem that continually impairs sleep and/or breathing, e.g.

- difficulty sleeping – the patient has problems sleeping and may start to snore; in severe cases, some patients may develop sleep apnoea (irregular breathing during sleep and excessive sleepiness during the day) due to enlarged adenoids
- recurrent or persistent problems with the ears – such as middle ear infections (otitis media) or glue ear (where the middle ear becomes filled with fluid)
- recurrent or persistent sinusitis – leading to symptoms such as a constantly runny nose, facial pain and nasal-sounding speech
- All clinical circumstances which meet the above eligibility criteria, must have failed conservative medical treatment, before being eligible for surgical intervention.

Investigations for suspected or proven malignancy are outside the scope of this policy and should be treated in line with the relevant cancer pathway.

Activity data 2018/19

Number of Procedures	BSOL	Sandwell
	6,786	2,281

Number of procedures undertaken overall and by CCG

Due to limited data collection by the providers service activity data is available by headcount only not protected characteristic.
The Joint Strategic Needs Assessments for Birmingham, Solihull and Sandwell are available via the links below.

Sandwell

Birmingham

Solihull

This means (for patients who DO NOT meet the above criteria) the CCG will only fund the treatment if an Individual Funding Request (IFR) application proves exceptional clinical need and that is supported by the CCG.

2. Research

What evidence have you identified and considered? This can include national research, surveys, reports, NICE guidelines, focus groups, pilot activity evaluations, clinical experts or working groups, JSNA or other equality analyses.

Research/Publications	Working Groups	Clinical Experts
Guidance 1. NHS. Adenoids & Adenoidectomy 29.12.2016. https://www.nhs.uk/conditions/adenoids-and-adenoidectomy/ 2. Kamel RH[1], Ishak EA. 1990 Enlarged adenoid and adenoidectomy in adults: endoscopic approach and histopathological study. J Laryngol Otol. 1990 Dec;104(12):965-7. 3. Torretta S[1,2], Guastella C[3], Ibba T[4], Gaffuri M[5], Pignataro L[6] Prevalence of adenoid hypertrophy: A systematic review and meta-analysis. Clin Med. 2019 May 15;8(5). pii: E684. doi: 10.3390/jcm8050684. 4. Torretta S[1,2], Guastella C[3], Ibba T[4], Gaffuri M[5], Pignataro L[6] Surgical Treatment of Paediatric Chronic Rhinosinusitis. https://www.ncbi.nlm.nih.gov/pubmed/31096610 5. Vanneste P[1], Page C[1]. Otitis media with effusion in children: Pathophysiology, diagnosis, and treatment. A review. J Otol. 2019 Jun;14(2):33-39. doi: 10.1016/j.joto.2019.01.005. Epub 2019 Jan 31. https://www.ncbi.nlm.nih.gov/pubmed/31223299 6. Kugelman N[1,2], Ronen O[1,2], Stein N[3,2], Huberfeld O[1,2], Cohen-Kerem R[1,4,2]. Adenoid Obstruction Assessment in Children: Clinical Evaluation Versus Endoscopy and Radiography. Isr Med Assoc J. 2019 Jun;21(6):376-380. https://www.ncbi.nlm.nih.gov/pubmed/31280504 7. Durgut O[1], Dikici O[2]. The effect of adenoid hypertrophy on hearing thresholds in children with otitis media with effusion. Int J Pediatr		

Otorhinolaryngol. 2019 Jun 1;124:116-119. doi: 10.1016/j.ijporl.2019.05.046. https://www.ncbi.nlm.nih.gov/pubmed/31176025 8. Pereira L[1], Monyror J[2], Almeida FT[3], Almeida FR[4], Guerra E[5], Flores-Mir C[6], Pachêco-Pereira CPrevalence of adenoid hypertrophy: A systematic review and meta-analysis. Sleep Med Rev. 2018 Apr;38:101-112. doi: 10.1016/j.smrv.2017.06.001. Epub 2017 Jun 14. https://www.ncbi.nlm.nih.gov/pubmed/29153763		

3. Impact and Evidence:

In the following boxes detail the findings and impact identified (positive or negative) within the research detailed above; this should also include any identified health inequalities which exist in relation to this work.

Age: Describe age related impact and evidence. This can include safeguarding, consent and welfare issues:

There is an increased normal prevalence of adenoids in those who are under the age of adolescence. In most cases, by adulthood they will have disappeared completely.

Disability: Describe disability related impact and evidence. This can include attitudinal, physical, communication and social barriers as well as mental health/ learning disabilities, cognitive impairments:

No impact identified

Gender reassignment (including transgender): Describe any impact and evidence on transgender people. This can include issues such as privacy of data and harassment:

No impact identified

Marriage and civil partnership: Describe any impact and evidence in relation to marriage and civil partnership. This can include working arrangements, part-time working, and caring responsibilities:

No impact identified

3. Impact and Evidence:
Pregnancy and maternity: Describe any impact and evidence on pregnancy and maternity. This can include working arrangements, part-time working, and caring responsibilities: No impact identified
Race: Describe race related impact and evidence**.** This can include information on different ethnic groups, Roma gypsies, Irish travellers, nationalities, cultures, and language barriers: No impact identified
Religion or belief: Describe any religion, belief or no belief impact and evidence. This can include dietary needs, consent and end of life issues: No impact identified
Sex: Describe any impact and evidence on men and women. This could include access to services and employment: No impact identified
Sexual orientation: Describe any impact and evidence on heterosexual people as well as lesbian, gay and bisexual people. This could include access to services and employment, attitudinal and social barriers: No impact identified
Carers: Describe any impact and evidence on part-time working, shift-patterns, general caring responsibilities: No impact identified
Other disadvantaged groups: Describe any impact and evidence on groups experiencing disadvantage and barriers to access and outcomes. This can include lower socio-economic status, resident status (migrants, asylum seekers), homeless, looked after children, single parent households, victims of domestic abuse, victims of drugs / alcohol abuse: (This list is not exhaustive) No impact identified

4. Health Inequalities	Yes/No	Evidence
Could health inequalities be created or persist by the proposals?	No	This condition is not linked to a

4. Health Inequalities	Yes/No	Evidence
		health inequality.
Is there any impact for groups or communities living in particular geographical areas?	No	No impact identified
Is there any impact for groups or communities affected by unemployment, lower educational attainment, low income, or poor access to green spaces?	No	No impact identified
How will you ensure the proposals reduce health inequalities? No impact identified		

5. FREDA Principles/ Human Rights	Question	Response
Fairness – Fair and equal access to services	How will this respect a person's entitlement to access this service?	Yes, this decision has been made in line with clinical recommendation and NICE guidance.
Respect – right to have private and family life respected	How will the person's right to respect for private and family life, confidentiality and consent be upheld?	No evidence of impact from this policy
Equality – right not to be discriminated against based on your protected characteristics	How will this process ensure that people are not discriminated against and have their needs met and identified?	No discrimination identified
	How will this affect a person's right to freedom of thought, conscience and religion?	N/A
Dignity – the right not to be treated in a degrading way	How will you ensure that individuals are not being treated in an inhuman or degrading way?	Policy will be applied with due regard to this consideration.
Autonomy – right to respect for private & family life; being able to make informed decisions and choices	How will individuals have the opportunity to be involved in discussions and decisions about their own healthcare?	An individual can discuss the impact with their GP and has the option for an IFR request to be made
Right to **Life**	Will or could it affect someone's right to life? How?	No evidence of impact from this policy
Right to **Liberty**	Will or could someone be deprived of their liberty? How?	No evidence of impact on this policy

6. Social Value

Consider how you might use the opportunity to improve health and reduce health inequalities and so achieve wider public benefits, through action on the social determinants of health.

Marmot Policy Objective	What actions are you able to build into the procurement activity and/or contract to achieve wider public benefits?
Enable all people to have control over their lives and maximise their capabilities	None
Create fair employment and good work for all	None
Create and develop health and sustainable places and communities	None
Strengthen the role and impact of ill-health prevention	None

7. Engagement, Involvement and Consultation

If relevant, please state what engagement activity has been undertaken and the date and with which protected groups:

Engagement Activity	Protected Characteristic/ Group/ Community	Date

For each engagement activity, please state the key feedback and how this will shape policy / service decisions (E.g. patient told us …. So we will …..):

As part of the process further targeted engagement is planned with representative groups from among Sandwell, Birmingham and Solihull Patients. In addition, it has been identified that patient and clinician information is key in ensuring that the harmonised treatment policy review delivers effective outcomes. To this end an information briefing leaflet on each procedure has been developed to give more information on the procedure, eligibility criteria and signposting to further information sources, such as NHS Choices. These information sheets are also designed to help facilitate discussions between GPs and patients. Information briefing leaflets have already been tested for the Phase 1 and Phase 2 policies in the Harmonised Clinical Treatment Policy Programmes for Birmingham and Solihull CCG and for Sandwell and West Birmingham CCG. Due regard will be given to both the accessible information standard and the potential need to translate such leaflets into relevant local languages.

The engagement team used every possible route throughout the engagement period to encourage people to feedback on the proposed policy. Unfortunately, despite the wide communication undertaken through all communication and engagement channels available, 49 questionnaires were completed online and there was no interest from stakeholders, patients and the public to attend any of the five stakeholder events arranged. As a result, the events were cancelled, and the engagement team looked at other routes to encourage engagement with patients directly. A possible reason for the general lack feedback from stakeholders, patients and the public is most likely due to

7. Engagement, Involvement and Consultation

this clinical treatments policy widening the scope of the current service provision to include adults as opposed to further restricting access for patients.

Also, in Phase 3 of the Harmonised Clinical Treatment Policy Programme clinicians had been integral to the development of the policies from the beginning of the process. It could therefore be argued the proposed policy shared for public engagement was to some extent already informed from a local patient experience and outcomes perspective.

As the scope of this policy was to widen the treatment so it is also available to adults, the potential impact on patients is therefore minimal. Approximately 67% of respondents agreed with the proposed policy and was seen as a positive improvement to allow adults who may suffer with this condition within the eligibility criteria.

8. Summary of Analysis

Considering the evidence and engagement activity you listed above, please summarise the impact of your work:

The restriction of this policy will have limited impact on those who would wish to receive the treatments. This must be balanced against the need to adhere to the clinical effectiveness evidence and when all other conservative treatments have been exhausted.

Only when documented medical problems caused by obstruction of the airway which continually impairs sleep and/or breathing by the enlarged adenoids will surgical intervention be necessary.

It is noted that investigations for suspected or proven malignancy are outside the scope of this policy and should be treated in line with the relevant cancer pathway.

The opportunity for any exceptional cases to be considered via IFR remains.

9. Mitigations and Changes :

Please give an outline of what you are going to do, based on the gaps, challenges and opportunities you have identified in the summary of analysis section. This might include action(s) to mitigate against any actual or potential adverse impacts, reduce health inequalities, or promote social value. Identify the **recommendations** and any **changes** to the proposal arising from the equality analysis.

None identified

10. Contract Monitoring and Key Performance Indicators

Detail how and when the service will be monitored and what key equality performance indicators or reporting requirements will be included within the contract (refer to NHS Standard Contract SC12 and 13):

This policy is not linked to a contract however, prospective providers remain bound by their contracts with the CCG.

11. Procurement

Detail the key equality, health inequalities, human rights, and social value criteria that will be included as part of the procurement activity (to evaluate the providers ability to deliver the service in line with these areas):

N/A

12. Publication

How will you share the findings of the Equality Analysis?

This can include: reports into committee or Governing Body, feedback to stakeholders including patients and the public, publication on the web pages. All Equality Analysis should be recommended for publication unless they are deemed to contain sensitive information.

Publication on the CCG's website.

Following approval all finalised Equality Analysis should be sent to the Communications and Engagement team for publication: bsol.comms@nhs.net

13. Sign Off

The Equality Analysis will need to go through a process of **quality assurance** by the Senior Manager for Equality and Diversity, Senior Manager for Assurance and Compliance or Equality and Human Rights Manager **and** signed-off by a delegated committee

	Name	Date
Quality Assured By:		
Which Committee will be considering the findings and signing off the EA?		

Minute number (to be inserted following presentation to committee)		

Please send to Balvinder Everitt or Michelle Dunne, Equality, Diversity and Inclusion for Quality Assurance.

Once you have committee sign off, please send to Caroline Higgs, Communications & Engagement Team for publication: bsol.comms@nhs.net

Equality Analysis

(Health Inequalities, Human Rights, Social Value)

Policy for Bariatric Surgery in Adults

Before completing this equality analysis it is recommended that you:

- ✓ Contact your equality and diversity lead for advice and support
- ✓ Take time to read the accompanying policy and guidance document on how to complete an equality analysis

NHS Birmingham and Solihull Clinical Commissioning Group
NHS Sandwell and West Birmingham Clinical Commissioning Group

1. Background

EA Title	Policy for Bariatric Surgery in Adults		
EA Author	David King	**Team**	
Date Started	4/7/2019	**Date Completed**	4/12/2019
EA Version	4	**Reviewed by E&D**	

What are the intended outcomes of this work? Include outline of objectives and function aims

Obesity is commonly defined as a Body Mass Index (BMI) of 30 kg/m2 or greater (see Table 1). Individuals living with obesity are at greater risk of a variety of different health conditions. These include type 2 diabetes mellitus (T2DM), non-alcoholic fatty liver disease, hypertension, asthma, gastro-oesophageal reflux disease, depression and a variety of other conditions [1]. The risk of developing obesity-related co-morbidities increases as an individual's BMI increases [2].

Table 1.

Definition	BMI range (kg/m2)
Underweight	Under 18.5
Normal	18.5 to less than 25
Overweight	25 to less than 30
Obese	30 to less than 40
Obese I	30 to less than 35
Obese II	35 to less than 40
Morbidly obese	40 and over

Source: NICE. Obesity: identification, assessment and management [1]

Epidemiology

Obesity is a global problem, estimated to have affected over six hundred million adults worldwide in 2014 [14]. In England, in both men and women, more than one in four adults are obese (28.2%) and 2.7% are classed as morbidly obese [15].

The prevalence of obesity in the UK rose between 1993 and 2014, the rate of increase began to slow in 2001 but the overall trend is still continuing to rise. According to the Health Survey for England, 61.7% of adults were overweight or obese in 2014, with more men being obese (65.3%) than women (58.1%) [16, 17]. Over the same time period, the prevalence of morbid obesity has also continued to climb, with a sharp rise in female prevalence between 2007 and 2011 (see Figure 4). Whilst the trend for males appears to have levelled off in recent years, the current level still represents a sizeable increase from that seen in the early 1990's. The number of people classed as obese in

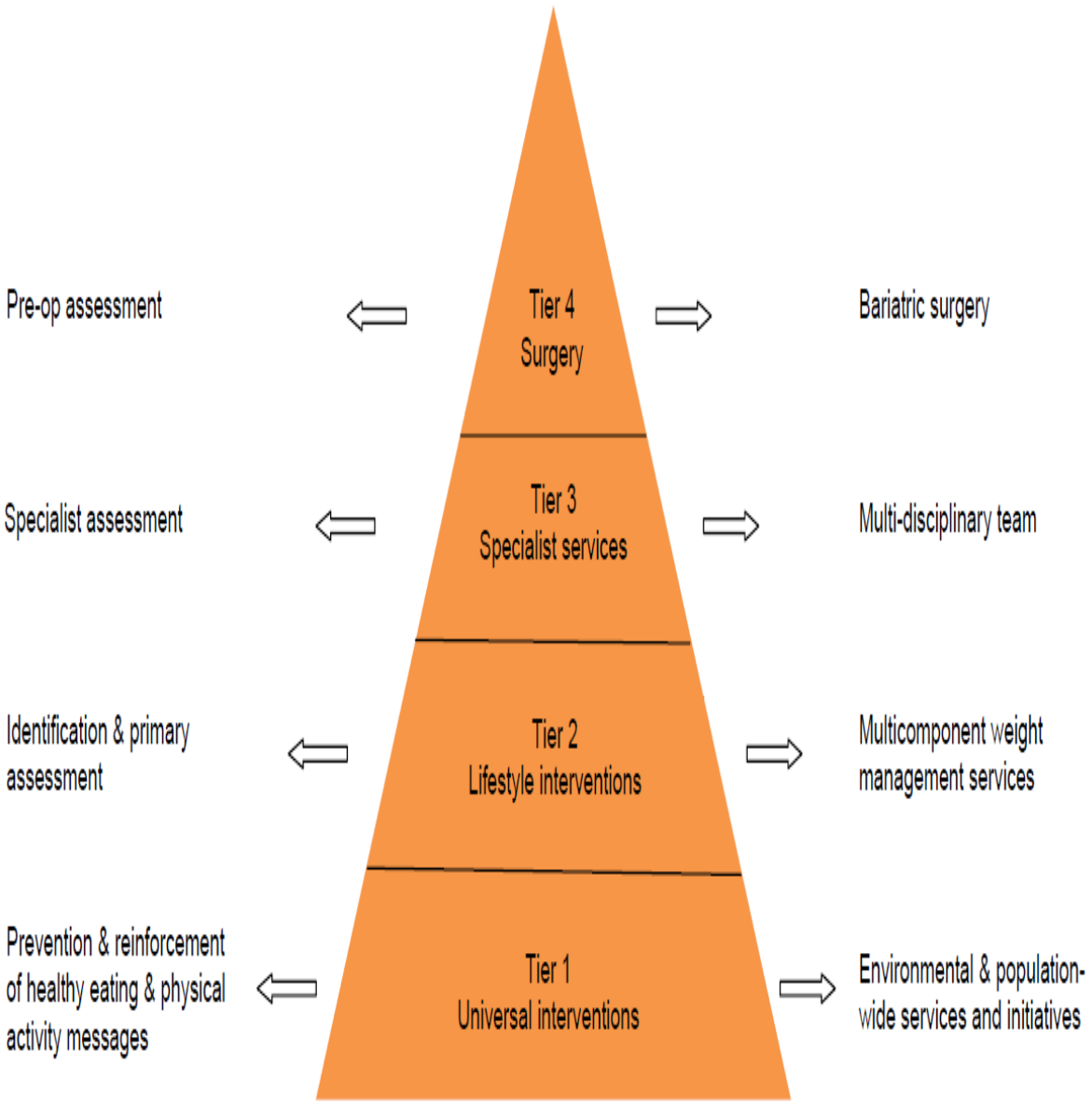
the UK is expected to increase by 11 million by 2030, with a likely corresponding increase in those with morbid obesity [18].

According to forecasts produced by the World Health Organisation, 31% of men and 30% of women will be obese by 2020, rising to 36% and 33% respectively by 2030 [19].

National Guidance

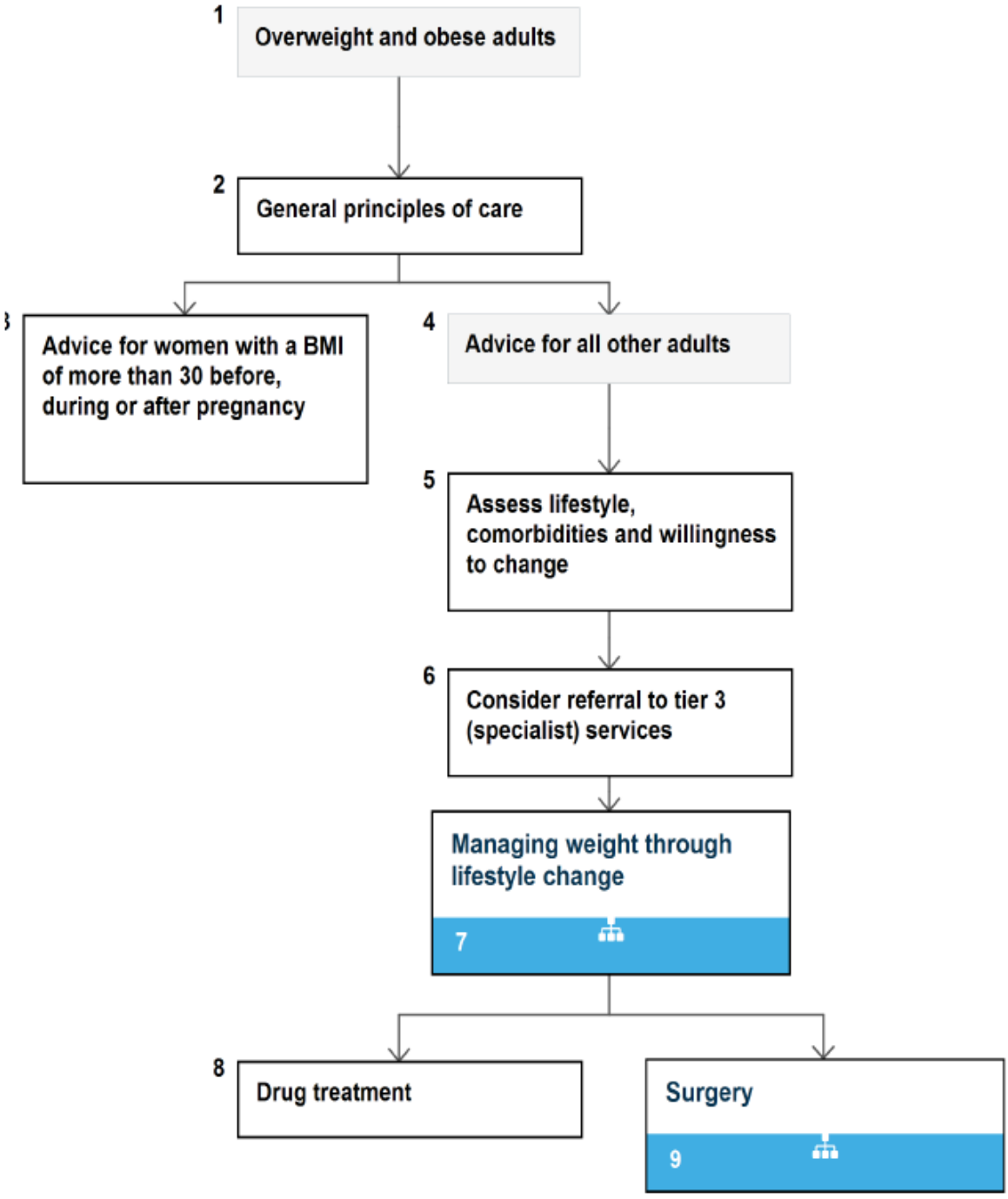
In England, obesity is managed through a tiered system (Figure 1), ranging from preventive population-based health promotion strategies (Tier 1) and lifestyle interventions (including diet, exercise, and behavioural) in primary care settings (Tier 2), through to more intensive specialist services provided by multi-disciplinary teams (Tier 3) and bariatric surgery (Tier 4) [3].

Figure 1: Tiered management of obesity



In November 2014, NICE published clinical guidance on the identification, assessment and management of obesity (NICE clinical guideline 189). [1]. The proposed NICE pathway is outlined below in Figure 2.

Figure 2: NICE pathway for overweight and obese adults



Co-Morbidities

The health issues associated with being overweight or obese include type 2 diabetes mellitus, cardiovascular disease and musculoskeletal disorders amongst others. People aged 35 to 59 with a BMI measurement of between 40 kg/m2 and 50 kg/m2 are five

times more likely to die from ischaemic heart disease than those with a BMI of 22.5 kg/m2 to 25 kg/m2.

Between the same groups, the risk of dying from stroke was 6.5 times higher and the risk of dying from diabetes was 22.5 times higher. Vascular risk factors also exhibit a strong relationship with BMI; both systolic and diastolic blood pressure increases with BMI [20].
The prevalence of diabetes amongst those with normal weight was around 1.5%, compared to 15% in the severely obese [20].
On its own, BMI is a strong predictor of mortality and is strongly associated with diabetes for which sex-specific prevalence may rise more than five-fold from baseline across the BMI range. Table 3 shows a simplified version of the relationship between BMI and health risk.

Table 3: Co-Morbidity Risk by BMI Classification

Classification	BMI (kg/m2)	Risk of Obesity Related Co-Morbidities
Underweight	<18.5	Low risk (but risk of other clinical problems increased)
Normal Range	18.50 – 24.99	Average risk
Overweight	≥25.0	Increased risk
Obese	≥30.0	Medium to high risk
Morbidly Obese	≥40.0	Very high risk

Non-Surgical Interventions

Non-surgical interventions for obesity consist of a wide variety of measures which may be used in varying combinations as part of a multi-component pathway. Generally, this comprises dietary intake, physical activity levels and behaviour change and may also include pharmacological interventions [25]. These should be clinically led and involve multi-disciplinary assessment [13].

The current Tier 3 offer differs across Birmingham and Solihull and is going through a process of harmonisation whereby Tier 3 service are being modelled to accommodate a range of patients in need of clinically-led weight management support. Once finalised, the patient will follow the Tier 3 commissioned pathway.

The Tier 3 service should be provided via a multidisciplinary team containing a bariatric physician, dietitian, specialist nurse, clinical psychologist and a liaison psychiatry professional. In addition to this there should also be access to a physical therapist.

Non-surgical weight-management interventions (also known as ‘Lifestyle Interventions’) are commonly split into four categories:
1. Behavioural interventions
2. Physical activity
3. Behaviour change

4. Pharmacological interventions.

Interventions should be seen as multicomponent and incorporate combinations of the interventions described below.

Behavioural interventions

Behavioural interventions are provided with the support of an appropriately trained professional and include various strategies for adults which are incorporated as appropriate. These include (but are not limited to) self-monitoring of behaviour and progress, stimulus control, goal setting, ensuring social support is available, cognitive restructuring (modifying thoughts), reinforcement of changes and providing strategies for dealing with weight regain [1].

Physical Activity

Encouragement should be given to increase levels of physical activity, regardless of whether this will lead to weight-loss. This is due to the general fitness improvements it can bring and the associated reduced risk of cardiovascular disease and type 2 diabetes. This may comprise of 45-60 minutes of moderate-intensity exercise per day, increasing to 60-90 minutes for those who have already lost weight to prevent regaining of excess weight. Suitable activities include brisk walking, gardening, cycling, supervised exercise programmes, swimming, stair-climbing etc [1].

Dietary

Dietary interventions should not be unduly restrictive but should be tailored to individual food preferences and also be nutritionally balanced. As with physical activity, dietary improvements should be encouraged for reasons other than weight loss alone due to the associated health benefits which a balanced diet can bring. The primary requirement for a dietary intervention however is to reduce energy intake to a point below energy expenditure by approximately 600 kcal/day or by reducing fat content. This should be partnered with expert support and intensive follow-up. Low (800-1600 kcal/day) and very low (800 kcal/day or less) calorie diets should be used with some degree of caution due to issues around nutritional completeness [1].

Pharmacological Interventions

Pharmacological interventions should only be considered after behavioural, physical and dietary interventions have been started and evaluated. This applies especially to those service-users who have not achieved their target weight loss or have plateaued. It may also be utilised to maintain weight-loss as opposed to continuing weight loss [1]. Orlistat is the only pharmacological treatment for obesity currently recommended by NICE. This medication is a lipase inhibitor which works through preventing approximately a third of consumed fat from being absorbed, However, in addition to the well-documented side effects, there are potential issues related to the heightened risk of kidney problems [26].

Bariatric Surgery

Bariatric surgery includes a group of procedures that promote weight loss. They are usually performed laparoscopically, with decreased time in hospital and a shorter recovery time compared to open procedures. In the UK and Ireland, there were over 18,000 bariatric surgery operations in the three financial years ending 2011, 2012, and 2013; 95.4% of all primary operations were performed laparoscopically over this period [22]. More recently, minimally invasive surgical techniques also include robotic procedures, though their feasibility and safety are debated. Bariatric surgery may be categorised under three headings: restrictive; malabsorptive and combined procedures.

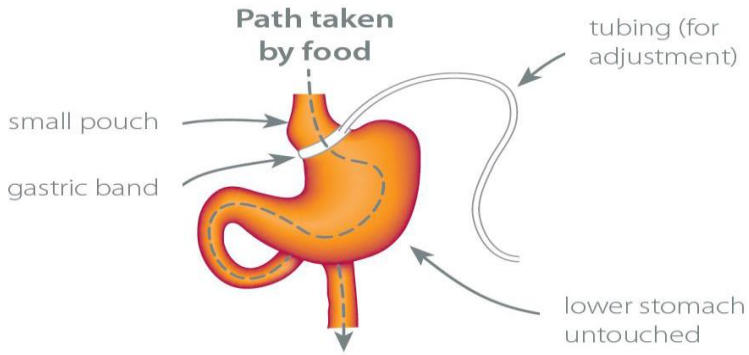
Restrictive procedures

Restrictive procedures, described below, lead to a fixed or adjustable reduction in the size of the upper gastrointestinal tract.

Adjustable gastric banding (AGB)

This procedure places an adjustable silicone band around the upper stomach, creating a small pouch above the band and a narrowing between the pouch and main part of the stomach below it (Figure 6). This restricts the amount of food that can be eaten and reduces hunger sensations by pressing on the surface of the stomach. The band may be tightened or loosened by injecting or removing saline through a portal under the skin that is connected to the band. The procedure is reversible and relatively non-invasive. AGB has replaced the older restrictive gastroplasty (horizontal, vertical, and banded) procedures that are no longer performed in the UK due to poorer performance. Gastric banding made up 22.3% of all bariatric surgery operations in the UK between 2011 and 2013 [22, 23, 24].

Figure 6: Diagrammatic representation of a gastric band in place

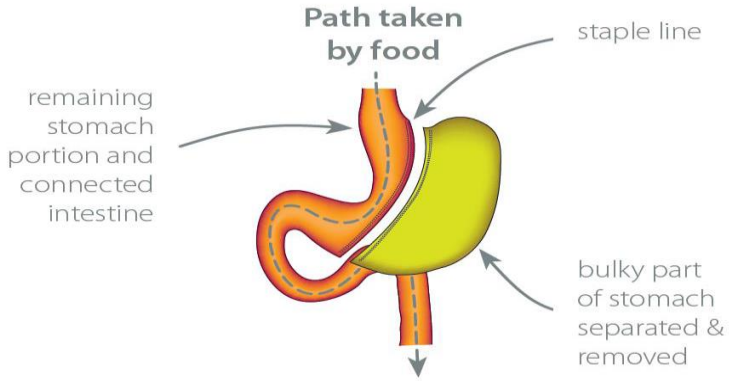


Source: National Bariatric Surgery Register. NSBR Second Registry Report. 2014 [22]

Sleeve gastrectomy (SG)

This procedure divides the stomach vertically to reduce its size by seventy-five percent, whilst keeping the stomach function and digestion unaltered by leaving the pyloric valve intact (see Figure 7). The procedure is not reversible but is relatively quick to perform and is one of the most commonly performed restrictive procedures. It was initially used as the first of a two-part procedure for patients at high risk from bariatric surgery, followed by a conversion to either a Roux-en-Y gastric bypass or a duodenal switch (see below). However, as some patients achieve significant weight loss with the sleeve gastrectomy alone, it is now also used as a stand-alone procedure. In some patients, the procedure may be followed by a duodenojejunal bypass, which involves bypassing the first part of the small intestine, resulting in food moving directly to the latter part of the small intestine, thereby reducing absorption of calories. SG made up 20.8% of all bariatric surgery operations in the UK between 2011 and 2013 [22]. A further 12 (0.07%) SG procedures were performed in combination with a biliopancreatic diversion with duodenal switch

Figure 7: The basics of a sleeve gastrectomy procedure



Source: National Bariatric Surgery Register. NSBR Second Registry Report. 2014 [22]

Intragastric balloon (IGB)

Intragastric balloon procedures involve placing a silicon balloon endoscopically to float freely inside the stomach, thereby reducing the volume of the stomach, leading to an earlier sensation of satiety. It is typically used either in patients who are at least 40% of their optimal weight, or in morbidly obese patients for whom surgery is high risk. IGB made up 2.1% of all bariatric surgery operations in the UK between 2011 and 2013 [22].

Gastric plication (or gastric imbrication)

A newer procedure that reduces the stomach volume by folding the stomach into itself and stitching it to create a narrow tube shape, similar to that of SG, but without removing any stomach tissue (Figure 6). The Registry report does not present the exact number or proportion of all November 2017 bariatric surgery operations that involve gastric plication. However, it is less than the 2.1% procedures labelled as ‘other’ in the Registry report [22].

Malabsorptive procedures

Malabsorptive procedures bypass a section of the intestine, with less physical restriction of food intake.

Biliopancreatic diversion (without duodenal switch)

This procedure is typically no longer performed in the UK due to risk of postgastrectomy syndrome (including, for example, dumping syndrome, bile reflux, diarrhoea). It involved portions of the stomach being removed through a horizontal gastrectomy (a restrictive procedure), with the small remaining pouch being connected to the final section of the small intestine. This is now replaced with the biliopancreatic diversion with duodenal switch (BDDS) procedure, which may be classed as a combined procedure (see group 3 below).

Jejunoileal bypass (JIB)

This procedure is no longer performed in the UK, where a significant part of the small intestine was detached and set to the side.

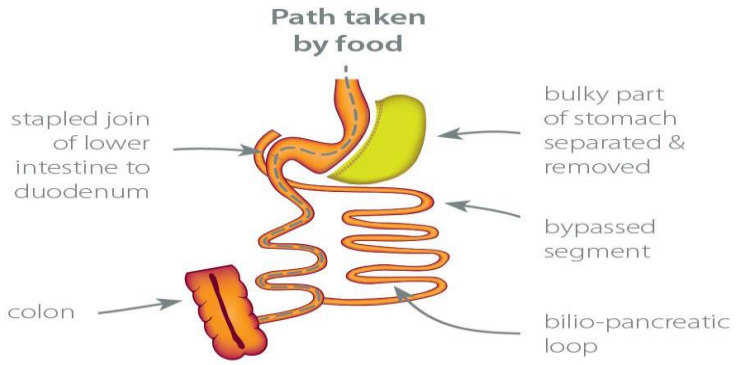
Combined procedures

Combined procedures include both restrictive and malabsorptive components.

Biliopancreatic diversion with duodenal switch (BDDS)

Biliopancreatic diversion with duodenal switch involves an initial restrictive vertical gastrectomy, followed by the malabsorptive component which re-routes a long portion of the small intestine, creating two separate pathways and one common channel (Figure 8). The shorter of the two pathways, the digestive loop, takes food from the stomach to the common channel. The longer pathway, the biliopancreatic loop, carries bile from the liver to the common channel. This procedure reduces the amount of time the body has to capture calories from food in the small intestine, and selectively limits the absorption of fat. The procedure is partially reversible, but there were only 19 BDDS procedures (0.1%), together with a further 12 procedures combined with SG in the UK between 2011 and 2013 [22].

Figure 8: Biliopancreatic diversion with duodenal switch

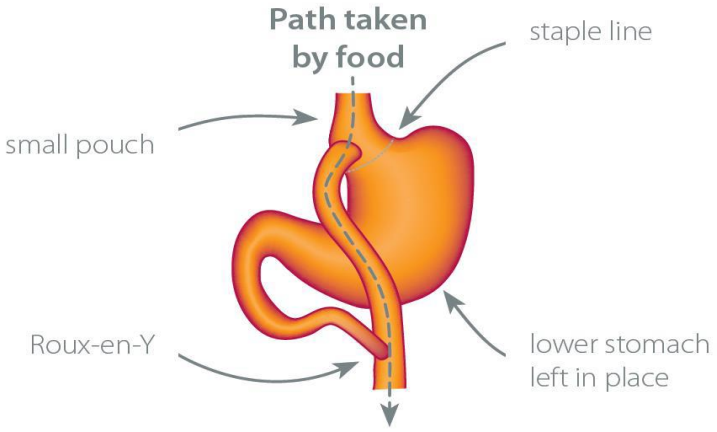


Source: National Bariatric Surgery Register. NSBR Second Registry Report. 2014 [22]

Roux-en-Y gastric bypass (RYGB)

Roux-en-Y gastric bypass has replaced the older banded gastric bypass, and involves creating a small pouch from the stomach which remains attached to the oesophagus at one end, and connected to a section of the small intestine at the other end, thereby bypassing the remaining stomach and the initial loop of small intestine (Figure 9). This procedure reduces intestinal absorption. Adaptations of the procedure have been used to increase malabsorption and increase weight loss. The procedure is technically reversible. Roux en Y gastric bypass comprises 52.1% of bariatric surgery in the United Kingdom [22].

Figure 9: Diagrammatic representation of a Roux-en-Y gastric bypass procedure



A key aim of this policy is to increase capacity and reduce waiting times for patients most in need of surgery, as set out in the criteria.

Who will be affected by this work? e.g. staff, patients, service users, partner organisations etc.

Eligibility Criteria: Restricted

Eligibility Criteria: Restricted

Patients eligible for surgery must have the following:

- BMI of >35kg/m2
  AND
  Type 2 diabetes mellitus which has been diagnosed within the last 10 years.
  OR
- BMI of >50kg/m2

The choice of surgery must be undertaken by a specialist bariatric surgeon following a shared decision making discussion with the patient:

- Listen to patients and respond to their concerns and preferences.
- Give patients the information they want or need in a way they can understand.
- Respect patients' right to reach decisions with the doctor about their treatment and care.
- Support patients in caring for themselves to improve and maintain their health.

This means **(for patients who DO NOT meet the above criteria)** the CCG will **only** fund the treatment if an Individual Funding Request (IFR) application proves exceptional clinical need and that is supported by the CCG.

Activity data 2018/19

	BSOL	Sandwell
Number of Procedures	116	61

It is not possible to tell definitively from the data if any of the above procedures would not have been undertaken based on this policy however it is believed that these procedures undertaken represent patients who would receive bariatric surgery under this policy.

Number of procedures undertaken overall and by CCG

Due to limited data collection by the providers service activity data is available by headcount only not protected characteristic.
The Joint Strategic Needs Assessments for Birmingham, Solihull and Sandwell are available via the links below.

Sandwell

Birmingham

Solihull

2. Research

What evidence have you identified and considered? This can include national research, surveys, reports, NICE guidelines, focus groups, pilot activity evaluations, clinical experts or working groups, JSNA or other equality analyses.

Research/Publications	Working Groups	Clinical Experts
Guidance 1. National Institute for Health and Care Excellence. Obesity: identification, assessment and management (CG189) [Internet]. 2014 [cited 2017 July 2017]; Available from: https://www.nice.org.uk/guidance/cg189/chapter/Introduction. 2. NHS England. Clinical Commissioning Policy: Complex and Specialised Obesity Surgery. 2013 3. Department of Health. Developing a specification for lifestyle weight management services. 2013 4. National Institute for Health and Care Excellence. Costing template: Obesity: identification, assessment and management of overweight and obesity in children, young people and adults (CG189) [Internet]. [cited 2017 July 31st];Available from: https://www.nice.org.uk/guidance/cg189/resources. 5. National Institute for Health and Care Excellence. Implantation of a duodenal–jejunal bypass sleeve for managing obesity (IPG471) [Internet]. [cited 2017 July 31st];Available from: https://www.nice.org.uk/guidance/IPG471 6. National Institute for Health and Care Excellence. Laparoscopic gastric plication for the treatment of severe obesity (IPG432) [Internet]. [cited 2017 July 31st];Available from: https://www.nice.org.uk/guidance/IPG432 7. National Institute for Health and Care Excellence. Overweight and obese adults - NICE Pathways [Internet]. [cited 2017 July 31st];Available from: http://pathways.nice.org.uk/pathways/obesity#path=view%3A/pathways/obesity/overweight-and-obese-adults.xml&content=view-index 8. Public Health England Obesity & Healthy Weight Team. Report of the working group into joined up clinical pathways for obesity.pdf [Internet]. 2014. Available from: https://www.england.nhs.uk/wp-content/uploads/2014/03/owg-join-clinc-path.pdf 9. PHE. National mapping of weight management services. 2015 10. National Institute for Health and Care Excellence. Weight management: lifestyle services for overweight or obese adults (PH53) [Internet]. 2014 [cited 2017 July 31st];Available from: https://www.nice.org.uk/guidance/ph53 11. National Institute for Health and Care Excellence. Managing weight through lifestyle change in adults - NICE Pathways [Internet]. [cited 2017 July 31st];Available from: https://pathways.nice.org.uk/pathways/lifestyle-		

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3. Impact and Evidence:

In the following boxes detail the findings and impact identified (positive or negative) within the research detailed above; this should also include any identified health inequalities which exist in relation to this work.

3. Impact and Evidence:

Age: Describe age related impact and evidence. This can include safeguarding, consent and welfare issues:

Age range data is not available for the profile of patients requesting the procedure. Some link may be identified between obesity and reduced mobility.

As the treatment has been restricted, those who meet the criteria will be able to access treatment, who are the group who are deemed to benefit most. For patients not eligible alternative less invasive options are available to help reduce their BMI.

Disability: Describe disability related impact and evidence. This can include attitudinal, physical, communication and social barriers as well as mental health/ learning disabilities, cognitive impairments:

As with age obesity is itself a life limiting condition and is commonly found as a co morbidity with other conditions. It has not been shown the restricting this treatment will impact on this group negatively since those who would benefit most can access surgery and for others alternative approaches are better.

It is noted that exercise may be more difficult / impossible for patients with some conditions which reduce mobility. In such case the approach would give due regard to reasonable adjustments.

Gender reassignment (including transgender): Describe any impact and evidence on transgender people. This can include issues such as privacy of data and harassment:

No impact identified

Marriage and civil partnership: Describe any impact and evidence in relation to marriage and civil partnership. This can include working arrangements, part-time working, and caring responsibilities:

No impact identified

Pregnancy and maternity: Describe any impact and evidence on pregnancy and maternity. This can include working arrangements, part-time working, and caring responsibilities:

3. Impact and Evidence:

No impact identified on the basis of available data, a link may be made between pregnancy and increased weight during and post birth.

Race: Describe race related impact and evidence**.** This can include information on different ethnic groups, Roma gypsies, Irish travellers, nationalities, cultures, and language barriers:

Patients from BAME backgrounds (including South Asian and African Caribbean) have a higher risk of developing type 2 diabetes at a lower BMI. Therefore the criteria to be considered for Bariatric Surgery could have an adverse impact on people from these communities in the prevention of developing type 2 diabetes.

The TPCDG Committee spent considerable time discussing this issue and how to manage this. The criteria for surgery are in line with NICE recommendation for bariatric surgery, where the threshold for surgery is lower (i.e. BMI>35 as opposed to BMI>50) when the patient has type 2 diabetes to take into consideration the fact that those patient in certain ethnic groups have a higher risk of developing diabetes at a lower BMI.

Religion or belief: Describe any religion, belief or no belief impact and evidence. This can include dietary needs, consent and end of life issues:

No impact identified

Sex: Describe any impact and evidence on men and women. This could include access to services and employment:

No impact identified

Sexual orientation: Describe any impact and evidence on heterosexual people as well as lesbian, gay and bisexual people. This could include access to services and employment, attitudinal and social barriers:

No impact identified

Carers: Describe any impact and evidence on part-time working, shift-patterns, general caring responsibilities:

No impact identified

Other disadvantaged groups: Describe any impact and evidence on groups experiencing disadvantage and barriers to access and outcomes. This can include lower socio-economic status, resident status (migrants, asylum seekers), homeless, looked after children, single parent households, victims of domestic abuse, victims of drugs / alcohol abuse: (This list is not exhaustive)

3. Impact and Evidence:
No impact identified

4. Health Inequalities	Yes/No	Evidence
Could health inequalities be created or persist by the proposals?	No	This condition could be linked to a health inequality due to the prevalence of obesity. As the surgical procedures remain available it is not anticipated that a health inequality will be made worse.
Is there any impact for groups or communities living in particular geographical areas?	Yes	A limited link between obesity and areas of high deprivation has been made.
Is there any impact for groups or communities affected by unemployment, lower educational attainment, low income, or poor access to green spaces?	Yes	The ability to access better diet quality and exercise may be reduced for those in low socio economic groups. Due regard to this will need to be given in supporting such patients.
How will you ensure the proposals reduce health inequalities? The intention of the policy is to support patients with very high BMI through a number of interventions with surgery being the final option.		

5. FREDA Principles/ Human Rights	Question	Response

Fairness – Fair and equal access to services	How will this respect a person's entitlement to access this service?	Yes, this decision has been made in line with clinical recommendation and NICE guidance
Respect – right to have private and family life respected	How will the person's right to respect for private and family life, confidentiality and consent be upheld?	No evidence of impact from this policy
Equality – right not to be discriminated against based on your protected characteristics	How will this process ensure that people are not discriminated against and have their needs met and identified?	No discrimination identified
	How will this affect a person's right to freedom of thought, conscience and religion?	N/A
Dignity – the right not to be treated in a degrading way	How will you ensure that individuals are not being treated in an inhuman or degrading way?	Policy will be applied with due Regard to this consideration.
Autonomy – right to respect for private & family life; being able to make informed decisions and choices	How will individuals have the opportunity to be involved in discussions and decisions about their own healthcare?	An individual can discuss the impact with their GP and has the option for an IFR request to be made
Right to **Life**	Will or could it affect someone's right to life? How?	No evidence of impact from this policy
Right to **Liberty**	Will or could someone be deprived of their liberty? How?	No evidence of impact from this policy

6. Social Value

Consider how you might use the opportunity to improve health and reduce health inequalities and so achieve wider public benefits, through action on the social determinants of health.

Marmot Policy Objective	**What actions are you able to build into the procurement activity and/or contract to achieve wider public benefits?**
Enable all people to have control over their lives and maximise their capabilities	None
Create fair employment and good work for all	None

Create and develop health and sustainable places and communities	None
Strengthen the role and impact of ill-health prevention	None

7. Engagement, Involvement and Consultation

If relevant, please state what engagement activity has been undertaken and the date and with which protected groups:

Engagement Activity	Protected Characteristic/ Group/ Community	Date

For each engagement activity, please state the key feedback and how this will shape policy / service decisions (E.g. patient told us …. So we will …..):

As part of the process further targeted engagement is planned with representative groups from among Sandwell, Birmingham and Solihull Patients. In addition, it has been identified that patient and clinician information is key in ensuring that the harmonised treatment policies review delivers effective outcomes. To this end an information briefing sheets on each procedure will be developed to give more information on the procedure, eligibility criteria and signposting to further information sources, such as NHS Choices. These information sheets are also designed to help facilitate discussions between GPs and patients. Information briefing sheets have already been tested and uploaded onto the GP systems for the first 45 harmonised treatment policies for Birmingham and Solihull. Due regard will be given to both the accessible information standard and the potential need to translate such leaflets into relevant local languages.

The engagement team used every possible route throughout the engagement period to encourage people to feedback on the proposed policy. Unfortunately, despite the wide communication undertaken through all communication and engagement channels available, 49 questionnaires were completed online and there was no interest from stakeholders, patients and the public to attend any of the five stakeholder events arranged. As a result, the events were cancelled, and the engagement team looked at other routes to encourage engagement with patients directly where possible. A possible reason for the general lack of interest and feedback from stakeholders, patients and the public is most likely because this clinical treatments policy either widening the scope of the current service provision, providing policies to protect the current service provision or the intervention is for somewhat rare conditions.

Also, in phase 3 of the harmonisation of policies programme clinicians had been integral to the development of the policies from the beginning of the process. It could therefore be argued the proposed policy shared for public engagement was to some extent already informed from a local patient experience and outcomes perspective.

As there is currently no policy for the bariatric surgery to promote weight loss, the potential impact on patients was therefore minimal as the treatment will be offered based on specific criteria. Although over 50% agreed with the proposed policy criteria,

7. Engagement, Involvement and Consultation

healthcare professionals questioned the eligibility criteria. Particular concerns were also raised that the proposed policy may exclude those who are in drastic need of the surgery and may oppose current NICE guidelines.

8. Summary of Analysis

Considering the evidence and engagement activity you listed above, please summarise the impact of your work:

The restriction of this policy will have limited impact on those who would wish to receive the treatments, this must be balanced against the need to adhere to NICE guidelines and the clinical effectiveness evidence. The opportunity for any exceptional cases to be considered via IFR remains and will ensure treatment is available in an exceptional case.

9. Mitigations and Changes :

Please give an outline of what you are going to do, based on the gaps, challenges and opportunities you have identified in the summary of analysis section. This might include action(s) to mitigate against any actual or potential adverse impacts, reduce health inequalities, or promote social value. Identify the **recommendations** and any **changes** to the proposal arising from the equality analysis.

Consideration will need to be given to what additional support patients from a low socio economic background will require and how due regard can be given to reasonable adjustments in approach for disabled persons.

10. Contract Monitoring and Key Performance Indicators

Detail how and when the service will be monitored and what key equality performance indicators or reporting requirements will be included within the contract (refer to NHS Standard Contract SC12 and 13):

This policy is not linked to a contract however, prospective providers remain bound by their contracts with the CCG.

11. Procurement

Detail the key equality, health inequalities, human rights, and social value criteria that will be included as part of the procurement activity (to evaluate the providers ability to deliver the service in line with these areas):

N/A

12. Publication

How will you share the findings of the Equality Analysis?

This can include: reports into committee or Governing Body, feedback to stakeholders including patients and the public, publication on the web pages. All Equality Analysis should be recommended for publication unless they are deemed to contain sensitive information.

Publication on the CCG's website.

Following approval all finalised Equality Analysis should be sent to the Communications and Engagement team for publication: bsol.comms@nhs.net

13. Sign Off

The Equality Analysis will need to go through a process of **quality assurance** by the Senior Manager for Equality and Diversity, Senior Manager for Assurance and Compliance or Equality and Human Rights Manager **and** signed-off by a delegated committee

	Name	Date
Quality Assured By:		
Which Committee will be considering the findings and signing off the EA?		
Minute number (to be inserted following presentation to committee)		

Please send to Balvinder Everitt or Michelle Dunne, Equality, Diversity and Inclusion for Quality Assurance.

Once you have committee sign off, please send to Caroline Higgs, Communications & Engagement Team for publication: bsol.comms@nhs.net

Equality Analysis

(Health Inequalities, Human Rights, Social Value)

Policy for the use of Biological Mesh

Before completing this equality analysis it is recommended that you:

- ✓ Contact your equality and diversity lead for advice and support
- ✓ Take time to read the accompanying policy and guidance document on how to complete an equality analysis

NHS Birmingham and Solihull Clinical Commissioning Group
NHS Sandwell and West Birmingham Clinical Commissioning Group

1. Background

EA Title	Policy for the use of Biological Mesh		
EA Author	David King	**Team**	Equality and Diversity
Date Started	13/08/2019	**Date Completed**	4/12/2019
EA Version	4	**Reviewed by E&D**	

What are the intended outcomes of this work? Include outline of objectives and function aims

Surgical Mesh

Surgical mesh is a screen-like material that is used as a reinforcement for tissue or bone. It can be made of synthetic polymers or biopolymers.

Materials used for surgical mesh include:

- Non-absorbable synthetic polymers (polypropylene)
- Absorbable synthetic polymers (polyglycolic acid or polycaprolactone)
- Biologic (acellular collagen sourced from cows or pigs)
- Composite (a combination of any of the three previous materials e.g. Biosynthetic)

Mesh implants may be used in a number of surgical procedures to provide additional support when repairing weakened or damaged tissue.

Over recent years attention has increased on complications that can occur with the use of this mesh in urogynaecological procedures to treat pelvic organ prolapse (POP) and stress urinary incontinence (SUI). These complications may include persistent pain, sexual problems, mesh exposure through vaginal tissues and occasionally injury to nearby organs, such as the bladder or bowel. There has been an acknowledgement from the NHS England Mesh Working Group that there is a lack of comprehensive data on these complications. Work is ongoing to ensure that patients are encouraged to report complications and clinicians report adverse events.

Currently, the use of mesh in urogynaecological procedures to treat pelvic organ prolapse and stress urinary incontinence is not supported across the NHS and a wider NHS England review of the use of mesh in these clinical circumstances, means that at the current time in line with NHSE recommendation, the CCG does not support the use of mesh implants in these urogynaecological procedures.

However, surgical mesh implants (non-biological mesh) are routinely used across the NHS to address the clinical problem of hernia. A hernia may be inguinal, femoral; umbilical; para-umbilical or incisional. These implants typically restore structural domain to the abdominal/pelvic wall and prevent extrusion of visceral contents. Surgery takes place either as an open or laprascopic procedure.

Open surgery
The surgeon makes a single cut (incision) over the hernia. This incision is usually about 6 to 8cm long. The surgeon then places the lump of fatty tissue or loop of bowel back into your abdomen (tummy). A mesh is placed in the abdominal wall, at the weak spot where the hernia came through, to strengthen it. When the repair is complete, your skin will be sealed with stitches. These stitches usually dissolve on their own over the course of a few days after the operation.

If the hernia has become strangulated and part of the bowel is damaged, the affected segment may need to be removed and the 2 ends of healthy bowel rejoined. This is a bigger operation and you may need to stay in hospital for 4 to 5 days.

Laparoscopic (keyhole) surgery
During keyhole surgery, the surgeon usually makes 3 small incisions in your abdomen instead of a single larger incision. A thin tube containing a light source and a camera (laparoscope) is inserted through one of these incisions so the surgeon can see inside your abdomen. Special surgical instruments are inserted through the other incisions so the surgeon can pull the hernia back into place.

There are 2 types of keyhole surgery.

1. Transabdominal preperitoneal (TAPP)

Instruments are inserted through the muscle wall of your abdomen and through the lining covering your organs (the peritoneum).

A flap of the peritoneum is then peeled back over the hernia and a piece of mesh is stapled or glued to the weakened area in your abdomen wall to strengthen it.

2. Totally extraperitoneal (TEP)

This is the newest keyhole technique and involves repairing the hernia without entering the peritoneal cavity.

Once the repair is complete, the incisions in your skin are sealed with stitches or surgical glue.

Evidence Review

A review of the clinical evidence found mixed clinical review, with no strong basis for the use of biological mesh over standard mesh in standard or first line hernia repair operations (inguinal; umbilical; paraumbilical or incisional). The standard of the evidence reviewed comprised mainly of retrospective studies of low to moderate quality, but with hernia reoccurrence being slightly higher following the use of biological mesh, but no significant difference was determined in the occurrence of wound and mesh infection. It is possible due to the nature of the studies that the high rates of reoccurrence could be accounted for due to the more complex nature of the hernia repairs where biological mesh was utilised. Therefore, in light of the currently available low quality evidence, to support the use of biological mesh over standard mesh, in first line or standard hernia repair procedures, the use of biological or bio-synthetic mesh is not routinely commissioned.

However, the use of biological or biosynthetic mesh in hernia repair may be undertaken when first line hernia repair surgery with permanent synthetic mesh or conservative treatment has failed or is inappropriate to use synthetic mesh and the use of biological / biosynthetic mesh has been deemed the most clinically appropriate surgical intervention by a complex abdominal wall repair multidisciplinary team.

Who will be affected by this work? e.g. staff, patients, service users, partner organisations etc.

Eligibility Criteria: Restricted

The use of biological or biosynthetic mesh in standard hernia (inguinal; femoral; umbilical, para-umbilical and incisional) repair is Not Routinely Commissioned.
The use of biological or biosynthetic mesh in hernia repair is only to be undertaken when:

- first line hernia repair surgery with permanent synthetic mesh followed by conservative wound care management has failed

OR

- first line hernia repair surgery with permanent synthetic mesh followed by conservative wound care management is deemed inappropriate

In ALL surgical cases, where the use of biological / biosynthetic mesh is to be considered for use in hernia repair, the patient must be reviewed by a specialist complex abdominal wall repair MDT and the use of biological / biosynthetic mesh must be deemed the most clinically appropriate surgical intervention by a complex abdominal wall repair MDT.

Conservative wound care management is defined as follows:

- Wound care management plan developed for the individual patient by the specialist wound care management team has failed.

Investigations for suspected or proven malignancy are outside the scope of this policy and should be treated in line with the relevant cancer pathway.

This means the CCG will <u>only</u> fund the treatment if an Individual Funding Request (IFR) application proves exceptional clinical need and that is supported by the CCG.

Activity data 2018/19 –

This is currently not available, due to the lack of granular coding detail to determine between **synthetic** and **biological / biosynthetic mesh**. The number of IFR requests are <10 per year in 17/18 and 18/19.

Number of procedures undertaken overall and by CCG

Due to limited data collection by the providers service activity data is available by headcount only not protected characteristic.
The Joint Strategic Needs Assessments for Birmingham, Solihull and Sandwell are available via the links below.

Sandwell

Birmingham

Solihull

2. Research

What evidence have you identified and considered? This can include national research, surveys, reports, NICE guidelines, focus groups, pilot activity evaluations, clinical experts or working groups, JSNA or other equality analyses.

Research/Publications	Working Groups	Clinical Experts
Guidance 1. Barber,S. 2018 BRIEFING PAPER: Surgical mesh implants Number CBP 8108, 15 January 2018. House of Commons Library. https://www.baus.org.uk/_userfiles/pages/files/Patients/CBP-8108.pdf 2. RCOG. Use of Vaginal Mesh. (2019) https://www.rcog.org.uk/globalassets/documents/guidelines/safety-alerts/nhs-mesh-letter-extension-of-pause-on-the-use-of-vaginal-mesh-29-march-2019.pdf 3. F. Köckerling, N. N. Alam, S. A. Antoniou, I. R. Daniels, F. Famiglietti, R. H. Fortelny, M. M. Heiss, F. Kallinowski, I. Kyle-Leinhase, F. Mayer, M. Miserez, A. Montgomery, S. Morales-Conde, F. Muysoms, S. K. Narang, A. Petter-Puchner, W. Reinpold, H. Scheuerlein, M. Smietanski, B. Stechemesser, C. Strey, G. Woeste, N. J. Smart. What is the evidence for the use of biologic or biosynthetic meshes in abdominal wall reconstruction? Hernia. 2018; 22(2): 249–269. Published online 2018 Jan 31. doi: 10.1007/s10029-018-1735-y		

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5978919/

4. Biologic versus Synthetic Mesh Reinforcement: What are the Pros and Cons?
James F. FitzGerald, Anjali S. Kumar. Clin Colon Rectal Surg. 2014 Dec; 27(4): 140–148. doi: 10.1055/s-0034-1394155
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4477030/

5. Majumder A[1], Winder JS[2], Wen Y[1], Pauli EM[2], Belyansky I[3], Novitsky YW[4] Comparative analysis of biologic versus synthetic mesh outcomes in contaminated hernia repairs. Surgery. 2016 Oct;160(4):828-838. doi: 10.1016/j.surg.2016.04.041. Epub 2016 Jul 21. https://www.ncbi.nlm.nih.gov/pubmed/27452954

6. Carver DA, Kirkpatrick AW, Eberle TL, *et al.* Performance of biological mesh materials in abdominal wall reconstruction: study protocol for a randomised controlled trial
BMJ Open 2019;9:e024091. doi: 10.1136/bmjopen-2018-024091 .
https://bmjopen.bmj.com/content/9/2/e024091

7. C. S. Seefeldt; J. S. Meyer; J. Knievel; A. Rieger; R. Geißen,R. Lefering; M. M. Heiss (2019) BIOLAP: biological versus synthetic mesh in laparo-endoscopic inguinal hernia repair: study protocol for a randomized, multicenter, self-controlled clinical trial. *Trials*2019**20**:55. https://doi.org/10.1186/s13063-018-3122-5https://trialsjournal.biomedcentral.com/articles/10.1186/s13063-018-3122-5

8. Loes Knaapen, Otmar Buyne, Harry van Goor, Nicholas J (2016) Synthetic vs biologic mesh for the repair and prevention of parastomal hernia. *World J Meta-Anal* 2017 December 26; 5(6): 150-166. DOI: 10.13105/wjma.v5.i6.150.
https://f6publishing.blob.core.windows.net/66e60003-20b2-4ada-9595-26b5152dc122/WJMA-5-150.pdf

9. David A Carver, Andrew W Kirkpatrick, Tammy L Eberle, Chad G Ball (2019)Performance of biological mesh materials in abdominal wall reconstruction: study protocol for a randomised controlled trial

BMJ Open. 2019; 9(2): e024091. Published online 2019 Feb 15. doi: 10.1136/bmjopen-2018-024091

10. Hubert Scheuerlein, Andreas Thiessen, Christine Schug-Pass, Ferdinand Köckerling. (2018) What Do We Know About Component Separation Techniques for Abdominal Wall Hernia Repair? Front Surg. 2018; 5: 24. Published online 2018 Mar 27. doi: 10.3389/fsurg.2018.00024

3. Impact and Evidence:

In the following boxes detail the findings and impact identified (positive or negative) within the research detailed above; this should also include any identified health inequalities which exist in relation to this work.

Age: Describe age related impact and evidence. This can include safeguarding, consent and welfare issues:

Although developing a hernia can affect those from birth up to old age, the most common type diagnosed is often associated with ageing, the diaphragm becoming weaker with age and repeated strain/pressure on the stomach.

Disability: Describe disability related impact and evidence. This can include attitudinal, physical, communication and social barriers as well as mental health/ learning disabilities, cognitive impairments:

No impact identified based on available data, however a link can be made with degenerative conditions where the person experiencing is likely to have a disability. Limiting this procedure may have an impact on this group as a result. This should be balanced against the lack of clinical evidence.

Gender reassignment (including transgender): Describe any impact and evidence on transgender people. This can include issues such as privacy of data and harassment:

No impact identified

3. Impact and Evidence:
Marriage and civil partnership: Describe any impact and evidence in relation to marriage and civil partnership. This can include working arrangements, part-time working, and caring responsibilities: No impact identified
Pregnancy and maternity: Describe any impact and evidence on pregnancy and maternity. This can include working arrangements, part-time working, and caring responsibilities: Those who are pregnant may have an increased risk of hernias because of the increased pressure pregnancy puts on the abdomen.
Race: Describe race related impact and evidence**.** This can include information on different ethnic groups, Roma gypsies, Irish travellers, nationalities, cultures, and language barriers: No impact identified
Religion or belief: Describe any religion, belief or no belief impact and evidence. This can include dietary needs, consent and end of life issues: Biological mesh although restricted can be made from porcine / bovine or human tissues due regard to a patient's faith should be taken into consideration if biological mesh is commissioned.
Sex: Describe any impact and evidence on men and women. This could include access to services and employment: Depending on the type of hernia diagnosed there is a correlation that males and females are more prone to a developing particular type due to the nature of the condition. However, the most common type diagnosed mainly affects men.
Sexual orientation: Describe any impact and evidence on heterosexual people as well as lesbian, gay and bisexual people. This could include access to services and employment, attitudinal and social barriers: No impact identified
Carers: Describe any impact and evidence on part-time working, shift-patterns, general caring responsibilities: No impact identified

3. Impact and Evidence:
Other disadvantaged groups: Describe any impact and evidence on groups experiencing disadvantage and barriers to access and outcomes. This can include lower socio-economic status, resident status (migrants, asylum seekers), homeless, looked after children, single parent households, victims of domestic abuse, victims of drugs / alcohol abuse: (This list is not exhaustive) No impact identified

4. Health Inequalities	Yes/No	Evidence
Could health inequalities be created or persist by the proposals?	No	This condition is not linked to a health inequality.
Is there any impact for groups or communities living in particular geographical areas?	No	No impact identified
Is there any impact for groups or communities affected by unemployment, lower educational attainment, low income, or poor access to green spaces?	No	No impact identified
How will you ensure the proposals reduce health inequalities?		

5. FREDA Principles/ Human Rights	Question	Response
Fairness – Fair and equal access to services	How will this respect a person's entitlement to access this service?	Yes, this decision has been made in line with clinical recommendation.
Respect – right to have private and family life respected	How will the person's right to respect for private and family life, confidentiality and consent be upheld?	No evidence of impact from this policy
Equality – right not to be discriminated against based on your protected characteristics	How will this process ensure that people are not discriminated against and have their needs met and identified?	No discrimination identified
	How will this affect a person's right to freedom of thought, conscience and religion?	If biological mesh is commissioned due regard to a patient's faith must be taken into consideration. (Regard to use of pork / bovine derived products

		and their unacceptability to those of certain faith groups)
Dignity – the right not to be treated in a degrading way	How will you ensure that individuals are not being treated in an inhuman or degrading way?	Policy will be applied with due regard to this consideration.
Autonomy – right to respect for private & family life; being able to make informed decisions and choices	How will individuals have the opportunity to be involved in discussions and decisions about their own healthcare?	An individual can discuss the impact with their GP and has the option for an IFR request to be made.
Right to **Life**	Will or could it affect someone's right to life? How?	No evidence of impact from this policy
Right to **Liberty**	Will or could someone be deprived of their liberty? How?	No evidence of impact from this policy

6. Social Value

Consider how you might use the opportunity to improve health and reduce health inequalities and so achieve wider public benefits, through action on the social determinants of health.

Marmot Policy Objective	**What actions are you able to build into the procurement activity and/or contract to achieve wider public benefits?**
Enable all people to have control over their lives and maximise their capabilities	None
Create fair employment and good work for all	None
Create and develop health and sustainable places and communities	None
Strengthen the role and impact of ill-health prevention	None

7. Engagement, Involvement and Consultation

If relevant, please state what engagement activity has been undertaken and the date and with which protected groups:

Engagement Activity	**Protected Characteristic/ Group/ Community**	**Date**

For each engagement activity, please state the key feedback and how this will shape policy / service decisions (E.g. patient told us …. So we will …..):

As part of the process further targeted engagement is planned with representative groups from among Sandwell, Birmingham and Solihull Patients. In addition, it has been identified that patient and clinician information is key in ensuring that the

7. Engagement, Involvement and Consultation

harmonised treatment policies review delivers effective outcomes. To this end an information briefing sheets on each procedure will be developed to give more information on the procedure, eligibility criteria and signposting to further information sources, such as NHS Choices. These information sheets are also designed to help facilitate discussions between GPs and patients. Information briefing sheets have already been tested and uploaded onto the GP systems for the first 45 harmonised treatment policies for Birmingham and Solihull. Due regard will be given to both the accessible information standard and the potential need to translate such leaflets into relevant local languages.

The engagement team used every possible route throughout the engagement period to encourage people to feedback on the proposed policy. Unfortunately, despite the wide communication undertaken through all communication and engagement channels available, 49 questionnaires were completed online and there was no interest from stakeholders, patients and the public to attend any of the five stakeholder events arranged. As a result, the events were cancelled, and the engagement team looked at other routes to encourage engagement with patients directly. A possible reason for the general lack of interest and feedback from stakeholders, patients and the public is most likely because this clinical treatments policy either widening the scope of the current service provision, providing policies to protect the current service provision or the intervention is for somewhat rare conditions.

Also, in phase 3 of the harmonisation of policies programme clinicians had been integral to the development of the policies from the beginning of the process. It could therefore be argued the proposed policy shared for public engagement was to some extent already informed from a local patient experience and outcomes perspective.

The potential impact on patients was thought to be minimal as there is no policy in place for the use of biological mesh in hernia repair. Out of the four people who had accessed this service, only one respondent felt this would have a negative impact and the decision to offer this treatment should be left with the patient and GP. There was a consensus that as other meshes are available and used, therefore not using biological mesh should not have a great impact on patients. However, some feedback also suggested that more evidence around the use and impact of synthetic mesh was required.

8. Summary of Analysis

Considering the evidence and engagement activity you listed above, please summarise the impact of your work:

The restriction of this policy will have limited impact on those who would wish to receive the treatments as there is no clear evidence to support the use of biological mesh over standard mesh in standard hernia repair. For those whose initial surgery has failed or use of synthetic mesh is inappropriate, the patient will be reviewed by a specialist complex abdominal wall MDT.

This must be balanced against the need to adhere to the clinical effectiveness evidence. The opportunity for any exceptional cases to be considered via IFR remains.

9. Mitigations and Changes :

Please give an outline of what you are going to do, based on the gaps, challenges and opportunities you have identified in the summary of analysis section. This might include action(s) to mitigate against any actual or potential adverse impacts, reduce health inequalities, or promote social value. Identify the **recommendations** and any **changes** to the proposal arising from the equality analysis.

None identified

10. Contract Monitoring and Key Performance Indicators

Detail how and when the service will be monitored and what key equality performance indicators or reporting requirements will be included within the contract (refer to NHS Standard Contract SC12 and 13):

This policy is not linked to a contract however, prospective providers remain bound by their contracts with the CCG.

11. Procurement

Detail the key equality, health inequalities, human rights, and social value criteria that will be included as part of the procurement activity (to evaluate the providers ability to deliver the service in line with these areas):

N/A

12. Publication

How will you share the findings of the Equality Analysis?

This can include: reports into committee or Governing Body, feedback to stakeholders including patients and the public, publication on the web pages. All Equality Analysis should be recommended for publication unless they are deemed to contain sensitive information.

Publication on the CCG's website.
Following approval all finalised Equality Analysis should be sent to the Communications and Engagement team for publication: bsol.comms@nhs.net

13. Sign Off

The Equality Analysis will need to go through a process of **quality assurance** by the Senior Manager for Equality and Diversity, Senior Manager for Assurance and Compliance or Equality and Human Rights Manager **and** signed-off by a delegated committee

	Name	Date
Quality Assured By:		
Which Committee will be considering the findings and signing off the EA?		
Minute number (to be inserted following presentation to committee)		

Please send to Balvinder Everitt or Michelle Dunne, Equality, Diversity and Inclusion for Quality Assurance.

Once you have committee sign off, please send to Caroline Higgs, Communications & Engagement Team for publication: bsol.comms@nhs.net

Equality Analysis

(Health Inequalities, Human Rights, Social Value)

Policy for use of Domiciliary Continuous Positive Airway Pressure Devices in Obstructive Sleep Apnoea Hypnoea Syndrome

Before completing this equality analysis it is recommended that you:

- ✓ Contact your equality and diversity lead for advice and support
- ✓ Take time to read the accompanying policy and guidance document on how to complete an equality analysis

NHS Birmingham and Solihull Clinical Commissioning Group
NHS Sandwell and West Birmingham Clinical Commissioning Group

1. Background

EA Title	Policy for use of domiciliary Non-Invasive Ventilation		
EA Author	David King	**Team**	Equality and Diversity Team
Date Started		**Date Completed**	4/12/2019
EA Version	4	**Reviewed by E&D**	

What are the intended outcomes of this work? Include outline of objectives and function aims

Obstructive Sleep Apnoea Hypopnea Syndrome (OSAHS)

Apnoea is defined as a temporary absence or cessation of breathing. Obstructive Sleep Apnoea hypopnea syndrome (OSAHS) is a condition, in which, a person experiences repeated episodes of apnoea because of a narrowing or closure of the pharyngeal airway during sleep. This is caused by a decrease in the tone of the muscles supporting the airway during sleep. Complete closure (obstruction) stops airflow (apnoea) whereas partial obstruction decreases airflow (hypopnoea). OSAHS results in episodes of brief awakening from sleep to restore normal breathing.

Moderate to severe OSAHS can be diagnosed from patient history and a sleep study using oximetry or other monitoring devices carried out in the person's home. In some cases, further studies that monitor additional physiological variables in a sleep laboratory or at home may be required, especially when alternative diagnoses are being considered. The severity of OSAHS is usually assessed on the basis of both severity of symptoms (particularly the degree of sleepiness) and the sleep study, by using either the apnoea/hypopnoea index (AHI) or the oxygen desaturation index. OSAHS is considered mild when the AHI is 5–14 in a sleep study, moderate when the AHI is 15–30, and severe when the AHI is over 30. In addition to the AHI, the severity of symptoms is also important.

The symptoms of OSAHS include impaired alertness, cognitive impairment, excessive daytime sleepiness, snoring, nocturia, morning headaches and sexual dysfunction. The sleep quality of partners may also be affected. Excessive daytime sleepiness can adversely affect cognitive function, mood and quality of life. OSAHS is associated with high blood pressure, which increases the risk of cardiovascular disease and stroke. OSAHS has also been associated with an increased risk of road traffic accidents.

Major risk factors for developing OSAHS are increasing age, obesity and being male. OSAHS is also associated with certain specific craniofacial characteristics (such as retrognathia), enlarged tonsils and enlarged tongue. Use of alcohol or sedatives can also increase the risk or severity of the condition. OSAHS has been reported to affect up to 4% of middle-aged men and 2% of middle-aged women in the UK. It is estimated that 1% of men in the UK may have severe OSAHS.

The use of Continuous Positive Airway Pressure in OSAHS.

Treatment for OSAHS aims to reduce daytime sleepiness by reducing the number of episodes of apnoea/hypopnoea experienced during sleep. In the clinical management of sleep apnoea, continuous positive airway pressure (CPAP) is the most commonly use intervention for patients with moderate or severe diagnosis of OSAHS.

The potential alternative treatment to CPAP are:

- lifestyle management,
- dental devices
- surgery.

Lifestyle management involves helping people to lose weight, stop smoking and/or decrease alcohol consumption.

Dental devices are designed to keep the upper airway open during sleep. The efficacy of dental devices has been established in clinical trials, but these devices are traditionally viewed as a treatment option only for mild and moderate OSAHS.

Surgery involves resection of the uvula and redundant retrolingual soft tissue. However, there is a lack of evidence of clinical effectiveness, and surgery is not routinely used in clinical practice.

A CPAP device consists of a unit that generates airflow, which is directed to the airway via a mask. Positive pressure is generated by the airflow, which prevents upper airway collapse. For CPAP treatment to be effective the patient must always wear their device when they go to sleep.

Reasons for not adhering to CPAP treatment include poor mask fit, pressure intolerance and, more commonly, upper airway symptoms such as nasal dryness, nasal bleeding and throat irritation. Humidification devices are now commonly used in conjunction with CPAP devices in order to reduce these side effects. Masks should be replaced at least annually, and long-term follow-up of patients is critical to ensure adherence.

There are two types of CPAP devices. Fixed CPAP devices deliver air at constant pressure throughout the night, and the person will continue to receive this pressure until a further titration study is performed to determine whether the set pressure is still appropriate. Auto-titrating CPAP devices continually adjust the pressure delivered throughout the night, with the aim of improving comfort and thus adherence.

Who will be affected by this work? e.g. staff, patients, service users, partner organisations etc.

Eligibility Criteria: Restricted

1. Continuous positive airway pressure (CPAP) is commissioned as a treatment option for adults with moderate or severe symptomatic obstructive sleep apnoea/hypopnoea syndrome (OSAHS).

OR

2. CPAP is only recommended as a treatment option for adults with mild OSAHS if:

    a. The OSAHS is causing severe functional impairment, which is impacting on the patient's ability to carry out activities of daily living

AND

    b. lifestyle advice and any other relevant treatment options have been unsuccessful or are considered inappropriate

The diagnosis and treatment of OSAHS, and the monitoring of the response, should always be carried out by a specialist service with appropriately trained medical and support staff.

N.B. The definition of OSAHS following a sleep study is as follows:
Mild OSAHS= Apnoea–Hypopnoea Index (AHI) 5–14.
Moderate OSAHS = AHI is 15–30.
Severe OSAHS = AHI is over 30.

Functional impairment is defined as preventing activities of daily living to be undertaken independently, i.e. sleeping; eating; walking, driving.

Exclusion criteria:

- Inability to remove mask independently (with no waking night carer)
- Cognitive / behavioural limitation affecting ability to comply safely with NIV
- Intolerance of acute NIV
- Multiple co-morbidities limiting utility of NIV

Funding will be provided for the following if the patient meets the above clinical criteria:

- One CPAP machine
- 1-2 lengths of tubing per year
- 1-2 masks per year

In a small proportion of OSA patients, CPAP proves insufficient to control apnoea and it becomes necessary to use bi-level NIV. If a patient has failed treatment with CPAP, but continues to meet the eligibility criteria outlined above, a further funding application will be considered for:

- One Bi-level NIV machine
- 1-2 lengths of tubing per year
- 1-2 masks per year

Number of procedures undertaken overall and by CCG

	BSOL	Sandwell
	Data is not available for this procedure	

The providers have not collected this data and it is not possible to collate this retrospectively.

The Joint Strategic Needs Assessments for Birmingham, Solihull and Sandwell are available via the links below.

Sandwell

Birmingham

Solihull

2. Research

What evidence have you identified and considered? This can include national research, surveys, reports, NICE guidelines, focus groups, pilot activity evaluations, clinical experts or working groups, JSNA or other equality analyses.

Research/Publications	Working Groups	Clinical Experts
Guidance: CPAP 1. Corrado A, Gorini M, Melej R, et al. Iron lung versus mask ventilat exacerbation of COPD: a randomised crossover study. *Intensive* (2009 Apr. 35(4):648-55. 2. Parke RL, McGuinness SP. Pressures delivered by nasal high flo during all phases of the respiratory cycle. *Respir Care*. 2013 Oct. 4. 3. Spoletini G, Alotaibi M, Blasi F, Hill NS. Heated Humidified High-F Oxygen in Adults: Mechanisms of Action and Clinical Implications Jul. 148 (1):253-61. 4. Ozsancak A, Sidhom S, Liesching TN, Howard W, Hill NS. EVALU THE TOTAL FACE MASKTM FOR NONINVASIVE VENTILATION ACUTE RESPIRATORY FAILURE. *Chest*. 2011 Feb 17. 5. Wysocki M, Richard JC, Meshaka P. Noninvasive proportional ass compared with noninvasive pressure support ventilation in hyperc respiratory failure. *Crit Care Med*. 2002 Feb. 30 (2):323-9. 6. Fernández-Vivas M, Caturla-Such J, González de la Rosa J, Acos J, Alvarez-Sánchez B, Cánovas-Robles J. Noninvasive pressure s proportional assist ventilation in acute respiratory failure. *Intensive* 2003 Jul. 29 (7):1126-33. 7. Hoo, G. 2018. Noninvasive Ventilation. Medscape. https://emedicine.medscape.com/article/304235-overview#a5 8. British Thoracic Society/Intensive Care Society Acute Hypercapni Failure Guideline Development Group. 2016. BTS/ICS Guidelines Ventilatory Management of Acute Hypercapnic Respiratory Failur Journal of the British Thoracic Society. http://thorax.bmj.com/site/about/guidelines.xhtml#open **9.** 18. National Institute for Health and Clinical Excellence (NICE). M disease: assessment and management**.** NICE guideline [NG42] P February 2016 Last updated: July 2019 10. 19. National Institute for Health and Clinical Excellence (NICE). *C Obstructive Pulmonary Disease in Over 16s: Diagnosis and Mana [CG101]*. London, England: NICE; 2010. https://www.nice.org.uk/		
Guidance - OSA		

1. NICE. 2008. Continuous positive airway pressure for the treatmer obstructive sleep apnoea/hypopnoea syndrome. Technology app guidance. Published: 26 March 2008. Updated Feb 2014. nice.org.uk/guidance/ta139

2. Hypoglossal nerve stimulation for moderate to severe obstructive apnoea (2017) - https://www.nice.org.uk/guidance/ipg598

3. Soft-palate implants for obstructive sleep apnoea (2007) - https://www.nice.org.uk/guidance/ipg241

4. A meta-analysis of continuous positive airway pressure therapy in cardiovascular events in patients with obstructive sleep apnoea (2 https://academic.oup.com/eurheartj/article-abstract/39/24/2291/4563763?redirectedFrom=fulltext

5. Sleep-disordered Breathing in Heart Failure (2015) - https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6159414/

6. The official website of The Epworth Sleepiness Scale (ESS) - http://epworthsleepinessscale.com/about-the-ess/

7. The Epworth Sleepiness Scale: Minimum Clinically Important Diff Obstructive Sleep Apnea (2018) - https://www.atsjournals.org/doi/abs/10.1164/rccm.201704-0672LE

8. Minimum important difference of the Epworth Sleepiness Scale in sleep apnoea: estimation from three randomised controlled trials (https://thorax.bmj.com/content/early/2018/08/11/thoraxjnl-2018-21

9. Cardiorespiratory interaction with continuous positive airway pres http://jtd.amegroups.com/article/view/18553/14525

10. Continuous positive airway pressure for the treatment of obstructi apnoea/hypopnoea syndrome (2008, reviewed 2012) - https://www.nice.org.uk/guidance/ta139

3. Impact and Evidence:

In the following boxes detail the findings and impact identified (positive or negative) within the research detailed above; this should also include any identified health inequalities which exist in relation to this work.

Age: Describe age related impact and evidence. This can include safeguarding, consent and welfare issues:

Obstructive Sleep Apnoea Hypopnea Syndrome (OSAHS)

It has been recognised that there is a link to developing OSAHS due to increasing age and alongside other conditions such as obesity. It is also noted that certain specific craniofacial characteristics (such as retrognathia), enlarged tonsils and enlarged tongue are associated with the condition and therefore may be prevalent from birth.

Disability: Describe disability related impact and evidence. This can include attitudinal, physical, communication and social barriers as well as mental health/ learning disabilities, cognitive impairments:

A link can be made with degenerative conditions where the person experiencing is likely to have a disability. Restricting this procedure may have an impact on this group as a result.

The patient must be able to remove the NIV mask either independently or the patient must have a waking night carer whom can remove the mask for them as required. This is a clinical safety issue, as if for example the patient coughs up secretions then if the mask cannot be removed to clear the secretions, then the secretions will be pushed back into the patient's airway which may cause the airway to occlude. Therefore this is a safety requirement to prevent harm to the patient when using the device.

However, an individual can discuss the impact with their GP and has the option for an individual funding request (IFR) request to be made.

Gender reassignment (including transgender): Describe any impact and evidence on transgender people. This can include issues such as privacy of data and harassment:

No Impact identified

Marriage and civil partnership: Describe any impact and evidence in relation to marriage and civil partnership. This can include working arrangements, part-time working, and caring responsibilities:

3. Impact and Evidence:
No impact identified
Pregnancy and maternity: Describe any impact and evidence on pregnancy and maternity. This can include working arrangements, part-time working, and caring responsibilities: If any of those conditions are present, then the pregnancy must be managed as the condition may worsen throughout pregnancy.
Race: Describe race related impact and evidence**.** This can include information on different ethnic groups, Roma gypsies, Irish travellers, nationalities, cultures, and language barriers: No impact identified
Religion or belief: Describe any religion, belief or no belief impact and evidence. This can include dietary needs, consent and end of life issues: No impact identified
Sex: Describe any impact and evidence on men and women. This could include access to services and employment: Depending on the diagnosis of the patient some conditions are more commonly seen in one gender over the other. Obstructive sleep apnoea hypopnea syndrome (OSAHS) is slightly more evident in males who are obese than females due to how fat is stored in the body. Where the condition has arisen from long term lifestyle choices this could affect either gender.
Sexual orientation: Describe any impact and evidence on heterosexual people as well as lesbian, gay and bisexual people. This could include access to services and employment, attitudinal and social barriers: No impact identified
Carers: Describe any impact and evidence on part-time working, shift-patterns, general caring responsibilities: No impact identified

3. Impact and Evidence:
Other disadvantaged groups: Describe any impact and evidence on groups experiencing disadvantage and barriers to access and outcomes. This can include lower socio-economic status, resident status (migrants, asylum seekers), homeless, looked after children, single parent households, victims of domestic abuse, victims of drugs / alcohol abuse: (This list is not exhaustive) Health inequalities are present in an area of deprivation – which combines factors such as income, employment, health and education which has the greatest impact on someone's likelihood of smoking.

4. Health Inequalities	Yes/No	Evidence
Could health inequalities be created or persist by the proposals?	No	This condition could be linked to a health inequality due to the prevalence of smoking. As the procedures remains available it is not anticipated that a health inequality will be made worse.
Is there any impact for groups or communities living in particular geographical areas?	Yes	A possible link between smoking and areas of high deprivation has been made.
Is there any impact for groups or communities affected by unemployment, lower educational attainment, low income, or poor access to green spaces?	Yes	A possible link between the likelihood of someone smoking and unemployment, low income and education has been made. Due regard to this will need to be given in supporting such patients.

How will you ensure the proposals reduce health inequalities?

The intention of the policy is to support patients with ventilatory support without using an invasive artificial airway method. For those patients where the condition has been a result of a long-term lifestyle choice, as in obesity, support should be provided to those patients through a number of interventions to help the patient loose weight.

5. FREDA Principles/ Human Rights	Question	Response
Fairness – Fair and equal access to services	How will this respect a person's entitlement to access this service?	Yes, this decision has been made in line with clinical recommendation and NICE guidance.
Respect – right to have private and family life respected	How will the person's right to respect for private and family life, confidentiality and consent be upheld?	No evidence of impact from this policy
Equality – right not to be discriminated against based on your protected characteristics	How will this process ensure that people are not discriminated against and have their needs met and identified?	No discrimination identified
	How will this affect a person's right to freedom of thought, conscience and religion?	N/A
Dignity – the right not to be treated in a degrading way	How will you ensure that individuals are not being treated in an inhuman or degrading way?	Policy will be applied with due regard to this consideration.
Autonomy – right to respect for private & family life; being able to make informed decisions and choices	How will individuals have the opportunity to be involved in discussions and decisions about their own healthcare?	An individual can discuss the impact with their GP and has the option for an IFR request to be made
Right to **Life**	Will or could it affect someone's right to life? How?	No evidence of impact from this policy
Right to **Liberty**	Will or could someone be deprived of their liberty? How?	No evidence of impact from this policy

6. Social Value

Consider how you might use the opportunity to improve health and reduce health inequalities and so achieve wider public benefits, through action on the social determinants of health.

Marmot Policy Objective	What actions are you able to build into the procurement activity and/or contract to achieve wider public benefits?
Enable all people to have control over their lives and maximise their capabilities	
Create fair employment and good work for all	
Create and develop health and sustainable places and communities	
Strengthen the role and impact of ill-health prevention	

7. Engagement, Involvement and Consultation

If relevant, please state what engagement activity has been undertaken and the date and with which protected groups:

Engagement Activity	Protected Characteristic/ Group/ Community	Date

For each engagement activity, please state the key feedback and how this will shape policy / service decisions (E.g. patient told us …. So we will …..):

As part of the process further targeted engagement is planned with representative groups from among Sandwell, Birmingham and Solihull Patients. In addition, it has been identified that patient and clinician information is key in ensuring that the harmonised treatment policies review delivers effective outcomes. To this end an information leaflet on each procedure will be developed to give more information on the procedure, eligibility criteria and signposting to further information sources, such as NHS Choices. These information leaflets

are also designed to help facilitate discussions between GPs and patients. Information briefing sheets have already been tested and uploaded onto the GP systems for the first 45 harmonised treatment policies for Birmingham and Solihull. Due regard will be given to both the accessible information standard and the potential need to translate such leaflets into relevant local languages.

The engagement team used every possible route throughout the engagement period to encourage people to feedback on the proposed policy. Unfortunately, despite the wide communication undertaken through all communication and engagement channels available, 49 questionnaires were completed online and there was no interest from stakeholders, patients and the public to attend any of the five stakeholder events arranged. As a result, the events were cancelled, and the engagement team looked at other routes to encourage engagement with patients directly. A possible reason for the general lack of interest and feedback from stakeholders, patients and the public is most likely because this clinical treatments policy either widening the scope of the

current service provision, providing policies to protect the current service provision or the intervention is for somewhat rare conditions.

Also, in phase 3 of the harmonisation of policies programme clinicians had been integral to the development of the policies from the beginning of the process. It could therefore be argued the proposed policy shared for public engagement was to some extent already informed from a local patient experience and outcomes perspective.

On behalf of Birmingham and Solihull CCG and Sandwell and West Birmingham CCG, a letter was sent by a specialist respiratory ventilation physiotherapist based at one of the acute NHS providers, inviting 20 patients using domiciliary NIV / CPAP to attend a meeting at the hospital to feedback on the non-invasive ventilation policies. Patients who were unable to attend due to travel difficulties were invited to inform the CCG so that transport could be provided for them. Two people followed up the invitation by telephone to find out more about the meeting, however they decided they would prefer not to attend. One person was calling on behalf of her father and explained that although he would not be able to attend, she would go through the information with him available online. A further telephone meeting was offered, should her father wish to feedback verbally. The other person calling, completed the questionnaire over the telephone with the engagement officer.

The actual meeting on Friday 4 October was attended by a patient with muscular dystrophy and her daughter (also the patient's full-time carer). The patient used non-invasive ventilation to help with her condition during the day and night.

The patient and carer told the interviewer that they strongly agreed with the policy for non-invasive ventilation for neuromuscular patients. This was because they felt the implementation of the policy would help GPs to refer patients for the correct treatment promptly. The patient and carer felt the policy would raise awareness of the respiratory conditions associated with muscular dystrophy and provide guidance on when to refer patients into a specialist respiratory service.

There is currently no policy available and so the potential impact on patients is therefore minimal as the treatment will offered based on criteria. Of the 27 of the 49 people who provided responses to this policy, only 6 had actually received this treatment and their responses were mixed. There was a general agreement that people with respiratory issues should receive this treatment to improve their quality of life.

8. Summary of Analysis

Considering the evidence and engagement activity you listed above, please summarise the impact of your work:

The restriction of this policy will have an impact on those who would wish to receive the treatments, this must be balanced against the need to adhere to NICE guidelines and the clinical effectiveness evidence. The opportunity for any exceptional cases to be

considered via IFR remains and will ensure treatment is available in an exceptional case, which is supported by the CCG.

9. Mitigations and Changes :

Please give an outline of what you are going to do, based on the gaps, challenges and opportunities you have identified in the summary of analysis section. This might include action(s) to mitigate against any actual or potential adverse impacts, reduce health inequalities, or promote social value. Identify the **recommendations** and any **changes** to the proposal arising from the equality analysis.

Consideration will need to be given to what additional support patients from a low socio economic background will require and how due regard can be given to reasonable adjustments in approach for disabled persons.

10. Contract Monitoring and Key Performance Indicators

Detail how and when the service will be monitored and what key equality performance indicators or reporting requirements will be included within the contract (refer to NHS Standard Contract SC12 and 13):

This policy is not linked to a contract however, prospective providers remain bound by their contracts with the CCG.

11. Procurement

Detail the key equality, health inequalities, human rights, and social value criteria that will be included as part of the procurement activity (to evaluate the providers ability to deliver the service in line with these areas):

N/A

12. Publication

How will you share the findings of the Equality Analysis?

This can include: reports into committee or Governing Body, feedback to stakeholders including patients and the public, publication on the web pages. All Equality Analysis should be recommended for publication unless they are deemed to contain sensitive information.
Published on CCG website
Following approval all finalised Equality Analysis should be sent to the Communications and Engagement team for publication: bsol.comms@nhs.net

13. Sign Off

The Equality Analysis will need to go through a process of **quality assurance** by the Senior Manager for Equality Diversity and Inclusion or the Manager for Equality Diversity and Inclusion prior to approval from the delegated committee

	Name	Date
Quality Assured By:		
Which Committee will be considering the findings and signing off the EA?		
Minute number (to be inserted following presentation to committee)		

Please send to Balvinder Everitt or Michelle Dunne, Equality, Diversity and Inclusion for Quality Assurance.

Once you have committee sign off, please send to Caroline Higgs, Communications & Engagement Team for publication: bsol.comms@nhs.net

Equality Analysis

(Health Inequalities, Human Rights, Social Value)

Policy for Hysteroscopy

Before completing this equality analysis it is recommended that you:

- ✓ Contact your equality and diversity lead for advice and support
- ✓ Take time to read the accompanying policy and guidance document on how to complete an equality analysis

NHS Birmingham and Solihull Clinical Commissioning Group
NHS Sandwell and West Birmingham Clinical Commissioning Group

1. Background

EA Title	Policy for Hysteroscopy		
EA Author	David King	**Team**	Equality and Diversity
Date Started		**Date Completed**	4/12/2019
EA Version	3	**Reviewed by E&D**	

What are the intended outcomes of this work? Include outline of objectives and function aims

Heavy Menstrual Bleeding (HMB/ Heavy Periods)

Heavy Menstrual Bleeding (HMB) is common but can have a big effect on a woman's everyday life. HMB does not always have an underlying cause but can result from problems such as fibroids or endometriosis.

It's difficult to define exactly what a heavy period is because it varies from woman to woman. Heavy for one woman may be normal for another. Most women will lose less than 16 teaspoons of blood (80ml) during their period, with the average being around 6 to 8 teaspoons.

Heavy menstrual bleeding is defined as losing 80ml or more in each period, having periods that last longer than 7 days, or both.

However, it's not usually necessary to measure blood loss. Most women have a good idea of how much bleeding is normal for them during their period and can tell when this changes.

A good indication that your periods are heavy is if you:

- are having to change your sanitary products every hour or two
- are passing blood clots larger than 2.5cm (about the size of a 10p coin)
- are bleeding through to your clothes or bedding
- need to use two types of sanitary product together for example, tampons and pads

In about half of women with heavy menstrual bleeding, no underlying reason is found. But there are several conditions and some treatments that can cause heavy menstrual bleeding.

Some conditions of the womb and ovaries can cause heavy bleeding, including:

- fibroids – non-cancerous growths that develop in or around the womb and can cause heavy or painful periods
- endometriosis – where the tissue that lines the womb (endometrium) is found outside the womb, such as in the ovaries and fallopian tubes (although this is more likely to cause painful periods)

- adenomyosis – when tissue from the womb lining becomes embedded in the wall of the womb; this can also cause painful periods
- pelvic inflammatory disease (PID) – an infection in the upper genital tract (the womb, fallopian tubes or ovaries) that can cause symptoms like pelvic or abdominal pain, bleeding after sex or between periods, vaginal discharge and fever
- endometrial polyps – non-cancerous growths in the lining of the womb or cervix (neck of the womb)
- cancer of the womb – the most common symptom is abnormal bleeding, especially after the menopause
- polycystic ovary syndrome (PCOS) – a common condition that affects how the ovaries work; it causes irregular periods, and periods can be heavy when they start again

Other conditions that can cause heavy periods include:

- blood clotting disorders, such as Von Willebrand disease
- an underactive thyroid gland (hypothyroidism) – where the thyroid gland does not produce enough hormones, causing tiredness, weight gain and feelings of depression
- diabetes

Medical treatments that can sometimes cause heavy periods include:

- an IUD (intrauterine contraceptive device, or "the coil") – this can make your periods heavier for the first 3 to 6 months after insertion
- anticoagulant medication – taken to prevent blood clots
- some medicines used for chemotherapy
- some herbal supplements, which can affect your hormones and may affect your periods – such as ginseng, ginkgo and soya

Hysteroscopy

A hysteroscopy is a procedure used to examine the inside of the womb (uterus).
It is carried out using a hysteroscope, which is a narrow telescope with a light and camera at the end. Images are sent to a monitor so your doctor or specialist nurse can see inside your womb.

The hysteroscope is passed into your womb through your vagina and cervix (entrance to the womb), which means no cuts need to be made in your skin.
In deciding whether to offer the woman a hysteroscopy or ultrasound scan NICE Guidance 88 should be taken into consideration:

Women with suspected submucosal fibroids, polyps or endometrial pathology

Offer outpatient hysteroscopy to women with HMB if their history suggests submucosal fibroids, polyps or endometrial pathology because:

- they have symptoms such as persistent intermenstrual bleeding or
- they have risk factors for endometrial pathology

Women with possible larger fibroids.

Offer pelvic ultrasound to women with HMB if any of the following apply:

- their uterus is palpable abdominally
- history or examination suggests a pelvic mass
- examination is inconclusive or difficult, for example in women who are obese.

Women with suspected adenomyosis

Offer transvaginal ultrasound (in preference to transabdominal ultrasound or MRI) to women with HMB who have:

- significant dysmenorrhoea (period pain) or
- a bulky, tender uterus on examination that suggests adenomyosis.

If a woman declines transvaginal ultrasound or it is not suitable for her, consider transabdominal ultrasound or MRI, explaining the limitations of these techniques. Be aware that pain associated with HMB may be caused by endometriosis rather than adenomyosis (see NICE's guideline on endometriosis).

Other diagnostic tools

Do not use saline infusion sonography as a first-line diagnostic tool for HMB.
Do not use MRI as a first-line diagnostic tool for HMB.
Do not use dilatation and curettage alone as a diagnostic tool for HMB

Evidence Review

In reviewing the evidence NICE 2018 considered the following requirements:

- that the correct identification of the cause of HMB is important as this can impact the treatment options offered to women.
- If a test is sensitive, it may help the clinicians to choose the right initial treatment to be offered to women.
- It is important to avoid false positives because unnecessary treatment, especially surgical treatment, can cause harm.

- The evidence on diagnostic accuracy was assessed using adapted GRADE methodology. GRADE is a systematic approach to rating the certainty of evidence in systematic reviews and other evidence syntheses.
- The evidence on patient satisfaction or acceptability was assessed using Cochrane Collaboration's tool for assessing risk of bias.

NICE in their evidence review accepted that the quality of evidence in these reviews ranged from very low to moderate with most evidence being of very low quality. The NICE committee recognised that the evidence was fragmented and with several limitations. The NICE committee agreed that the quality of evidence was most often downgraded because of unclear sampling, unclear inclusion and exclusion criteria, unclear diagnostic criteria, and at times, considerable number of drop-outs.

However, national clinical consensus under NG 88 has recommended the use of hysteroscopy as a first line intervention in a limited number of clinical circumstances:

The patient must have suspected submucosal fibroids OR polyps OR endometrial pathology **AND** The patient has one of the following symptoms:

- persistent intermenstrual bleeding OR
- risk factors for endometrial pathology

Due to this national clinical expertise, the use of hysteroscopy will be commissioned in specified clinical circumstances in line with the clinical consensus achieved through NICE NG 88.

Who will be affected by this work? e.g. staff, patients, service users, partner organisations etc.

Eligibility Criteria: Restricted

Hysteroscopy for Heavy Menstrual Bleeding is commissioned as a first line investigation in the following clinical circumstances:

The patient must have suspected submucosal fibroids OR polyps OR endometrial pathology **AND**
The patient has one of the following symptoms:

- persistent intermenstrual bleeding OR
- risk factors for endometrial pathology

Risk factors for endometrial pathology are defined as:

- the patient has persistent intermenstrual or persistent irregular bleeding, and the patient has infrequent heavy bleeding and is obese or has polycystic ovary syndrome
- the patient taking tamoxifen

- the patient for whom treatment for HMB has been unsuccessful.

In other clinical circumstances diagnostic hysteroscopy is commissioned in the following clinical circumstances:

- First -line investigation using ultrasound scan has provided inconclusive results. For example, hysteroscopy is clinically required to determine the exact location of a fibroid or the exact nature of the abnormality.

N.B. investigation for suspected or proven malignancy is outside the scope of this policy and should in investigated in line with the relevant cancer pathway.

This means the CCG will only fund the treatment if an Individual Funding Request (IFR) application proves exceptional clinical need and that is supported by the CCG.

Activity data 2018/19

Number of Procedures	BSOL	Sandwell
	746	176

Due to limited data collection by the providers service activity data is available by headcount only not protected characteristic.
The Joint Strategic Needs Assessments for Birmingham, Solihull and Sandwell are available via the links below.

Sandwell

Birmingham

Solihull

2. Research

What evidence have you identified and considered? This can include national research, surveys, reports, NICE guidelines, focus groups, pilot activity evaluations, clinical experts or working groups, JSNA or other equality analyses.

Research/Publications	Working Groups	Clinical Experts
Abd Elkhalek 2016 Abd Elkhalek, Y. I., Kamel, O. F., El-Sabaa, H., Comparison of 3 dimensional sonohysterography and hysteroscopy in		

Premenopausal women with abnormal uterine bleeding, Egyptian Journal of Radiology and Nuclear Medicine, 47, 1117-22, 2016

Abdel Hak 2010
Abdel Hak, A. M., Accuracy of sonographic criteria for diagnosis of adenomyosis in perimenopausal women with menorrhagia, Middle East Fertility Society Journal, 15, 35-8, 2010

Abe 2008
Abe, M., Ogawa, H., Ayhan, A., The use of non-three-layer ultrasound in biopsy recommendation for premenopausal women, Acta Obstetricia et Gynecologica Scandinavica, 87, 2008

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Alborzi, S., Parsanezhad, M. E., Mahmoodian, N., Alborzi, S., Alborzi, M., Sonohysterography versus transvaginal sonography for screening of patients with abnormal uterine bleeding, International Journal of Gynaecology & Obstetrics, 96, 20-3, 2007

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Bazot, M., Darai, E., Rouger, J., Detchev, R., Cortez, A., Uzan, S., Limitations of transvaginal sonography for the diagnosis of adenomyosis, with histopathological correlation, Ultrasound in Obstetrics and Gynecology, 20, 605-11, 2002

Botsis 1998
Botsis, D., Kassanos, D., Antoniou, G., Pyrgiotis, E., Karakitsos, P., Kalogirou, D., Adenomyoma and leiomyoma: differential diagnosis with transvaginal sonography, Journal of Clinical Ultrasound, 26, 21-5, 1998

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Cicinelli, E., Romano, F., Anastasio, P. S., Blasi, N., Parisi, C., Galantino, P., Transabdominal sonohysterography, transvaginal sonography, and hysteroscopy in the evaluation of submucous myomas, Obstet GynecolObstetrics and gynecology, 85, 42-7, 1995

Cooper 2014 Cooper, N. A., Barton, P. M., Breijer, M., Caffrey, O., Opmeer, B. C., Timmermans, A., Mol, B. W., Khan, K. S., Clark, T. J., Cost-effectiveness of diagnostic strategies for the management of abnormal uterine bleeding (heavy menstrual

bleeding and post-menopausal bleeding): a decision analysis, Health Technology Assessment, 18, 1-201, 2014

Critchley 2004
Critchley, H. O. D., Warner, P., Lee, A. J., Brechin, S., Guise, J., Graham, B., Evaluation of abnormal uterine bleeding: Comparison of three outpatient procedures within cohorts defined by age and menopausal status, Health Technology Assessment, 8, iii-77, 2004

Dakhly 2016
Dakhly, D. M. R., Abdel Moety, G. A. F., Saber, W., Gad Allah, S. H., Hashem, A. T., Abdel Salam, L. O. E., Accuracy of Hysteroscopic Endomyometrial Biopsy in Diagnosis of Adenomyosis, Journal of Minimally Invasive Gynecology, 23, 364-71, 2016

Dasgupta 2011a
Dasgupta, S., Chakraborty, B., Karim, R., Aich, R. K., Mitra, P. K., Ghosh, T. K., Abnormal uterine bleeding in peri-menopausal age: Diagnostic options and accuracy, Journal of Obstetrics and Gynecology of India, 61, 189-94, 2011a

Dasgupta 2011b
Dasgupta, S., Sharma, P. P., Mukherjee, A., Ghosh, T. K., Ultrasound assessment of endometrial cavity in perimenopausal women on oral progesterone for abnormal uterine bleeding: comparison of diagnostic accuracy of imaging with hysteroscopy-guided biopsy, The journal of obstetrics and gynaecology research, 37, 2011b

Dueholm 2001a
Dueholm, M., Forman, A., Jensen, M. L., Laursen, H., Kracht, P., Transvaginal sonography combined with saline contrast sonohysterography in evaluating the uterine cavity in premenopausal patients with abnormal uterine bleeding, Ultrasound in Obstetrics and Gynecology, 18, 54-61, 2001a

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Dueholm, M., Lundorf, E., Hansen, E. S., Sorensen, J. S., Ledertoug, S., Olesen, F., Magnetic resonance imaging and transvaginal ultrasonography for the diagnosis of adenomyosis, Fertility and Sterility, 76, 588-94, 2001b

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and postmenopausal women with abnormal uterine bleeding, Menopause, 14, 2007

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Fakhar and Mahmud 2010
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Gkrozou 2015
Gkrozou, F., Dimakopoulos, G., Vrekoussis, T., Lavasidis, L., Koutlas, A., Navrozoglou, I., Stefos, T., Paschopoulos, M., Hysteroscopy in women with abnormal uterine bleeding: a meta-analysis on four major endometrial pathologies, Arch Gynecol Obstet, 291, 1347-54, 2015

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Krampl, E., Bourne, T., Hurlen-Solbakken, H., Istre, O., Transvaginal ultrasonography sonohysterography and operative hysteroscopy for the evaluation of abnormal uterine bleeding, Acta Obstetricia et Gynecologica Scandinavica, 80, 616-622, 2001

Meredith 2009
Meredith, S. M., Sanchez-Ramos, L., Kaunitz, A. M., Diagnostic accuracy of transvaginal sonography for the diagnosis of adenomyosis: systematic review and metaanalysis. American Journal of Obstetrics and Gynecology, 201:107, e1-6, 2009

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Najeeb 2010
Najeeb, R., Awan, A. S., Bakhtiar, U., Akhter, S., Role of transvaginal sonography in assessment of abnormal uterine bleeding in perimenopausal age group, Journal of Ayub Medical College, Abbottabad : JAMC, 22, 2010

Nanda 2002
Nanda, S., Chadha, N., Sen, J., Sangwan, K., Transvaginal sonography and saline infusion sonohysterography in the evaluation of abnormal uterine bleeding, Australian and New Zealand Journal of Obstetrics and Gynaecology, 42, 530-4, 2002

NHS 2018
NHS. 2018 Hysteroscopy. Last reviewed 05.12.2018. https://www.nhs.uk/conditions/hysteroscopy/

NHS 2018
NHS. 2018. Heavy Menstrual Bleeding. Last updated 07.06.2018. https://www.nhs.uk/conditions/heavy-periods/

NICE 2018
NICE 2018 NICE Guidelines: Heavy menstrual bleeding: Assessment and Management.
Published: 14 March 2018 nice.org.uk/guidance/ng88

NICE 2018
NICE 2018 NICE Guideline 88: Evidence Reviews.
March 2018. https://www.nice.org.uk/guidance/ng88/evidence/a-diagnostic-test-accuracy-pdf-4782293101

Pennant 2017
Pennant, M. E., Mehta, R., Moody, P., Hackett, G., Prentice, A., Sharp, S. J., Lakshman, R., Premenopausal abnormal uterine bleeding and risk of endometrial cancer, BJOG, 124, 404-11, 2017

RCOG and BSGE 2016
Royal Coll Royal College of Obstetricians and Gynaecologists, British Society for Gynaecological Endoscopy, Management of Endometrial Hyperplasia, Green-top Guideline No. 67, London: RCOG, 2016

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Royal College of Obstetricians and Gynaecologists, British Society for Gynaecological Endoscopy, Best Practice in Outpatient Hysteroscopu, Green-top Guideline No. 59, London: RCOG, 2011

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Soguktas, S., Cogendez, E., Kayatas, S. E., Asoglu, M. R., Selcuk, S., Ertekin, A., Comparison of saline infusion sonohysterography and hysteroscopy in diagnosis of premenopausal women with abnormal uterine bleeding, European Journal of Obstetrics, Gynecology, & Reproductive BiologyEur J Obstet Gynecol Reprod Biol, 161, 2012

Taylor 2001 Taylor, S., Jones, S., Dixon, A. M., O'Donovan, P., Evaluation of ultrasound in an outpatient hysteroscopy clinic: Does it alter management in premenopausal women?, Gynaecological Endoscopy, 10, 173-8, 2001 **Vercellini 1998** Vercellini, P., Cortesi, I., De Giorgi, O., Merlo, D., Carinelli, S. G., Crosignani, P. G., Transvaginal ultrasonography versus uterine needle biopsy in the diagnosis of diffuse adenomyosis, Human Reproduction, 13, 1998 **Vercellini 1997** Vercellini, P., Cortesi, I., Oldani, S., Moschetta, M., De Giorgi, O., Crosignani, P. G., The role of transvaginal ultrasonography and outpatient diagnostic hysteroscopy in the evaluation of patients with menorrhagia, Human Reproduction, 12, 1768-71, 1997 **Williams and Marshburn 1998** Williams, C. D., Marshburn, P. B., A prospective study of transvaginal hydrosonography in the evaluation of abnormal uterine bleeding, Am J Obstet GynecolAmerican journal of obstetrics and gynecology, 179, 292-8, 1998 **Yildiz 2009** Yildiz, A., Koksal, A., Ates, P. F., Ivit, H., Keklik, A., Cukurova, K., Hysteroscopy in the evaluation of intrauterine cavity. Is it more valuable than dilatation and curettage?, Turkiye Klinikleri Journal of Medical Sciences, 29, 2009		

3. Impact and Evidence:

In the following boxes detail the findings and impact identified (positive or negative) within the research detailed above; this should also include any identified health inequalities which exist in relation to this work.

Age: Describe age related impact and evidence. This can include safeguarding, consent and welfare issues:

Although, if clinically required Hysteroscopy can be performed once a person is menstruating the most common reasons to perform the investigative procedure is due to fibroids which usually appear in women between 30 and 50 years old, however, they can be present at any age.

3. Impact and Evidence:

Disability: Describe disability related impact and evidence. This can include attitudinal, physical, communication and social barriers as well as mental health/ learning disabilities, cognitive impairments:

No impact identified

Gender reassignment (including transgender): Describe any impact and evidence on transgender people. This can include issues such as privacy of data and harassment:

No impact identified

Marriage and civil partnership: Describe any impact and evidence in relation to marriage and civil partnership. This can include working arrangements, part-time working, and caring responsibilities:

No impact identified

Pregnancy and maternity: Describe any impact and evidence on pregnancy and maternity. This can include working arrangements, part-time working, and caring responsibilities:

Hysteroscopy cannot be performed during pregnancy.

Race: Describe race related impact and evidence**.** This can include information on different ethnic groups, Roma gypsies, Irish travellers, nationalities, cultures, and language barriers:

No impact identified

Religion or belief: Describe any religion, belief or no belief impact and evidence. This can include dietary needs, consent and end of life issues:

No impact identified

Sex: Describe any impact and evidence on men and women. This could include access to services and employment:

Due to the nature of the condition this procedure is only available to those who require uterus investigative work.

3. Impact and Evidence:
Sexual orientation: Describe any impact and evidence on heterosexual people as well as lesbian, gay and bisexual people. This could include access to services and employment, attitudinal and social barriers: No impact identified
Carers: Describe any impact and evidence on part-time working, shift-patterns, general caring responsibilities: No impact identified
Other disadvantaged groups: Describe any impact and evidence on groups experiencing disadvantage and barriers to access and outcomes. This can include lower socio-economic status, resident status (migrants, asylum seekers), homeless, looked after children, single parent households, victims of domestic abuse, victims of drugs / alcohol abuse: (This list is not exhaustive) No impact identified

4. Health Inequalities	Yes/No	Evidence
Could health inequalities be created or persist by the proposals?	No	This condition is not linked to a health inequality.
Is there any impact for groups or communities living in particular geographical areas?	No	No impact identified
Is there any impact for groups or communities affected by unemployment, lower educational attainment, low income, or poor access to green spaces?	No	No impact identified
How will you ensure the proposals reduce health inequalities?		

5. FREDA Principles/ Human Rights	Question	Response
Fairness – Fair and equal access to services	How will this respect a person's entitlement to access this service?	Yes, this decision has been made in line with clinical recommendation and NICE guidance.

Respect – right to have private and family life respected	How will the person's right to respect for private and family life, confidentiality and consent be upheld?	No evidence of impact from this policy
Equality – right not to be discriminated against based on your protected characteristics	How will this process ensure that people are not discriminated against and have their needs met and identified?	No discrimination identified
	How will this affect a person's right to freedom of thought, conscience and religion?	N/A
Dignity – the right not to be treated in a degrading way	How will you ensure that individuals are not being treated in an inhuman or degrading way?	Policy will be applied with due regard to this consideration.
Autonomy – right to respect for private & family life; being able to make informed decisions and choices	How will individuals have the opportunity to be involved in discussions and decisions about their own healthcare?	An individual can discuss the impact with their GP and has the option for an IFR request to be made
Right to **Life**	Will or could it affect someone's right to life? How?	No evidence of impact from this policy
Right to **Liberty**	Will or could someone be deprived of their liberty? How?	No evidence of impact from this policy

6. Social Value

Consider how you might use the opportunity to improve health and reduce health inequalities and so achieve wider public benefits, through action on the social determinants of health.

Marmot Policy Objective	**What actions are you able to build into the procurement activity and/or contract to achieve wider public benefits?**
Enable all people to have control over their lives and maximise their capabilities	None
Create fair employment and good work for all	None
Create and develop health and sustainable places and communities	None
Strengthen the role and impact of ill-health prevention	None

7. Engagement, Involvement and Consultation

If relevant, please state what engagement activity has been undertaken and the date and with which protected groups:

Engagement Activity	Protected Characteristic/ Group/ Community	Date

For each engagement activity, please state the key feedback and how this will shape policy / service decisions (E.g. patient told us …. So we will …..):

As part of the process further targeted engagement is planned with representative groups from among Sandwell, Birmingham and Solihull Patients. In addition, it has been identified that patient and clinician information is key in ensuring that the harmonised treatment policies review delivers effective outcomes. To this end an information briefing sheets on each procedure will be developed to give more information on the procedure, eligibility criteria and signposting to further information sources, such as NHS Choices. These information sheets are also designed to help facilitate discussions between GPs and patients. Information briefing sheets have already been tested and uploaded onto the GP systems for the first 45 harmonised treatment policies for Birmingham and Solihull. Due regard will be given to both the accessible information standard and the potential need to translate such leaflets into relevant local languages.

The engagement team used every possible route throughout the engagement period to encourage people to feedback on the proposed policy. Unfortunately, despite the wide communication undertaken through all communication and engagement channels available, 49 questionnaires were completed online and there was no interest from stakeholders, patients and the public to attend any of the five stakeholder events arranged. As a result, the events were cancelled, and the engagement team looked at other routes to encourage engagement with patients directly. A possible reason for the general lack of interest and feedback from stakeholders, patients and the public is most likely because this clinical treatments policy either widening the scope of the current service provision, providing policies to protect the current service provision or the intervention is for somewhat rare conditions.

Also, in phase 3 of the harmonisation of policies programme clinicians had been integral to the development of the policies from the beginning of the process. It could therefore be argued the proposed policy shared for public engagement was to some extent already informed from a local patient experience and outcomes perspective.

Feedback suggested that there was no or limited impact for patients. Over half of the respondents agreed with the proposed policy and there was a general consensus that the possibility of having a hysteroscopy as a first line of treatment in certain clinical circumstances was a welcomed as it would provide a quicker diagnosis.

8. Summary of Analysis

Considering the evidence and engagement activity you listed above, please summarise the impact of your work:

The restriction of this policy will have limited impact on those who would wish to receive the treatments as the procedure is commissioned as a first line investigation if

they meet the eligibility criteria. The opportunity for any exceptional cases to be considered via IFR remains and will ensure treatment is available.

9. Mitigations and Changes :

Please give an outline of what you are going to do, based on the gaps, challenges and opportunities you have identified in the summary of analysis section. This might include action(s) to mitigate against any actual or potential adverse impacts, reduce health inequalities, or promote social value. Identify the **recommendations** and any **changes** to the proposal arising from the equality analysis.

None identified

10. Contract Monitoring and Key Performance Indicators

Detail how and when the service will be monitored and what key equality performance indicators or reporting requirements will be included within the contract (refer to NHS Standard Contract SC12 and 13):

This policy is not linked to a contract however, prospective providers remain bound by their contracts with the CCG.

11. Procurement

Detail the key equality, health inequalities, human rights, and social value criteria that will be included as part of the procurement activity (to evaluate the providers ability to deliver the service in line with these areas):

N/A

12. Publication

How will you share the findings of the Equality Analysis?

This can include: reports into committee or Governing Body, feedback to stakeholders including patients and the public, publication on the web pages. All Equality Analysis should be recommended for publication unless they are deemed to contain sensitive information.

Publication on the CCG's website.

Following approval all finalised Equality Analysis should be sent to the Communications and Engagement team for publication: bsol.comms@nhs.net

13. Sign Off

The Equality Analysis will need to go through a process of **quality assurance** by the Senior Manager for Equality and Diversity, Senior Manager for Assurance and Compliance or Equality and Human Rights Manager **and** signed-off by a delegated committee

	Name	Date
Quality Assured By:		
Which Committee will be considering the findings and signing off the EA?		
Minute number (to be inserted following presentation to committee)		

Please send to Balvinder Everitt or Michelle Dunne, Equality, Diversity and Inclusion for Quality Assurance.

Once you have committee sign off, please send to Caroline Higgs, Communications & Engagement Team for publication: bsol.comms@nhs.net

Equality Analysis

(Health Inequalities, Human Rights, Social Value)

Policy Knee Arthroscopy for Acute Knee Injury

Before completing this equality analysis it is recommended that you:

- ✓ Contact your equality and diversity lead for advice and support
- ✓ Take time to read the accompanying policy and guidance document on how to complete an equality analysis

NHS Birmingham and Solihull Clinical Commissioning Group
NHS Sandwell and West Birmingham Clinical Commissioning Group

1. Background			
EA Title	Policy Knee Arthroscopy for Acute Knee Injury		
EA Author	David King	**Team**	Equality and Diversity
Date Started	September 2019	**Date Completed**	4/12/2019
EA Version	4	**Reviewed by E&D**	

What are the intended outcomes of this work? Include outline of objectives and function aims

The Knee

The 3 bones that meet in the knee are the:

- thigh bone (femur)
- shin bone (tibia)
- kneecap (patella)

These bones are connected by 4 ligaments – 2 collateral ligaments on the sides of the knee and 2 cruciate ligaments inside the knee.
Ligaments are tough bands of connective tissue. The ligaments in the knee hold the bones together and help keep the knee stable.
The menisci are thick pads of cartilage tissue within the knee which act as shock absorbers to absorb body weight and help improve smooth movement and stability of the knee.

The two main areas within the knee which may be damaged by an acute injury include:

1. Menisci (cartilage)
2. Ligaments

1. **Menisci.**

What is the knee meniscus?

The menisci are thick pads of cartilage tissue within the knee which act as shock absorbers to absorb body weight and help improve smooth movement and stability of the knee. Each knee joint contains a medial and lateral meniscus (inner and outer meniscus).

1. Background

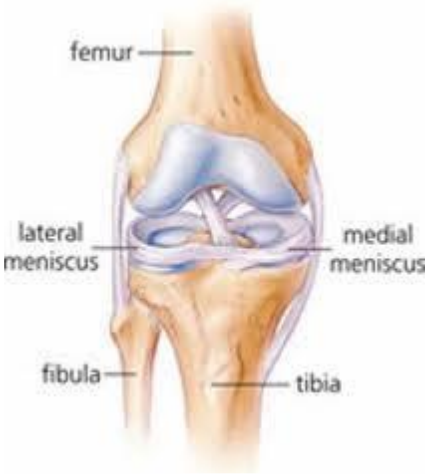


Figure 1. The Knee Joint

What is a meniscal injury?

There are varying degrees of damage a patient can do to the menisci. These range from bruising the menisci through to having large tears of the menisci. Meniscal tears can occur during sporting activities through twisting the knee whilst the foot is still in contact with the ground. In severe injuries, other parts of the knee may also be damaged in addition to a meniscal tear. For example, a patient may also sprain or tear a ligament. Meniscal cartilage does not always heal very well once it is torn. This is mainly because the central area of the meniscus does not have a good blood supply. The outer edge of each meniscus has some blood vessels, but the area in the centre has no direct blood supply.

Conservative Treatment

The PRICE protocol is effective for most sports-related injuries.

PRICE stands for Protection, Rest, Ice, Compression, and Elevation.

- Protection – protect the affected area from further injury – for example, by using a support.
- Rest – avoid exercise and reduce your daily physical activity. Using crutches or a walking stick may help if you can't put weight on your ankle or knee. A sling may help if you've injured your shoulder.
- Ice – apply an ice pack to the affected area for 15-20 minutes every two to three hours. A bag of frozen peas, or similar, will work well. Wrap the ice pack in a towel so that it doesn't directly touch your skin and cause an ice burn.
- Compression – use elastic compression bandages during the day to limit swelling.

1. Background

- Elevation – keep the injured body part raised above the level of your heart whenever possible. This may also help reduce swelling.

Non-steroidal anti-inflammatory medicines. Drugs like aspirin and ibuprofen reduce pain and swelling.

Physiotherapy for those whose symptoms do not resolve.

Surgical Treatment

Procedure. Knee arthroscopy is one of the most commonly performed surgical procedures. In it, a miniature camera is inserted through a small incision (portal). This provides a clear view of the inside of the knee. The orthopaedic surgeon, then inserts miniature surgical instruments through other portals to trim or repair the tear.

- Partial meniscectomy. In this procedure, the damaged meniscus tissue is trimmed away.
- Meniscus repair. Some meniscus tears can be repaired by suturing (stitching) the torn pieces together. Whether a tear can be successfully treated with repair depends upon the type of tear, as well as the overall condition of the injured meniscus. Because the meniscus must heal back together, recovery time for a repair is much longer than from a meniscectomy.

.

Risks of meniscal surgery

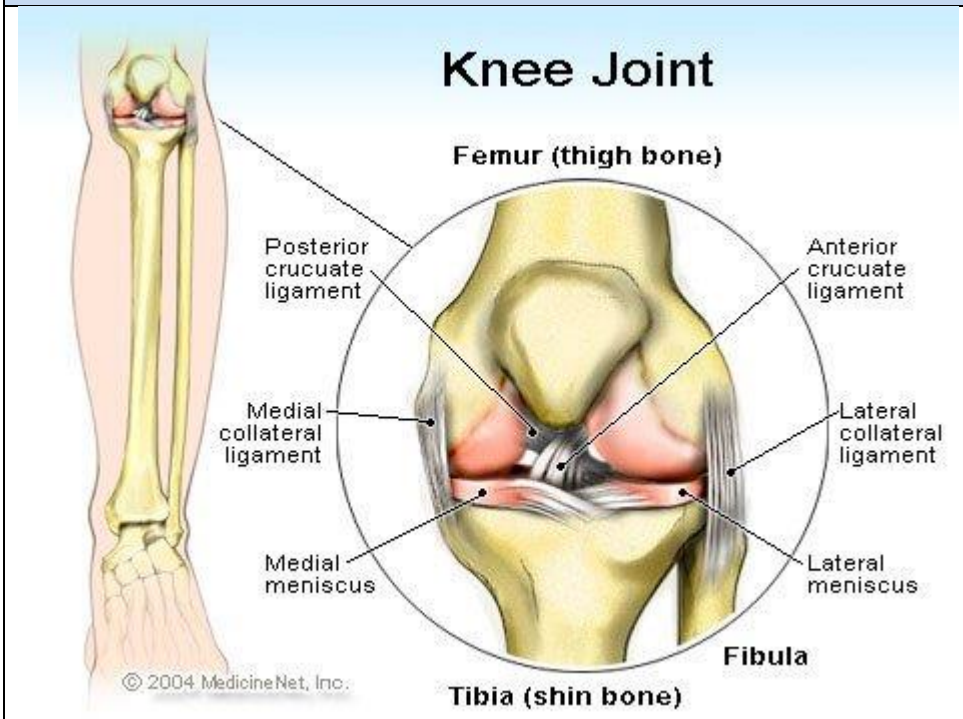
The knee may not be exactly like it was before the injury, and the patient may still have some pain and swelling.
This may be because of other injuries to the knee, such as tears or injuries to ligaments, which happened at the same time as or after the injury.
As with all types of surgery, there are some small risks associated with knee surgery, including infection, a blood clot, knee pain, and knee weakness and stiffness.

2. Ligaments (Anterior Cruciate Ligament (ACL); Posterior Cruciate Ligament (PCL); Collateral Ligaments R/LCL)

What are the Knee Ligaments?

The Ligaments found within the knee are tough bands of tissue joining the thigh bone to the shin bone at the knee joint.
The ligaments run diagonally through the inside of the knee and around each side which give the knee joint stability. It also helps to control the back-and-forth movement of the lower leg.

1. Background



Ligament injuries

Knee injuries can occur during sports such as skiing, tennis, squash, football and rugby. Ligament injuries, in particular Anterior Cruciate Ligament (ACL) injuries are one of the most common types of knee injuries, accounting for around 40% of all sports injuries.

A patient may tear the knee ligaments if the lower leg extends forwards too much. It can also be torn if the knee and lower leg are twisted.

Common causes of a ligament injury include:

- landing incorrectly from a jump
- stopping suddenly
- changing direction suddenly
- having a collision, such as during a football tackle

Conservative management

The PRICE protocol is effective for most sports-related injuries. PRICE stands for Protection, Rest, Ice, Compression, and Elevation.

- Protection – protect the affected area from further injury – for example, by using a support.
- Rest – avoid exercise and reduce your daily physical activity. Using crutches or a walking stick may help if you can't put weight on your ankle or knee. A sling may help if you've injured your shoulder.

1. Background

- Ice – apply an ice pack to the affected area for 15-20 minutes every two to three hours. A bag of frozen peas, or similar, will work well. Wrap the ice pack in a towel so that it doesn't directly touch your skin and cause an ice burn.
- Compression – use elastic compression bandages during the day to limit swelling.
- Elevation – keep the injured body part raised above the level of your heart whenever possible. This may also help reduce swelling.

Non-steroidal anti-inflammatory medicines. Drugs like aspirin and ibuprofen reduce pain and swelling.

Physiotherapy for those whose symptoms do not resolve.

Reconstructive Ligament surgery

A torn ligament cannot be repaired by stitching it back together, but it can be reconstructed by attaching (grafting) new tissue on to it.

The ligament, for example the ACL, may be reconstructed by removing what remains of the torn ligament and replacing it with a tendon from another area of the leg, such as the hamstring or patellar tendon.

The patellar tendon attaches the bottom of the kneecap (patella) to the top of the shinbone (tibia).

Risks of ligament surgery

The knee may not be exactly like it was before the injury, and you may still have some pain and swelling. This may be because of other injuries to the knee, such as tears or injuries to the cartilage, which happened at the same time as or after the ligament injury.

As with all types of surgery, there are some small risks associated with knee surgery, including infection, a blood clot, knee pain, and knee weakness and stiffness.

Evidence Review

There was **no NICE Guidance identified** which reviewed this surgical intervention, and no systematic reviews were identified.

Utsaerts et al. (2016) produced a follow-up paper to their RCT, which is considered high quality with long follow-up.

In this high quality randomised controlled trial, with minimal loss to follow-up, a strategy of rehabilitation plus early ACL reconstruction did not provide better results at five years than a strategy of initial rehabilitation with the option of having a later ACL

1. Background

reconstruction. Results did not differ between knees surgically reconstructed early or late and those treated with rehabilitation alone. These results should encourage clinicians and young active adult patients to consider rehabilitation as a primary treatment option after an acute ACL tear.

Frobell et al (2013) found there was no increased risk of osteoarthritis or meniscal surgery if the ACL injury was treated with physiotherapy alone compared with if it was treated with surgery. Neither was there any difference in patients' experiences of function, activity level, quality of life, pain, symptoms or general health.

Measures included Knee injury and osteoarthritis outcome score (KOOS), the Medical Outcomes Study 36-item short-form health survey (SF-36), short-form health survey (SF-36), and the Tegner activity scale. In the full analysis set, the mean change in KOOS4 score from baseline to five years was 42.9 points for patients assigned to rehabilitation plus early anterior cruciate ligament reconstruction and 44.9 points for those assigned to rehabilitation plus optional delayed reconstruction (between group difference 2.0 points, 95% confidence interval −8.5 to 4.5; P=0.54 after adjustment for the baseline score). No statistically significant differences in KOOS4, any of the five individual subscales of KOOS, SF-36, or Tegner activity scale between the two treatment strategies were identified at five years or in the change between two and five years.

In conclusion, the evidence does not support the use of surgical repair as a primary treatment immediately following injury. However, in cases where conservative treatment over 3 months has failed: physiotherapy; analgesia and PRICE, then the current evidence demonstrates that knee arthroscopy with ligament / menisci repair may be clinically appropriate.

Activity data 2018/19

Number of Procedures	BSOL	Sandwell
	35	10

Due to limited data collection by the providers service activity data is available by headcount only not protected characteristic.
The Joint Strategic Needs Assessments for Birmingham, Solihull and Sandwell are available via the links below.

- Sandwell
- Birmingham
- Solihull

1. Background

Who will be affected by this work? e.g. staff, patients, service users, partner organisations etc.

Knee Arthroscopy for Acute Knee injury is only commissioned in the following clinical circumstances:

- The patient **does not** have degenerative knee disease AND
- The patient has experienced an acute knee injury AND
- Following the acute knee injury, the patient has undergone clinician verified conservative treatment with physiotherapy; analgesia and PRICE which has failed AND
- The patient continues to have mechanical symptoms which are causing functional impairment.

The term degenerative knee disease is used to explicitly include patients with knee pain, particularly if they are >35 years old, with or without:

- Imaging evidence of osteoarthritis
- Meniscus tears
- Locking, clicking, or other mechanical symptoms except persistent objective locked knee **OR**
- Acute or subacute onset of symptoms

N.B. Functional impairment is defined as interfering with activities of daily living, i.e. walking; sleeping; eating.

Investigations for suspected or proven malignancy are outside the scope of this policy and should be treated in line with the relevant cancer pathway.

This means **(for patients who DO NOT meet the above criteria)** the CCG will **only** fund the treatment if an Individual Funding Request (IFR) application proves exceptional clinical need and that is supported by the CCG.

2. Research

What evidence have you identified and considered? This can include national research, surveys, reports, NICE guidelines, focus groups, pilot activity evaluations, clinical experts or working groups, JSNA or other equality analyses.

2. Research

Research/Publications	Working Groups	Clinical Experts
[1] Treatment for acute anterior cruciate ligament tear: five-year outcome of randomised trial. BMJ 2013; 346 doi: https://doi.org/10.1136/bmj.f232 [2] Mutsaerts ELAR, van Eck CF, van de Graaf VA, Doornberg JN, van den Bekerom MPJ. Surgical interventions for meniscal tears: a closer look at the evidence. Arch Orthop Trauma Surg 2016;136:361-37 [3] Smith TO, Davies L, Hing CB (2010) Early versus delayed surgery for anterior cruciate ligament reconstruction: a systematic review and meta-analysis. Knee Surg Sports Traumatol Arthrosc 18:304–311 [4] Webb,R., Brammah,T., Lunt,M., et al. (2004) Opportunities for prevention of 'clinically significant' knee pain: results from a population-based cross sectional survey. Journal of Public Health (Oxford). 26(3), 277-284 [5] Brophy RH, Zeltser D, Wright RW, et al. Anterior cruciate ligament reconstruction and concomitant articular cartilage injury: incidence and treatment. Arthroscopy. 2010;26:112-120. http://www.ncbi.nlm.nih.gov/pubmed/20117635?tool=bestpractice.com [6] Bowers AL, Spindler KP, McCarty EC, et al. Height, weight, and BMI predict intra-articular injuries observed during ACL reconstruction: evaluation of 456 cases from a prospective ACL database. Clin J Sport Med. 2005;15:9-13. http://www.ncbi.nlm.nih.gov/pubmed/15654185?tool=bestpractice.com [7] Mandalia V, Fogg AJ, Chari R, et al. Bone bruising of the knee. Clin Radiol. 2005;60:627-636. https://bestpractice.bmj.com/topics/en-gb/589/complications#referencePop109 [8] Rodkey WG, Steadman JR, Li ST. A clinical study of collagen meniscus implants to restore the injured meniscus. Clin Orthop Relat Res. 1999:S281-92. http://www.ncbi.nlm.nih.gov/pubmed/10546653?tool=bestpractice.com [9] NHS website: https://www.nhs.uk/conditions/arthroscopy/		

2. Research

[10] Kruseman N, Geesink RGT, van der Linden AJ *et al*. Acute knee injuries: diagnostic & treatment management proposals. http://arnos.unimasas.nl/show.cgi?fig1?46875 [11] Steve Bollen: Injuries of the sporting knee - Epidemiology of knee injuries: diagnosis and triage https://bjsm.bmj.com/content/34/3/227.2		

3. Impact and Evidence:

In the following boxes detail the findings and impact identified (positive or negative) within the research detailed above; this should also include any identified health inequalities which exist in relation to this work.

Age: Describe age related impact and evidence. This can include safeguarding, consent and welfare issues:

There is a link to those who participate in high impact sports and are subject to repetitive stress injury such as skiing, tennis, squash, football and rugby and therefore may be at a higher risk of getting injured. Also, those who with certain occupations that put constant repetitive pressure and stress on the joints such as kneeling, squatting may also be at an increased risk.

The chance of developing degenerative knee disease such as osteoarthritis increases with age as the ability of cartilage to heal decreases as you age. However, this must be balanced against the need to adhere to the clinical effectiveness evidence with those who suffer from this condition. The opportunity for any exceptional cases to be considered via IFR remains.

Disability: Describe disability related impact and evidence. This can include attitudinal, physical, communication and social barriers as well as mental health/ learning disabilities, cognitive impairments:

A link can be made with degenerative conditions such as arthritis where the person experiencing is likely to have a disability. Limiting this procedure may have an impact upon this group however the procedure is not be clinically evidence based to treat the arthritis and other treatments to relieve symptoms are available with good supporting clinical evidence of effectiveness. The decision must be balanced against the need to

3. Impact and Evidence:
adhere to the clinical effectiveness evidence, the potential risks and the overall benefit for the patient after surgery.
Gender reassignment (including transgender): Describe any impact and evidence on transgender people. This can include issues such as privacy of data and harassment: No impact identified
Marriage and civil partnership: Describe any impact and evidence in relation to marriage and civil partnership. This can include working arrangements, part-time working, and caring responsibilities: No impact identified
Pregnancy and maternity: Describe any impact and evidence on pregnancy and maternity. This can include working arrangements, part-time working, and caring responsibilities: No impact identified
Race: Describe race related impact and evidence**.** This can include information on different ethnic groups, Roma gypsies, Irish travellers, nationalities, cultures, and language barriers: No impact identified
Religion or belief: Describe any religion, belief or no belief impact and evidence. This can include dietary needs, consent and end of life issues: No impact identified
Sex: Describe any impact and evidence on men and women. This could include access to services and employment: No impact identified.

3. Impact and Evidence:
Sexual orientation: Describe any impact and evidence on heterosexual people as well as lesbian, gay and bisexual people. This could include access to services and employment, attitudinal and social barriers: No impact identified
Carers: Describe any impact and evidence on part-time working, shift-patterns, general caring responsibilities: No impact identified
Other disadvantaged groups: Describe any impact and evidence on groups experiencing disadvantage and barriers to access and outcomes. This can include lower socio-economic status, resident status (migrants, asylum seekers), homeless, looked after children, single parent households, victims of domestic abuse, victims of drugs / alcohol abuse: (This list is not exhaustive) No impact identified on the basis of the information available. Some interventions may not be suitable where the patient is homeless / of no fixed abode.

4. Health Inequalities	Yes/No	Evidence
Could health inequalities be created or persist by the proposals?	No	This condition is not linked to a health inequality.
Is there any impact for groups or communities living in particular geographical areas?	No	No impact identified
Is there any impact for groups or communities affected by unemployment, lower educational attainment, low income, or poor access to green spaces?	No	No impact identified
How will you ensure the proposals reduce health inequalities? .		

5. FREDA Principles/ Human Rights	Question	Response

Fairness – Fair and equal access to services	How will this respect a person's entitlement to access this service?	This decision has been made in line with clinical recommendation.
Respect – right to have private and family life respected	How will the person's right to respect for private and family life, confidentiality and consent be upheld?	No evidence of impact for this policy
Equality – right not to be discriminated against based on your protected characteristics	How will this process ensure that people are not discriminated against and have their needs met and identified?	No discrimination identified
	How will this affect a person's right to freedom of thought, conscience and religion?	N/A
Dignity – the right not to be treated in a degrading way	How will you ensure that individuals are not being treated in an inhuman or degrading way?	Policy will be applied with due regard to this consideration.
Autonomy – right to respect for private & family life; being able to make informed decisions and choices	How will individuals have the opportunity to be involved in discussions and decisions about their own healthcare?	An individual can discuss the impact with their GP and has the option for an IFR request to be made
Right to **Life**	Will or could it affect someone's right to life? How?	No evidence of impact for this policy
Right to **Liberty**	Will or could someone be deprived of their liberty? How?	No evidence of impact for this policy

6. Social Value

Consider how you might use the opportunity to improve health and reduce health inequalities and so achieve wider public benefits, through action on the social determinants of health.

Marmot Policy Objective	**What actions are you able to build into the procurement activity and/or contract to achieve wider public benefits?**
Enable all people to have control over their lives and maximise their capabilities	none
Create fair employment and good work for all	none
Create and develop health and sustainable places and communities	none
Strengthen the role and impact of ill-health prevention	none

7. Engagement, Involvement and Consultation

If relevant, please state what engagement activity has been undertaken and the date and with which protected groups:

Engagement Activity	Protected Characteristic/ Group/ Community	Date

For each engagement activity, please state the key feedback and how this will shape policy / service decisions (E.g. patient told us …. So we will …..):

As part of the process targeted engagement has been undertaken with representative groups from among Sandwell, Birmingham and Solihull Patients. In addition, it has been identified that patient and clinician information is key in ensuring that the harmonised treatment policies review delivers effective outcomes. To this end information briefing sheets on each procedure will be developed to give more information on the procedure, eligibility criteria and signposting to further information sources, such as NHS Choices. These information sheets are also designed to help facilitate discussions between GPs and patients. Information briefing sheets have already been tested for the Phase 1 and Phase 2 Harmonised Clinical Treatment Policies for Birmingham and Solihull CCG and Sandwell and West Birmingham CCG. Due regard will be given to both the accessible information standard and the potential need to translate such leaflets into relevant local languages.

The engagement team used every possible route throughout the engagement period to encourage people to feedback on the proposed policy. Unfortunately, despite the wide communication undertaken through all communication and engagement channels available, 49 questionnaires were completed online and there was little interest from stakeholders, patients and the public to attend any of the five stakeholder events arranged. As a result, the events were cancelled, and the engagement team looked at other routes to encourage engagement with patients directly. A possible reason for the general lack of interest and feedback from stakeholders, patients and the public is most likely because this proposed clinical treatment policy providing a policy to protect the current service provision and has clinical support.

Also, in Phase 3 of the Harmonisation of Clinical Treatment Policies programme clinicians had been integral to the development of the policies from the beginning of the process. It could therefore be argued the proposed policy shared for public engagement was to some extent already informed from a local patient experience and outcomes perspective.

The potential impact on patients was therefore minimal as the policy has been widened and treatment is offered based on specific criteria. Feedback from over 50% of respondents suggested they either agreed or strongly agreed to the proposed policy change. It is noted that within the additional comments the proposed change has been received positively to include acute knee injury, however concerns were raised over degenerative knee injury and subsequent management of this condition, which are outside the remit of this current policy.

7. Engagement, Involvement and Consultation

8. Summary of Analysis

Considering the evidence and engagement activity you listed above, please summarise the impact of your work:

Clinical evidence does not support the use of surgical repair as a primary treatment immediately following injury only in cases where conservative treatment over three months has failed: physiotherapy; analgesia and PRICE, then the current evidence demonstrates that knee arthroscopy with ligament / menisci repair may be clinically appropriate.

Investigations for suspected or proven malignancy are outside the scope of this policy and should be treated in line with the relevant cancer pathway.

The opportunity for any exceptional cases to be considered via IFR remains.

9. Mitigations and Changes:

Please give an outline of what you are going to do, based on the gaps, challenges and opportunities you have identified in the summary of analysis section. This might include action(s) to mitigate against any actual or potential adverse impacts, reduce health inequalities, or promote social value. Identify the **recommendations** and any **changes** to the proposal arising from the equality analysis.

None identified

10. Contract Monitoring and Key Performance Indicators

Detail how and when the service will be monitored and what key equality performance indicators or reporting requirements will be included within the contract (refer to NHS Standard Contract SC12 and 13):

This policy is not linked to a contract however, prospective providers remain bound by their contracts with the CCG.

11. Procurement

Detail the key equality, health inequalities, human rights, and social value criteria that will be included as part of the procurement activity (to evaluate the providers ability to deliver the service in line with these areas):

N/A

12. Publication

How will you share the findings of the Equality Analysis?

This can include: reports into committee or Governing Body, feedback to stakeholders including patients and the public, publication on the web pages. All Equality Analysis should be recommended for publication unless they are deemed to contain sensitive information.

Publication on the CCG's website.

Following approval all finalised Equality Analysis should be sent to the Communications and Engagement team for publication: bsol.comms@nhs.net

13. Sign Off

The Equality Analysis will need to go through a process of **quality assurance** by the Senior Manager for Equality Diversity and Inclusion or the Manager for Equality Diversity and Inclusion prior to approval from the delegated committee

	Name	Date
Quality Assured By:		
Which Committee will be considering the findings and signing off the EA?		
Minute number (to be inserted following presentation to committee)		

Please send to Balvinder Everitt or Michelle Dunne, Equality, Diversity and Inclusion for Quality Assurance.

Once you have committee sign off, please send to Caroline Higgs, Communications & Engagement Team for publication: bsol.comms@nhs.net

Equality Analysis

(Health Inequalities, Human Rights, Social Value)

Policy for the use of Liposuction in Lipoedema

Before completing this equality analysis it is recommended that you:

- ✓ Contact your equality and diversity lead for advice and support
- ✓ Take time to read the accompanying policy and guidance document on how to complete an equality analysis

NHS Birmingham and Solihull Clinical Commissioning Group
NHS Sandwell and West Birmingham Clinical Commissioning Group

1. Background

EA Title	**Policy for the use of Liposuction in Lipoedema**		
EA Author	David King	**Team**	Equality and Diversity Team
Date Started	September 2019	**Date Completed**	4/12/2019
EA Version	4	**Reviewed by E&D**	

What are the intended outcomes of this work? Include outline of objectives and function aims

Liposuction

Liposuction is normally deemed to be a cosmetic procedure used to remove unwanted body fat.

It involves sucking out small areas of fat that are hard to lose through exercise and a healthy diet. It is usually carried out on areas of the body where deposits of fat tend to collect, such as the buttocks, hips, thighs and tummy.

The aim is to alter body shape, and the results are generally long-lasting, providing a healthy weight is maintained.

It works best in people who are a normal weight and in areas where the skin is tight.

Liposuction carried out for cosmetic reasons is not normally available on the NHS. However, liposuction can sometimes be used by the NHS to treat certain health conditions.

Liposuction is usually carried out under general anaesthetic, although an epidural anaesthetic may be used to enable treatment on lower parts of the body.

The surgeon would mark on your body the area where fat is to be removed. He or she would then:

- **inject this area** with a solution containing anaesthetic and medication, to reduce blood loss, bruising and swelling
- **break up the fat cells** using high-frequency vibrations, a weak laser pulse or a high-pressure water jet
- **make a small incision (cut) and insert a suction tube attached to a vacuum machine** (several cuts may need to be made if the area is large)
- **move the suction tube back and forth** to loosen the fat and suck it out
- **drain** any excess fluid and blood
- **stitch up and bandage** the treated area

It usually takes one to three hours. Most people need to stay in hospital overnight.

Liposuction in Lipoedema: Category: Not Routinely Commissioned

Lipoedema is a long-term (chronic) condition where there is an abnormal build-up of fat cells in the legs, thighs and buttocks, and sometimes in the arms.

The condition usually only affects women, although in rare cases it can also affect men.

In lipoedema, the thighs, buttocks, lower legs, and sometimes the arms, become enlarged due to a build-up of abnormal fat cells. Both legs and/or the arms are usually enlarged at the same time and to the same extent.

The feet and hands are not affected, which creates a "bracelet" effect or "band-like" appearance just above the ankles and wrists.

Leg and arm size can vary between individuals with lipoedema, and the condition can gradually get worse over time.

As well as becoming enlarged, affected areas of the body may:

- feel soft, "doughy" and cold
- bruise easily
- ache or feel painful or tender
- have small broken veins under the skin

Someone with lipoedema may eventually get fluid retention (lymphoedema) in their legs. This type of swelling can worsen by the end of the day and may improve overnight, whereas the fatty swelling of lipoedema is constant.

Treatments for lipoedema

There has been little research into lipoedema, so there is some uncertainty about the best way to treat the condition.

If you have lipoedema it is important to avoid significant weight gain and obesity because putting on weight will make the fatty swelling worse.

Compression tights are helpful for some people because they support the fatty swelling and may reduce the pain.

Liposcution is the surgical option for the removal of fat.

Tumescent liposuction

Tumescent liposuction involves sucking out the unwanted fat through a tube. A liquid solution is first injected into the legs to help numb the area and reduce blood loss.

Fatty swelling of the legs may return after having the procedure if you subsequently gain weight.

Non-surgical treatments may also be needed for a long period after having tumescent liposuction. For example, you'll need to wear compression garments after surgery to prevent complications such as lymphoedema.

Treatments to prevent lipoedema progression

Non-surgical treatments can sometimes help improve pain and tenderness, prevent or reduce lipoedema, and improve the shape of affected limbs – although they often have little effect on the fatty tissue.

Several different treatments are designed to improve the management of the lipoedema, such as:

- compression therapy – wearing bandages or garments that squeeze the affected limbs
- exercise – usually low-impact exercises, such as swimming and cycling
- massage – techniques that help relieve the aching and heaviness often felt by patients

Treatments that do not work

Treatments used for some types of tissue swelling are generally unhelpful for lipoedema.

Lipoedema doesn't respond to:

- raising the legs
- diuretics (tablets to get rid of excess fluid)
- dieting – this tends to result in a loss of fat from areas not affected by lipoedema, with little effect on the affected areas

Causes of lipoedema

The cause of lipoedema is not known, but in some cases, there is a family history of the condition. It seems likely that the genes you inherit from your parents play a role.

Lipoedema tends to start at puberty or at other times of hormonal change, such during pregnancy or the menopause, which suggests hormones may also have an influence.

Although the accumulation of fat cells is often worse in obese people, lipoedema is not caused by obesity and can affect people who are a healthy weight. It should not be mistaken for obesity and dieting often makes little difference to the condition.

Evidence Review

There is no evidence available which directly compares liposuction with conservative management – where evidence testing the intervention is found, it is applied to patient cohorts that have already received conservative management.

The evidence identified during the evidence review consisted of three trials (totalling 274 patients), along with the NHS website (https://www.nhs.uk/conditions/lipoedema/) which states that this is a relatively new and under researched condition.

The largest study consisting of 164 patients, clearly stated that they had "undergone conservative therapy over a period of years" and as such the benefits stated can be viewed as over and above those offered by conservative treatment.

The results from all of the identified studies, suggests that there are both short and long-term sustained improvements in almost all dimensions around pain and Quality of Life measurements, and one study substantiates this as over and above conservative treatment. However, the number of patients across the research areas are very low and no randomised control trials were identified.

Whilst the three studies seem consistent in their findings, the evidence identified within the review reflects the lack of RCTs (or direct comparison to no treatment on two of the studies) and the need for further research in this area.

Therefore, in light of the paucity of evidence to support this intervention, liposuction for this clinical indication cannot be supported at the present time.

Who will be affected by this work? e.g. staff, patients, service users, partner organisations etc.

<u>Liposuction in Lipoedema: Category: Not Routinely Commissioned</u>

For patients with Lipoedema, Liposuction is Not Routinely Commissioned in these clinical circumstances due to a lack of evidence to support this intervention.

Investigations for suspected or proven malignancy are outside the scope of this policy and should be treated in line with the relevant cancer pathway.

This means the CCG will **only** fund the treatment if an Individual Funding Request (IFR) application proves exceptional clinical need and that is supported by the CCG.

Number of procedures undertaken overall and by CCG

	BSOL	Sandwell
	0	0
	Total is zero as procedure is currently not routinely commissioned	

Due to limited data collection by the providers service activity data is available by headcount only not protected characteristic.
The Joint Strategic Needs Assessments for Birmingham, Solihull and Sandwell are available via the links below.

Sandwell

Birmingham

Solihull

2. Research

What evidence have you identified and considered? This can include national research, surveys, reports, NICE guidelines, focus groups, pilot activity evaluations, clinical experts or working groups, JSNA or other equality analyses.

Research/Publications	Working Groups	Clinical Experts
Liposuction in Lipoedema		
Lipoedema (2017) - https://www.nhs.uk/conditions/lipoedema/		
Liposuction in the Treatment of Lipoedema: A Longitudinal Study (2017) - https://www.ncbi.nlm.nih.gov/pubmed/28728329		
Tumescent liposuction in lipoedema yields good long-term results (2017) - https://www.ncbi.nlm.nih.gov/pubmed/21824127		
Long-term benefit of liposuction in patients with lipoedema: a follow-up study after an average of 4 and 8 years (2015) - https://www.ncbi.nlm.nih.gov/pubmed/26574236		

3. Impact and Evidence:

In the following boxes detail the findings and impact identified (positive or negative) within the research detailed above; this should also include any identified health inequalities which exist in relation to this work.

Age: Describe age related impact and evidence. This can include safeguarding, consent and welfare issues:

Lipoedema

No data available on patient ages having the procedure, however there may be a link to the condition resulting to hormone change which occurs at the start of puberty, during pregnancy or those reaching the menopause.

Disability: Describe disability related impact and evidence. This can include attitudinal, physical, communication and social barriers as well as mental health/ learning disabilities, cognitive impairments:

Lipoedema

There is no available data to suggest disability has an impact on this condition.

Gender reassignment (including transgender): Describe any impact and evidence on transgender people. This can include issues such as privacy of data and harassment:

Lipoedema
No impact identified

Marriage and civil partnership: Describe any impact and evidence in relation to marriage and civil partnership. This can include working arrangements, part-time working, and caring responsibilities:
No impact identified

3. Impact and Evidence:

Lipoedema
No impact identified

Pregnancy and maternity: Describe any impact and evidence on pregnancy and maternity. This can include working arrangements, part-time working, and caring responsibilities:

Lipoedema

No available data to determine impact. However, there may be a correlation to those at the start of pregnancy when hormone levels are changing acquiring the condition, if they may already be genetically susceptible and if the condition is already prevalent within their family history.

Race: Describe race related impact and evidence**.** This can include information on different ethnic groups, Roma gypsies, Irish travellers, nationalities, cultures, and language barriers:

Lipoedema
No impact identified

Religion or belief: Describe any religion, belief or no belief impact and evidence. This can include dietary needs, consent and end of life issues:

Lipoedema
No impact identified

Sex: Describe any impact and evidence on men and women. This could include access to services and employment:

Lipoedema

Occurs almost exclusively in females and there is evidence that it is a genetic and inherited condition.

3. Impact and Evidence:

Sexual orientation: Describe any impact and evidence on heterosexual people as well as lesbian, gay and bisexual people. This could include access to services and employment, attitudinal and social barriers:

Lipoedema
No impact identified

Carers: Describe any impact and evidence on part-time working, shift-patterns, general caring responsibilities:

Lipoedema
No impact identified

Other disadvantaged groups: Describe any impact and evidence on groups experiencing disadvantage and barriers to access and outcomes. This can include lower socio-economic status, resident status (migrants, asylum seekers), homeless, looked after children, single parent households, victims of domestic abuse, victims of drugs / alcohol abuse: (This list is not exhaustive)

Lipoedema
No impact identified

4. Health Inequalities	Yes/No	Evidence
Could health inequalities be created or persist by the proposals?	No	This condition is not linked to a health inequality.
Is there any impact for groups or communities living in particular geographical areas?	No	No impact identified
Is there any impact for groups or communities affected by unemployment, lower educational attainment, low income, or poor access to green spaces?	No	No impact identified

How will you ensure the proposals reduce health inequalities?

5. FREDA Principles/ Human Rights	Question	Response
Fairness – Fair and equal access to services	How will this respect a person's entitlement to access this service?	Yes, this decision has been made in line with clinical recommendation.
Respect – right to have private and family life respected	How will the person's right to respect for private and family life, confidentiality and consent be upheld?	No evidence of impact from this policy
Equality – right not to be discriminated against based on your protected characteristics	How will this process ensure that people are not discriminated against and have their needs met and identified?	No discrimination identified
	How will this affect a person's right to freedom of thought, conscience and religion?	N/A
Dignity – the right not to be treated in a degrading way	How will you ensure that individuals are not being treated in an inhuman or degrading way?	Policy will be applied with due regard to this consideration.
Autonomy – right to respect for private & family life; being able to make informed decisions and choices	How will individuals have the opportunity to be involved in discussions and decisions about their own healthcare?	An individual can discuss the impact with their GP and has the option for an IFR request to be made
Right to **Life**	Will or could it affect someone's right to life? How?	No evidence of impact from this policy
Right to **Liberty**	Will or could someone be deprived of their liberty? How?	No evidence of impact from this policy

6. Social Value	
Consider how you might use the opportunity to improve health and reduce health inequalities and so achieve wider public benefits, through action on the social determinants of health.	
Marmot Policy Objective	**What actions are you able to build into the procurement activity and/or contract to achieve wider public benefits?**
Enable all people to have control over their lives and maximise their capabilities	None
Create fair employment and good work for all	None
Create and develop health and sustainable places and communities	None

Strengthen the role and impact of ill-health prevention	None

7. Engagement, Involvement and Consultation

If relevant, please state what engagement activity has been undertaken and the date and with which protected groups:

Engagement Activity	Protected Characteristic/ Group/ Community	Date

For each engagement activity, please state the key feedback and how this will shape policy / service decisions (E.g. patient told us …. So we will …..):

As part of the process further targeted engagement is planned with representative groups from among Sandwell, Birmingham and Solihull Patients. In addition, it has been identified that patient and clinician information is key in ensuring that the harmonised treatment policies review delivers effective outcomes. To this end an information briefing sheets on each procedure will be developed to give more information on the procedure, eligibility criteria and signposting to further information sources, such as NHS Choices. These information sheets are also designed to help facilitate discussions between GPs and patients. Information briefing sheets have already been tested and uploaded onto the GP systems for the first 45 harmonised treatment policies for Birmingham and Solihull. Due regard will be given to both the accessible information standard and the potential need to translate such leaflets into relevant local languages.

If any further available evidence has been submitted which has not been taken into consideration during this review will be looked at during the engagement period: 2nd September 2019 – 11th October 2019.

The engagement team used every possible route throughout the engagement period to encourage people to feedback on the proposed policy. Unfortunately, despite the wide communication undertaken through all communication and engagement channels available, 49 questionnaires were completed online and there was no interest from stakeholders, patients and the public to attend any of the five stakeholder events arranged. As a result, the events were cancelled, and the engagement team looked at other routes to encourage engagement with patients directly. A possible reason for the general lack of interest and feedback from stakeholders, patients and the public is most likely because this clinical treatments policy either widening the scope of the current service provision, providing policies to protect the current service provision or the intervention is for somewhat rare conditions.

Also, in phase 3 of the harmonisation of policies programme clinicians had been integral to the development of the policies from the beginning of the process. It could therefore be argued the proposed policy shared for public engagement was to some extent already informed from a local patient experience and outcomes perspective.

As there is currently no policy in place, half of the responses from Healthcare professional and patient feedback has welcomed the need to address support for those

who suffer with these conditions and, there is a consensus that further evidence is needed for liposuction for Lipoedema before the treatment is categorised as not routinely commissioned. However, it is recognised that in some conditions for Lymphoedema, conservative management is pointless where the condition is very advanced and those patients who have had liposuction have greatly benefited for the procedure.

8. Summary of Analysis

Considering the evidence and engagement activity you listed above, please summarise the impact of your work:

Lipoedema

The restriction of this policy will have limited impact on those who would wish to receive the treatments as a result of the limited clinical evidence to support this intervention as a clinically effective procedure. There is no evidence available which directly compares liposuction with conservative management.

However, it is hoped that a commissioning review will take place once further evidence has been published regarding the use of liposuction in lipoedema. If there is available evidence which has not been considered during this review, please do not hesitate to submit this evidence during the engagement period: 2nd September 2019 – 11th October 2019.

The opportunity for any exceptional cases to be considered via IFR remains and will ensure treatment is available.

It is noted that investigations for suspected or proven malignancy are outside the scope of this policy and should be treated in line with the relevant cancer pathway.

9. Mitigations and Changes :

Please give an outline of what you are going to do, based on the gaps, challenges and opportunities you have identified in the summary of analysis section. This might include action(s) to mitigate against any actual or potential adverse impacts, reduce health inequalities, or promote social value. Identify the **recommendations** and any **changes** to the proposal arising from the equality analysis.

None identified

10. Contract Monitoring and Key Performance Indicators

Detail how and when the service will be monitored and what key equality performance indicators or reporting requirements will be included within the contract (refer to NHS Standard Contract SC12 and 13):
This policy is not linked to a contract however, prospective providers remain bound by their contracts with the CCG.

11. Procurement

Detail the key equality, health inequalities, human rights, and social value criteria that will be included as part of the procurement activity (to evaluate the providers ability to deliver the service in line with these areas):
N/A

12. Publication

How will you share the findings of the Equality Analysis?

This can include: reports into committee or Governing Body, feedback to stakeholders including patients and the public, publication on the web pages. All Equality Analysis should be recommended for publication unless they are deemed to contain sensitive information.

Publication on the CCG's website.
Following approval all finalised Equality Analysis should be sent to the Communications and Engagement team for publication: bsol.comms@nhs.net

13. Sign Off

The Equality Analysis will need to go through a process of **quality assurance** by the Senior Manager for Equality Diversity and Inclusion or the Manager for Equality Diversity and Inclusion prior to approval from the delegated committee

	Name	Date

Quality Assured By:		
Which Committee will be considering the findings and signing off the EA?		
Minute number (to be inserted following presentation to committee)		

Please send to Balvinder Everitt or Michelle Dunne, Equality, Diversity and Inclusion for Quality Assurance.

Once you have committee sign off, please send to Caroline Higgs, Communications & Engagement Team for publication: bsol.comms@nhs.net

Equality Analysis

(Health Inequalities, Human Rights, Social Value)

Policy for the use of Liposuction in Lymphoedema

Before completing this equality analysis it is recommended that you:

- ✓ Contact your equality and diversity lead for advice and support
- ✓ Take time to read the accompanying policy and guidance document on how to complete an equality analysis

NHS Birmingham and Solihull Clinical Commissioning Group
NHS Sandwell and West Birmingham Clinical Commissioning Group

1. Background

EA Title	**Policy for the use of Liposuction in** **A. Lymphoedema**		
EA Author	David King	**Team**	Equality and Diversity Team
Date Started	September 2019	**Date Completed**	4/12/2019
EA Version	4	**Reviewed by E&D**	

What are the intended outcomes of this work? Include outline of objectives and function aims

Liposuction

Liposuction is normally deemed to be a cosmetic procedure used to remove unwanted body fat.

It involves sucking out small areas of fat that are hard to lose through exercise and a healthy diet. It's carried out on areas of the body where deposits of fat tend to collect, such as the buttocks, hips, thighs and tummy.

The aim is to alter body shape, and the results are generally long-lasting, providing you maintain a healthy weight.

It works best in people who are a normal weight and in areas where the skin is tight.

Liposuction carried out for cosmetic reasons is not normally available on the NHS. However, liposuction can sometimes be used by the NHS to treat certain health conditions.

Liposuction is usually carried out under general anaesthetic, although an epidural anaesthetic may be used to enable treatment on lower parts of the body.

The surgeon would mark on your body the area where fat is to be removed. He or she would then:

- **inject this area** with a solution containing anaesthetic and medication, to reduce blood loss, bruising and swelling
- **break up the fat cells** using high-frequency vibrations, a weak laser pulse or a high-pressure water jet
- **make a small incision (cut) and insert a suction tube attached to a vacuum machine** (several cuts may need to be made if the area is large)
- **move the suction tube back and forth** to loosen the fat and suck it out
- **drain** any excess fluid and blood
- **stitch up and bandage** the treated area

It usually takes one to three hours. Most people need to stay in hospital overnight.

After the procedure, you would be fitted with a compression garment. This helps to reduce swelling and bruising and should be worn constantly for several weeks after the operation.

You may need to take antibiotics straight after the procedure to reduce the risk of infection. Most people also take mild painkillers to ease any pain and swelling.

Recovery

It may take up to 12 weeks to make a full recovery.

If you had a general anaesthetic, someone would need to drive you home and stay with you for the first 24 hours. You would not be able to drive for a few days.

The compression garment may be taken off while you shower.

You would need to avoid strenuous activity for up to four weeks (but walking and general movement should be fine).

The results of the procedure are not always noticeable until the swelling has gone down or depending on the care plan for the individual patient, it may take more than one surgical episode before results are visible. It can take up to six months for the area to settle completely.

After about a week: Stitches would be removed (unless you had dissolvable stitches).

At four to six weeks: You should be able to resume any contact sports or strenuous activities you would normally do.

Side effects to expect

It is common after liposuction to have:

- **bruising and swelling**, which may last up to a couple of months
- **numbness**, which should go away in six months
- **scars**
- **inflammation** of the treated area, or the veins underneath
- **fluid** coming from the cuts
- **swollen ankles** (if the legs or ankles are treated)and it may require long-term compression garments to be worn.
- Pain which may last for up to a month
- Skin laxity

Liposuction can occasionally result in:

- **lumpy and uneven results, which is often due to skin laxity and cannot be resolved by further episodes of liposuction.**
- Seroma which is a collection of fluid under the skin
- **bleeding under the skin** (haematoma)
- **persistent numbness** that lasts for months
- **changes in skin colour** in the treated area
- **a build-up of fluid in the lungs** (pulmonary oedema) from the fluid injected into the body
- **a blood clot in the lungs** (pulmonary embolism)
- **damage to internal organs** during the procedure

Any type of operation also carries a small risk of:

- **excessive bleeding**
- **developing a blood clot** in a vein
- **infection**
- **an allergic reaction** to the anaesthetic

The surgeon should explain how likely these risks and complications are, and how they would be treated if they occurred.

Liposuction in Lymphoedema: Category: Restricted

Lymphoedema

Lymphoedema is a long-term (chronic) condition that causes swelling in the body's tissues. It can affect any part of the body, but usually develops in the arms or legs.

It develops when the lymphatic system does not work properly. The lymphatic system is a network of channels and glands throughout the body that helps fight infection and remove excess fluid.

There are two main types of lymphoedema:

- **primary lymphoedema** – caused by faulty genes that affect the development of the lymphatic system; it can develop at any age, but usually starts during infancy, adolescence, or early adulthood
- **secondary lymphoedema** – caused by damage to the lymphatic system or problems with the movement and drainage of fluid in the lymphatic system; it can be the result of an infection, injury, cancer treatment, inflammation of the limb, or a lack of limb movement

Lymphoedema is thought to affect more than 200,000 people in the UK. Primary lymphoedema is rare and is thought to affect around 1 in every 6,000 people. Secondary lymphoedema is much more common.

Secondary lymphoedema affects around 2 in 10 women with breast cancer, and 5 in 10 women with vulval cancer. About 3 in every 10 men with penile cancer get lymphoedema.

People who have treatment for melanoma in the lymph nodes in the groin can also get lymphoedema. Research has shown around 20-50% of people are affected.

Treating lymphoedema

There is no cure for lymphoedema, but it's usually possible to control the main symptoms using techniques to minimise fluid build-up and stimulate the flow of fluid through the lymphatic system.

These include wearing compression garments, taking good care of your skin, moving and exercising regularly, and having a healthy diet and lifestyle.

The recommended treatment for lymphoedema is decongestive lymphatic therapy (DLT).

DLT isn't a cure for lymphoedema, but it can help control the symptoms. Although it takes time and effort, the treatment can be used to bring lymphoedema under control.

Decongestive lymphatic therapy (DLT)

There are four components to DLT:

- **compression garments** – to complement exercise by moving fluid out of the affected limb and minimise further build-up
- **skin care** – to keep the skin in good condition and reduce the chances of infection
- **exercises** – to use muscles in the affected limb to improve lymph drainage
- **specialized massage techniques** – known as manual lymphatic drainage (MLD); this stimulates the flow of fluid in the lymphatic system and reduces swelling however, this technique is only appropriate for patients with cancer-related or primary lymphoedema.

DLT is an intensive phase of therapy, during which you may receive treatment up to 3 times per week for several weeks to help reduce the volume of the affected body part.

This is followed by a second phase called the maintenance phase. You will be encouraged to take over your care using simple self-massage techniques, wearing compression garments, and continuing to exercise.

This treatment phase aims to maintain the reduced size of the affected body part.

Surgery

In a small number of cases, surgery may be used to treat lymphoedema. There are three main types of surgery that may be useful for the condition:

- removal of sections of excess skin and underlying tissue (debulking)
- removal of fat from the affected limb (liposuction)
- restoration of the flow of fluid around the affected section of the lymphatic system – for example, by connecting the lymphatic system to nearby blood vessels (lymphaticovenular anastomosis)
- Lymph node transfer

These treatments may help reduce the size of areas of the body affected by lymphoedema, but some are still being evaluated – particularly lymphaticovenular anastomosis – and aren't in widespread use.

This policy ONLY covers the use of Liposuction for Lymphoedema.

Liposuction

Liposuction is where a thin tube is inserted through small cuts (incisions) in the skin to suck fat out of tissue. It can be used to remove excess fat from an affected limb to help reduce its size.

After surgery, you'll have to wear a compression garment on the affected limb day and night for at least a year to help keep the swelling down.

Evidence Review

Searches in the Cochrane Database and the identification of a number of systematic reviews show, good quality of evidence, which support the use of liposuction in patient diagnosed with lymphoedema in certain clinical circumstances.

The evidence demonstrated clear prevention of future illness, due to the nature of lymphoedema and the reduction in the likelihood of serious infections.

Moderate to large health improvement using this procedure was supported within the evidence review by long term follow up which demonstrated on-going clinical benefit to patients.

Current evidence on the safety and efficacy of liposuction for chronic lymphoedema is adequate to support the use of this procedure provided that standard arrangements are in place for clinical governance, consent and audit.

However, patient selection should only be done by a specialist lymphoedema multidisciplinary team as part of a lymphoedema service pathway.

Who will be affected by this work? e.g. staff, patients, service users, partner organisations etc.

Liposuction in Lymphoedema: Category: Restricted

For patients with Lymphoedema who have failed conservative management in line with the current patient pathway for the treatment of lymphoedema, patients will be eligible for treatment of their lymphoedema with liposuction.

Patient selection should only be done by a specialist lymphoedema multidisciplinary team as part of a lymphoedema service pathway.

Investigations for suspected or proven malignancy are outside the scope of this policy and should be treated in line with the relevant cancer pathway.

Conservative management of lymphoedema is defined as:

Current conservative treatments for lymphoedema include manual lymph drainage (MLD), which stimulates the movement of lymph away from the affected limb, and decongestive lymphatic therapy (DLT). DLT combines MLD massage techniques with compressive bandaging, skin care and decongestive exercises. Once DLT sessions are stopped the patient is fitted with a custom-made compression garment, which is worn every day.

This means **(for patients who DO NOT meet the above criteria)** the CCG will **only** fund the treatment if an Individual Funding Request (IFR) application proves exceptional clinical need and that is supported by the CCG.

Number of procedures undertaken overall and by CCG

	BSOL	Sandwell
	1	0

Due to limited data collection by the providers service activity data is available by headcount only not protected characteristic.
The Joint Strategic Needs Assessments for Birmingham, Solihull and Sandwell are available via the links below.

Sandwell

Birmingham

Solihull

2. Research

What evidence have you identified and considered? This can include national research, surveys, reports, NICE guidelines, focus groups, pilot activity evaluations, clinical experts or working groups, JSNA or other equality analyses.

Research/Publications	Working Groups	Clinical Experts
Liposuction in Lymphoedema		
Stuiver Martijn M, ten Tusscher Marieke R, McNeely Margaret L. Which are the best conservative interventions for lymphoedema after breast cancer surgery? BMJ 2017; 357 :j233		
Carl, H. M., Walia, G., Bello, R., Clarke-Pearson, E., Hassanein, A. H., Cho, B.Sacks, J. M. (Accepted/In press). Systematic Review of the Surgical Treatment of Extremity Lymphedema (. Journal of Reconstructive Microsurgery. https://doi.org/10.1055/s-0037- 1599100		
Schaverien MV, Munnoch DA, Brorson H. Liposuction Treatment of Lymphedema. Semin Plast Surg. 2018;32(1):42–47. doi:10.1055/s- 0038-1635116		
Greene AK and Maclellan Reid A (2016) Operative treatment of lymphedema using suction-assisted lipectomy. Annals of Plastic Surgery 77: 337-340.		
Lamprou DAA, Voesten HG, Damstra RJ et al. (2017) Circumferential suction-assisted lipectomy in the treatment of primary and secondary end-stage lymphoedema of the leg. The British journal of surgery 104, 84-89.		
Hoffner M, Bagheri S, Hansson E et al. (2017) SF-36 Shows Increased Quality of Life Following Complete Reduction of Postmastectomy Lymphedema with Liposuction. Lymphatic Research and Biology 15, 87-9		
https://www.nhs.uk/conditions/Lymphoedema/		
https://www.mayoclinic.org/diseases-conditions/lymphedema/symptoms-causes/syc-20374682		

3. Impact and Evidence:

In the following boxes detail the findings and impact identified (positive or negative) within the research detailed above; this should also include any identified health inequalities which exist in relation to this work.

Age: Describe age related impact and evidence. This can include safeguarding, consent and welfare issues:

Lymphoedema

Primary: For those with the condition of primary lymphoedema this is more commonly witnessed in infancy, adolescence or early adulthood however it can start at any age.

Secondary: No impact

Disability: Describe disability related impact and evidence. This can include attitudinal, physical, communication and social barriers as well as mental health/ learning disabilities, cognitive impairments:

Lymphoedema

Primary: There is no data available to suggest a link to disability as this is a genetic and, in most cases, an inherited condition. Those who have the condition of primary Lymphoedema can be anything from mild to a severe disability.

Secondary: Whilst there is no data available on whether the patients who have undergone this procedure have a disability, there may be a link to those who suffer from a disability connected to lack of limb movement such as a degenerative condition which results in problems arising in the lymphatic system and the drainage of fluid.

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Gender reassignment (including transgender): Describe any impact and evidence on transgender people. This can include issues such as privacy of data and harassment:

Lymphoedema
Primary/Secondary: No impact identified

3. Impact and Evidence:

Marriage and civil partnership: Describe any impact and evidence in relation to marriage and civil partnership. This can include working arrangements, part-time working, and caring responsibilities:
No impact identified

Lymphoedema
Primary/Secondary: No impact identified

Pregnancy and maternity: Describe any impact and evidence on pregnancy and maternity. This can include working arrangements, part-time working, and caring responsibilities:

Lymphoedema

Primary: Depending on the type of primary Lymphoedema diagnosed there may be a link to conditions worsening at the time of hormone changings such as pregnancy.

Secondary: No available data to suggest an impact however with primary Lymphoedema the changing to hormone levels may have an effect on this condition.

Race: Describe race related impact and evidence**.** This can include information on different ethnic groups, Roma gypsies, Irish travellers, nationalities, cultures, and language barriers:

Lymphoedema
Primary/Secondary: No impact identified

Religion or belief: Describe any religion, belief or no belief impact and evidence. This can include dietary needs, consent and end of life issues:

Lymphoedema
Primary/Secondary: No impact identified

Sex: Describe any impact and evidence on men and women. This could include access to services and employment:

3. Impact and Evidence:

Lymphoedema

Primary: No impact identified based on available data however females may be at more risk of having this genetic disorder.

Secondary: No data available as the condition is a result of damage or problems to the lymphatic system rather than genetics. However, there is a relationship to those who have already undergone cancer treatment for cancers which are gender specific then acquiring the condition. Approximately, around 2 in 10 women with breast cancer, and 5 in 10 women with vulval cancer. About 3 in every 10 men with penile cancer get lymphoedema.

Sexual orientation: Describe any impact and evidence on heterosexual people as well as lesbian, gay and bisexual people. This could include access to services and employment, attitudinal and social barriers:

Lymphoedema
Primary/Secondary: No impact identified

Carers: Describe any impact and evidence on part-time working, shift-patterns, general caring responsibilities:

Lymphoedema
Primary/Secondary: No impact identified

Other disadvantaged groups: Describe any impact and evidence on groups experiencing disadvantage and barriers to access and outcomes. This can include lower socio-economic status, resident status (migrants, asylum seekers), homeless, looked after children, single parent households, victims of domestic abuse, victims of drugs / alcohol abuse: (This list is not exhaustive)

Lymphoedema
Primary/Secondary: No impact identified

4. Health Inequalities	Yes/No	Evidence
Could health inequalities be created or persist by the proposals?	No	This condition is not linked to a

		health inequality.
Is there any impact for groups or communities living in particular geographical areas?	No	No impact identified
Is there any impact for groups or communities affected by unemployment, lower educational attainment, low income, or poor access to green spaces?	No	No impact identified
How will you ensure the proposals reduce health inequalities?		

5. FREDA Principles/ Human Rights	**Question**	**Response**
Fairness – Fair and equal access to services	How will this respect a person's entitlement to access this service?	Yes, this decision has been made in line with clinical recommendation.
Respect – right to have private and family life respected	How will the person's right to respect for private and family life, confidentiality and consent be upheld?	No evidence of impact from this policy
Equality – right not to be discriminated against based on your protected characteristics	How will this process ensure that people are not discriminated against and have their needs met and identified?	No discrimination identified
	How will this affect a person's right to freedom of thought, conscience and religion?	N/A
Dignity – the right not to be treated in a degrading way	How will you ensure that individuals are not being treated in an inhuman or degrading way?	Policy will be applied with due regard to this consideration.
Autonomy – right to respect for private & family life; being able to make informed decisions and choices	How will individuals have the opportunity to be involved in discussions and decisions about their own healthcare?	An individual can discuss the impact with their GP and has the option for an IFR request to be made
Right to **Life**	Will or could it affect someone's right to life? How?	No evidence of impact from this policy
Right to **Liberty**	Will or could someone be deprived of their liberty? How?	No evidence of impact from this policy

6. Social Value

Consider how you might use the opportunity to improve health and reduce health inequalities and so achieve wider public benefits, through action on the social determinants of health.	
Marmot Policy Objective	**What actions are you able to build into the procurement activity and/or contract to achieve wider public benefits?**
Enable all people to have control over their lives and maximise their capabilities	None
Create fair employment and good work for all	None
Create and develop health and sustainable places and communities	None
Strengthen the role and impact of ill-health prevention	None

7. Engagement, Involvement and Consultation

If relevant, please state what engagement activity has been undertaken and the date and with which protected groups:

Engagement Activity	Protected Characteristic/ Group/ Community	Date

For each engagement activity, please state the key feedback and how this will shape policy / service decisions (E.g. patient told us …. So we will …..):

As part of the process further targeted engagement is planned with representative groups from among Sandwell, Birmingham and Solihull Patients. In addition, it has been identified that patient and clinician information is key in ensuring that the harmonised treatment policies review delivers effective outcomes. To this end an information briefing sheets on each procedure will be developed to give more information on the procedure, eligibility criteria and signposting to further information sources, such as NHS Choices. These information sheets are also designed to help facilitate discussions between GPs and patients. Information briefing sheets have already been tested and uploaded onto the GP systems for the first 45 harmonised treatment policies for Birmingham and Solihull. Due regard will be given to both the accessible information standard and the potential need to translate such leaflets into relevant local languages.

If any further available evidence has been submitted which has not been taken into consideration during this review will be looked at during the engagement period: 2nd September 2019 – 11th October 2019.

The engagement team used every possible route throughout the engagement period to encourage people to feedback on the proposed policy. Unfortunately, despite the wide communication undertaken through all communication and engagement channels available, 49 questionnaires were completed online and there was no interest from stakeholders, patients and the public to attend any of the five stakeholder events arranged. As a result, the events were cancelled, and the engagement team looked at other routes to encourage engagement with patients directly. A possible reason for the

general lack of interest and feedback from stakeholders, patients and the public is most likely because this clinical treatments policy either widening the scope of the current service provision, providing policies to protect the current service provision or the intervention is for somewhat rare conditions.

Also, in phase 3 of the harmonisation of policies programme clinicians had been integral to the development of the policies from the beginning of the process. It could therefore be argued the proposed policy shared for public engagement was to some extent already informed from a local patient experience and outcomes perspective.

As there is currently no policy in place, half of the responses from Healthcare professional and patient feedback has welcomed the need to address support for those who suffer with Lymphoedema and that some patients where conservative treatment has failed have greatly benefited for the procedure.

8. Summary of Analysis

Considering the evidence and engagement activity you listed above, please summarise the impact of your work:

Lymphoedema

Primary/Secondary: The restriction of this policy will have limited impact on those who would wish to receive the treatments as the procedure is available where conservative management in line with the current patient pathway has not worked. Moderate to large health improvement using this procedure was supported within the evidence review by long term follow up which demonstrated on-going clinical benefit to patients. This must be balanced against the need to adhere to the clinical effectiveness evidence and services being commissioned continue to be safe and clinically effective to patients. The opportunity for any exceptional cases to be considered via IFR remains and will ensure treatment is available.

Investigations for suspected or proven malignancy are outside the scope of this policy and should be treated in line with the relevant cancer pathway.

9. Mitigations and Changes :

Please give an outline of what you are going to do, based on the gaps, challenges and opportunities you have identified in the summary of analysis section. This might include action(s) to mitigate against any actual or potential adverse impacts, reduce health inequalities, or promote social value. Identify the **recommendations** and any **changes** to the proposal arising from the equality analysis.

None identified

10. Contract Monitoring and Key Performance Indicators

Detail how and when the service will be monitored and what key equality performance indicators or reporting requirements will be included within the contract (refer to NHS Standard Contract SC12 and 13):
This policy is not linked to a contract however, prospective providers remain bound by their contracts with the CCG.

11. Procurement

Detail the key equality, health inequalities, human rights, and social value criteria that will be included as part of the procurement activity (to evaluate the providers ability to deliver the service in line with these areas):
N/A

12. Publication

How will you share the findings of the Equality Analysis? This can include: reports into committee or Governing Body, feedback to stakeholders including patients and the public, publication on the web pages. All Equality Analysis should be recommended for publication unless they are deemed to contain sensitive information.
Publication on the CCG's website.
Following approval all finalised Equality Analysis should be sent to the Communications and Engagement team for publication: bsol.comms@nhs.net

13. Sign Off		
The Equality Analysis will need to go through a process of **quality assurance** by the Senior Manager for Equality Diversity and Inclusion or the Manager for Equality Diversity and Inclusion prior to approval from the delegated committee		
	Name	**Date**
Quality Assured By:		
Which Committee will be considering the findings and signing off the EA?		
Minute number (to be inserted following presentation to committee)		

Please send to Balvinder Everitt or Michelle Dunne, Equality, Diversity and Inclusion for Quality Assurance.

Once you have committee sign off, please send to Caroline Higgs, Communications & Engagement Team for publication: bsol.comms@nhs.net

Equality Analysis

(Health Inequalities, Human Rights, Social Value)

Policy for use of Domiciliary Non-Invasive Ventilation in COPD & NMD

Before completing this equality analysis it is recommended that you:

- ✓ Contact your equality and diversity lead for advice and support
- ✓ Take time to read the accompanying policy and guidance document on how to complete an equality analysis

NHS Birmingham and Solihull Clinical Commissioning Group
NHS Sandwell and West Birmingham Clinical Commissioning Group

1. Background

EA Title	Policy for use of domiciliary Non-Invasive Ventilation		
EA Author	David King	**Team**	Equality and Diversity Team
Date Started		**Date Completed**	4/12/2019
EA Version	4	**Reviewed by E&D**	

What are the intended outcomes of this work? Include outline of objectives and function aims

Why is Non-Invasive Ventilation (NIV) used and what is it?

When we breathe in, we take oxygen out of the air to keep us alive - this oxygen is transferred to our blood in our lungs. The body then uses the oxygen and produces a waste gas called carbon dioxide, which we breathe out. The process of this exchange is ventilation.

Some people with severe lung disease, have problems getting enough oxygen into the body, which results in hypoxaemia. If their oxygen level drops below a certain level, it is relatively easy to give extra oxygen for them to breathe, which is called oxygenation. However, in some severe cases of obstructive lung conditions, muscle weakness or neurological impairment, the extra effort of trying to keep the oxygen at a satisfactory level in the blood and to expel carbon dioxide results in the person tiring and leading to hypoventilation and hypercapnia causing respiratory failure.

Respiratory failure is more difficult to deal with. It is a particular problem with diseases that cause obstruction to our airways, such as chronic obstructive pulmonary disease (COPD). In COPD, the airways are narrowed, making it harder to get oxygen into the lungs and carbon dioxide out. Patients who have weak or denervated respiratory muscles in neuromuscular/neurological conditions are also unable to take in a sufficient volume of air to expel carbon dioxide. In all these conditions, a person can develop type 2 respiratory failure which cannot be corrected with oxygenation as the person needs help to ventilate to expel carbon dioxide. Type 2 respiratory failure can lead to high heart rate and cardiac complications.

The aim of using Non-Invasive ventilation (NIV) is not only to obtain satisfactory oxygen levels, but also to expire carbon dioxide. It is often first used at night when the patient is asleep and carbon dioxide levels increase, but as the patient's condition progresses, NIV may be required in the day when the patient has diurnal respiratory failure. It is also important to ease the work of breathing associated with respiratory failure as when a patient with respiratory failure becomes overly tired, this can lead to fatigue, further respiratory compromise and potential respiratory arrest. NIV also aims to take some of the effort out of breathing because the patient's chest muscles don't have to work as hard, so it helps to ease the feelings of breathlessness.

People receiving NIV need to wear a cushioned mask or use a mouthpiece, which is connected to an air pump machine. This mask fits either over the nose alone, or over

both the nose and mouth; a strap holds the mask firmly in place, but it can be easily removed, to enable, for example, the patient to eat and drink.

Types of Non-Invasive Ventilation

Noninvasive ventilation (NIV) refers to the administration of ventilatory support without using an invasive artificial airway (endotracheal tube or tracheostomy tube). The use of noninvasive ventilation has markedly increased over the past three decades, and noninvasive ventilation has now become an integral tool in the management of both acute and chronic respiratory failure, in both the home setting and in critical care.

In its simplest terms, noninvasive ventilation differs from invasive ventilation by the interface between the patient and the ventilator. Invasive ventilatory support is provided via either an endotracheal tube or tracheostomy tube. Noninvasive ventilatory support uses a variety of interfaces, and these have continued to evolve with modifications based on patient comfort and efficacy. Many of the interfaces or masks were initially used in patients with obstructive sleep apnoea before they were adapted for use in patients to provide noninvasive ventilatory support.

Nasal masks and orofacial masks were the earliest interfaces, with subsequent development and use of full-face masks, mouthpieces, nasal pillows, and helmets. Hybrid masks and orofacial masks are still the most commonly used interfaces. Orofacial masks are used almost twice as frequently as nasal masks. Both have advantages and disadvantages in the application of noninvasive ventilation.

Noninvasive positive-pressure ventilation

Positive-pressure ventilation delivered through a mask, has become the predominant method of providing noninvasive ventilatory support. Early bedside physiological studies in healthy patients and in patients with respiratory conditions document successful ventilatory support (i.e., reduction in respiratory rate, increase in tidal volume, decrease in dyspnoea) with reduction in diaphragmatic electromyography (EMG), transdiaphragmatic pressures, work of breathing and improvement in oxygenation with a reduction in hypercapnia.

Ventilatory support can be achieved through a variety of interfaces (mouth piece or nasal, face, or helmet mask), using a variety of ventilatory modes (e.g., volume ventilation, pressure support, bilevel positive airway pressure [BiPAP], proportional-assist ventilation [PAV]) with either ventilators dedicated to noninvasive ventilation (NIV) or those capable of providing support through an endotracheal tube or mask. Older models of noninvasive ventilators required oxygen to be bled into the system, but current models incorporate oxygen blenders for precise delivery of the fraction of inspired oxygen (FIO_2).

Current use of Non-invasive Ventilation devices.

Bilevel positive airway pressure (BiPAP) is probably the most common mode of noninvasive positive pressure ventilation and provides for inspiratory positive airway pressure (IPAP) and expiratory positive airway pressure (EPAP). The difference

between IPAP and EPAP reflects the amount of pressure support ventilation provided to the patient, and EPAP is synonymous with positive end-expiratory pressure (PEEP). Some noninvasive ventilation is provided using proportional-assist ventilation (PAV), which provides flow and volume assistance with each breath. Clinical trials have not demonstrated a significant difference between PAV and pressure-support ventilation with BiPAP. [5, 6] However, BiPAP is the most commonly available and more frequently used modality for noninvasive ventilation. PAV remains available on many ventilator models, but use is much less common than BiPAP.

National context

National Guidance for the provision of aspects of specialist non-ventilation services to patients exists for some individual patient groups e.g. Motor Neurone Disease (MND), Duchene's Muscular Dystrophy (DMD); and for broader categories of patients e.g. weaning guidance; and around specific technologies e.g. diaphragmatic pacing and tracheostomies. There are some national standards (NICE, 2010; 2016) available and some specialist society guidance (BTS/ICS 2016).

Provision of complex home ventilation services also falls within the NHS Outcomes Framework:
Domain 1 - preventing people from dying prematurely where Improvement Area 1a specifically identifies reducing mortality from respiratory disease,
Domain 2 – enhancing quality of life for patients with long term conditions
Domain 3 – helping patients to recover after an episode of acute illness, where post-acute admission, non-invasive ventilation has been shown to help people recover better in the community and reduce readmission rates.

Guidance supports delivery of care by respiratory specialists working within MDTs. For example, the National Institute for Health and Clinical Excellence (NICE) clinical guideline around the use of NIV in MND states that "multidisciplinary teams (MDT) should coordinate and provide on-going management and treatment for patients with MND, including regular respiratory assessment and provision of non-invasive ventilation. The team should include a neurologist, a respiratory physician, a MND specialist nurse, a respiratory specialist nurse, a specialist respiratory physiotherapist, a respiratory physiologist, a specialist in palliative care and a speech and language therapist". The guidance also outlines the support and training which need to be provided to the patient and their family and carers: "support and assistance to manage non-invasive ventilation which should include training on using non-invasive ventilation and ventilator interfaces, for example emergency procedures, night-time assistance if the patient is unable to use the equipment independently (for example, emergency removal or replacement of interfaces), how to use the equipment with a wheelchair or other mobility aids, if required, what to do if the equipment fails, assistance with secretion management, information on general palliative strategies, an offer of on-going emotional and psychological support for the patient and their family and carers".

Ensuring NIV is delivered by competent respiratory professionals is emphasised in NICE MND guidance and also in the National Patient Safety Agency (NPSA) alert which identified cases where problems with administering NIV were stated as causing at least moderate harm: key issues included shortage of staff skills or staff time to set up and monitor NIV.

Local context

The CCG, based on strong supporting evidence for the clinical effectiveness of the intervention, will commission the use of domiciliary non-invasive ventilation in the following clinical conditions where the patient's individual clinical circumstances meet the relevant clinical eligibility criteria outlined in Sections A & B respectively:

- Chronic Obstructive Pulmonary Disease (Section A)
- Neuro-muscular and Neurological Weakness Patients (Section B)

Please note the provision of treatment for patients with Cystic Fibrosis and patients with Spinal Muscular Atrophy are specialised services commissioned by NHSE.

NIV – Section A – Chronic Obstructive Pulmonary Disease (COPD)

Chronic obstructive pulmonary disease (COPD) is the collective name for a group of lung conditions that may cause breathing difficulties.

It includes:

- **emphysema** – damage to the air sacs in the lungs
- **chronic bronchitis** – long-term inflammation of the airways

COPD is a common condition that mainly affects middle-aged or older adults who have a smoking history. The breathing problems tend to get gradually worse over time and can limit the patient's normal activities, although treatment can help keep the condition under control.

Symptoms of COPD
The main symptoms of COPD are:

- increasing breathlessness, particularly when the patient is active
- a persistent chesty cough with phlegm
- frequent chest infections
- persistent wheezing

Without treatment, the symptoms usually get slowly worse. There may also be periods when they get suddenly worse, known as a flare-up or exacerbation.

Causes of COPD
COPD occurs when the lungs become inflamed, damaged and narrowed. The main cause is smoking, although the condition can sometimes affect people who have never smoked.

The likelihood of developing COPD increases the more a patient smokes and the longer the patient has smoked. Some cases of COPD are caused by long-term exposure to harmful fumes, or dust or occur as a result of a rare genetic problem that means the lungs are more vulnerable to damage.

The damage to the lungs caused by COPD is permanent, but treatment can help slow down the progression of the condition.

Treatments include:

- smoking cessation – if a patient is diagnosed with COPD still smokes, stopping smoking is the most important thing a patient can do
- **inhalers and medications**
- **pulmonary rehabilitation** – a specialised programme of exercise and education
- **surgery or a** lung transplant –an option for a very small number of people

Chronic obstructive pulmonary disease (COPD) is characterized by recurrent exacerbations that can cause intermittent periods of severe clinical deterioration requiring hospitalisation and ventilator support. Although treating patients with COPD and acute respiratory failure with non-invasive ventilation improves outcomes, persistent hypercapnia after an exacerbation is associated with excess mortality and early rehospitalization. In 2013, the 28-day COPD readmission rate was around 20%, (Suh et al. 2015).

NIV – Section B –Patients with Neuro-muscular and Neurological weakness

A number of chronic neuromuscular disorders, for example muscular dystrophy and motor neurone disease lead to progressive respiratory muscle dysfunction, which in turn can lead to respiratory failure and death. Nocturnal and daytime Non-Invasive Ventilation (NIV) is the preferred method of treatment for these disorders[1].

Non-invasive ventilation as a treatment for neuromuscular disease has several benefits. It has been shown to:

- Improves lung mechanics and gas exchange
- Decrease work of breathing
- Improve symptoms of fatigue
- Reduce daytime sleepiness
- Improve survival in Duchenne Muscular Dystrophy (DMD) and Motor Neurone Disease (MND) patients.

Patients with one of the following conditions will be considered for funding when the patient also meets the eligibility criteria outlined below.

- Motor Neurone Disease
- Muscular Dystrophies including Duchenne Muscular Dystrophy
- Spinal cord injury
- Multiple Sclerosis
- Guillain-Barre Syndrome
- Post polio syndrome with respiratory impairment

- Syringomyelia
- Tuberculosis infection with residual respiratory insufficiency
- Other neuromuscular impairment which is known to cause respiratory muscle weakness or upper airway functional impairment which are the commissioning responsibility of the CCG.

Who will be affected by this work? e.g. staff, patients, service users, partner organisations etc.

NIV – Section A – Chronic Obstructive Pulmonary Disease (COPD)

Eligibility Criteria: Restricted

For patients with COPD the CCG will commission the use of domiciliary non-invasive ventilation in the following clinical circumstances:

The patient has a diagnosis of COPD, identified by post bronchodilator Forced Expiratory Volume (FEV)1 / Forced Vital Capacity (FVC) <0.70

AND

4 weeks post-acute admission the patient has a paCO2 over 7 kPa.

AND

the patient must have ONE of the following:

- A reduction in Quality of life identified by symptoms consistent with Sleep Disordered Breathing Problems (see pg12 for definition)
    - If the patient has reduced quality of life, then overnight oximetry should be undertaken to demonstrate that the patient meets ONE of the following criteria:
        - An apnoea/hypopnoea index >10/hour on respiratory polysomnography or multi-channel respiratory sleep study
        - Four or more episodes of SpO2 <92%
        - Drops in SpO2 of at least 4% per hour of sleep

OR

- A co-morbidity secondary to hypoxemia
    - Pulmonary Hypertension
    - Heart Failure

If the patient has co-morbidities secondary to hypoxemia then the patient should also meet the following criteria:

- Recurrent NIV admissions (2 or more in a 12month period OR difficulty weaning / unable to tolerate weaning)
  AND
- Acute use of NIV has been well tolerated

N.B. Symptoms consistent with Sleep Disordered Breathing Problems are defined as:

- Excessive daytime somnolence (a state of strong desire for sleep, or sleeping for unusually long periods as per the Epworth Sleepiness Score)
- Headache
- Confusion
- Increased shortness of breath
- Resting tremor

Exclusion criteria:

- Inability to remove mask independently (with no waking night carer)
- Cognitive / behavioural limitation affecting ability to comply safely with NIV
- Intolerance of acute NIV
- Multiple co-morbidities limiting utility of NIV

Funding will be provided for the following if the patient with COPD meets the above clinical criteria:

- One NIV machine
- +/- Humidifier as required
- 1-2 lengths of tubing per year
- 1-2 masks per year

This means **(for patients who DO NOT meet the above criteria)** the CCG will **only** fund the treatment if an Individual Funding Request (IFR) application proves exceptional clinical need and that is supported by the CCG.

NIV – Section B –Patients with Neuro-muscular and Neurological weakness
Patients with one of the following conditions will be considered for funding when the patient also meets the eligibility criteria outlined below.

- Motor Neurone Disease
- Muscular Dystrophies including Duchenne Muscular Dystrophy
- Spinal cord injury
- Multiple Sclerosis
- Guillain-Barre Syndrome
- Post polio syndrome with respiratory impairment
- Syringomyelia
- Tuberculosis infection with residual respiratory insufficiency
- Other neuromuscular impairment which is known to cause respiratory muscle weakness or upper airway functional impairment which are the commissioning responsibility of the CCG.

Eligibility Criteria: Restricted

For patients diagnosed with a neuromuscular condition as outlined above, the patient must meet the following criteria for funding f non-invasive ventilation to be approved:

Nocturnal Ventilation

The patient must meet ONE of the following criteria:

- Signs (<50% predicted/<1l) or symptoms of hypoventilation
- MIP< 60cmH_2O
- A baseline SpO_2 <95%
- Blood or end tidal pCO2 >45mmHg whilst awake
- Four or more episodes of SpO2 <92%
- Drops in SpO2 of at least 4% per hour of sleep

Daytime Ventilation (in addition to meeting the above criteria the patient must also meet ONE of the following criteria):

- Abnormal deglutition due to dyspnoea, which is relieved by ventilatory assistance
- Inability to speak in full sentences without breathlessness
- Symptoms of hypoventilation with baseline SpO2 <95%
- Blood or end tidal pCO2 >45mmHG whilst awake
- Symptoms of awake dyspnoea are present

Exclusion criteria:

- Inability to remove mask independently (with no waking night carer)
- Cognitive / behavioural limitation affecting ability to comply safely with NIV
- Intolerance of acute NIV
- Multiple co-morbidities limiting utility of NIV

Funding will be provided for the following if the patient meets the above clinical criteria:

Below 14 hours of ventilation required.

- One NIV machine
- +/- Humidifier as required
- 1-2 lengths of tubing per year
- 1-2 masks per year

Above 14 hours / 24-hour period of ventilation required.

- Two NIV machines
- +/- ONE Humidifier as required
- 2-4 lengths of tubing per year
- 2-4 masks per year

This means **(for patients who DO NOT meet the above criteria)** the CCG will **only** fund the treatment if an Individual Funding Request (IFR) application proves exceptional clinical need and that is supported by the CCG.

Number of procedures undertaken overall and by CCG

	BSOL	Sandwell
	Data is not available for this procedure	

The providers have not collected this data and it is not possible to collate this retrospectively.

The Joint Strategic Needs Assessments for Birmingham, Solihull and Sandwell are available via the links below.

Sandwell

Birmingham

Solihull

2. Research		
What evidence have you identified and considered? This can include national research, surveys, reports, NICE guidelines, focus groups, pilot activity evaluations, clinical experts or working groups, JSNA or other equality analyses.		
Research/Publications	**Working Groups**	**Clinical Experts**
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3. Impact and Evidence:

In the following boxes detail the findings and impact identified (positive or negative) within the research detailed above; this should also include any identified health inequalities which exist in relation to this work.

Age: Describe age related impact and evidence. This can include safeguarding, consent and welfare issues:

NIV – Section A – Chronic Obstructive Pulmonary Disease (COPD)

Long term lifestyle choices (smoking) in most cases is the most common reason for diagnoses, as such COPD is a common condition that mainly affects middle aged or older people who smoke.

It is recognised that genetic conditions can predispose younger people to developing such conditions as COPD.

NIV – Section B – Neuro-Muscular Patients

Depending upon the diagnosed condition of the patient if it's an inherited genetic condition this will be present at birth which may or may not show symptoms until later in life.

However, the condition may link to age in cases of motor neurones disease where cells in the brain and nerves stop working over-time, and mainly affects people in their 60's and 70s, but it can affect adults of all ages.

Disability: Describe disability related impact and evidence. This can include attitudinal, physical, communication and social barriers as well as mental health/ learning disabilities, cognitive impairments:

A link can be made with degenerative conditions where the person experiencing is likely to have a disability. Restricting this procedure may have an impact on this group as a result.

The patient must be able to remove the NIV mask either independently or the patient must have a waking night carer whom can remove the mask for them as required. This is a clinical safety issue, as if for example the patient coughs up secretions then if the mask cannot be removed to clear the secretions, then the secretions will be pushed back into the patient's airway which may cause the airway to occlude. Therefore this is a safety requirement to prevent harm to the patient when using the device.

However, an individual can discuss the impact with their GP and has the option for an individual funding request (IFR) request to be made.

3. Impact and Evidence:
Gender reassignment (including transgender): Describe any impact and evidence on transgender people. This can include issues such as privacy of data and harassment: No Impact identified
Marriage and civil partnership: Describe any impact and evidence in relation to marriage and civil partnership. This can include working arrangements, part-time working, and caring responsibilities: No impact identified
Pregnancy and maternity: Describe any impact and evidence on pregnancy and maternity. This can include working arrangements, part-time working, and caring responsibilities: If any of those conditions are present, then the pregnancy must be managed as the condition may worsen throughout pregnancy.
Race: Describe race related impact and evidence**.** This can include information on different ethnic groups, Roma gypsies, Irish travellers, nationalities, cultures, and language barriers: No impact identified
Religion or belief: Describe any religion, belief or no belief impact and evidence. This can include dietary needs, consent and end of life issues: No impact identified
Sex: Describe any impact and evidence on men and women. This could include access to services and employment: Depending on the diagnosis of the patient some conditions are more commonly seen in one gender over the other. For example, motor neurone disease although a rare condition is more likely to effect males than females.. Where the condition has arisen from long term lifestyle choices e.g. smoking and COPD, this could affect either gender.

3. Impact and Evidence:
Sexual orientation: Describe any impact and evidence on heterosexual people as well as lesbian, gay and bisexual people. This could include access to services and employment, attitudinal and social barriers: No impact identified
Carers: Describe any impact and evidence on part-time working, shift-patterns, general caring responsibilities: No impact identified
Other disadvantaged groups: Describe any impact and evidence on groups experiencing disadvantage and barriers to access and outcomes. This can include lower socio-economic status, resident status (migrants, asylum seekers), homeless, looked after children, single parent households, victims of domestic abuse, victims of drugs / alcohol abuse: (This list is not exhaustive) Health inequalities are present in an area of deprivation – which combines factors such as income, employment, health and education which has the greatest impact on someone's likelihood of smoking.

4. Health Inequalities	Yes/No	Evidence
Could health inequalities be created or persist by the proposals?	No	This condition could be linked to a health inequality due to the prevalence of smoking. As the procedures remains available it is not anticipated that a health inequality will be made worse.
Is there any impact for groups or communities living in particular geographical areas?	Yes	A possible link between smoking and areas of high

		deprivation has been made.
Is there any impact for groups or communities affected by unemployment, lower educational attainment, low income, or poor access to green spaces?	Yes	A possible link between the likelihood of someone smoking and unemployment, low income and education has been made. Due regard to this will need to be given in supporting such patients.
How will you ensure the proposals reduce health inequalities? The intention of the policy is to support patients with ventilatory support without using an invasive artificial airway method. For those patients where the condition has been a result of a long-term lifestyle choice, as in smoking, support should be provided to those patients through a number of interventions to help the patient stop smoking.		

5. FREDA Principles/ Human Rights	**Question**	**Response**
Fairness – Fair and equal access to services	How will this respect a person's entitlement to access this service?	Yes, this decision has been made in line with clinical recommendation and NICE guidance.
Respect – right to have private and family life respected	How will the person's right to respect for private and family life, confidentiality and consent be upheld?	No evidence of impact from this policy
Equality – right not to be discriminated against based on your protected characteristics	How will this process ensure that people are not discriminated against and have their needs met and identified?	No discrimination identified
	How will this affect a person's right to freedom	N/A

	of thought, conscience and religion?	
Dignity – the right not to be treated in a degrading way	How will you ensure that individuals are not being treated in an inhuman or degrading way?	Policy will be applied with due regard to this consideration.
Autonomy – right to respect for private & family life; being able to make informed decisions and choices	How will individuals have the opportunity to be involved in discussions and decisions about their own healthcare?	An individual can discuss the impact with their GP and has the option for an IFR request to be made
Right to **Life**	Will or could it affect someone's right to life? How?	No evidence of impact from this policy
Right to **Liberty**	Will or could someone be deprived of their liberty? How?	No evidence of impact from this policy

6. Social Value	
Consider how you might use the opportunity to improve health and reduce health inequalities and so achieve wider public benefits, through action on the social determinants of health.	
Marmot Policy Objective	**What actions are you able to build into the procurement activity and/or contract to achieve wider public benefits?**
Enable all people to have control over their lives and maximise their capabilities	
Create fair employment and good work for all	
Create and develop health and sustainable places and communities	
Strengthen the role and impact of ill-health prevention	

7. Engagement, Involvement and Consultation		
If relevant, please state what engagement activity has been undertaken and the date and with which protected groups:		
Engagement Activity	**Protected Characteristic/ Group/ Community**	**Date**
For each engagement activity, please state the key feedback and how this will shape policy / service decisions (E.g. patient told us …. So we will …..):		

As part of the process further targeted engagement is planned with representative groups from among Sandwell, Birmingham and Solihull Patients. In addition, it has been identified that patient and clinician information is key in ensuring that the harmonised treatment policies review delivers effective outcomes. To this end an information briefing sheets on each procedure will be developed to give more information on the procedure, eligibility criteria and signposting to further information sources, such as NHS Choices. These information sheets are also designed to help facilitate discussions between GPs and patients. Information briefing sheets have already been tested and uploaded onto the GP systems for the first 45 harmonised treatment policies for Birmingham and Solihull. Due regard will be given to both the accessible information standard and the potential need to translate such leaflets into relevant local languages.

The engagement team used every possible route throughout the engagement period to encourage people to feedback on the proposed policy. Unfortunately, despite the wide communication undertaken through all communication and engagement channels available, 49 questionnaires were completed online and there was no interest from stakeholders, patients and the public to attend any of the five stakeholder events arranged. As a result, the events were cancelled, and the engagement team looked at other routes to encourage engagement with patients directly. A possible reason for the general lack of interest and feedback from stakeholders, patients and the public is most likely because this clinical treatments policy either widening the scope of the current service provision, providing policies to protect the current service provision or the intervention is for somewhat rare conditions.

Also, in phase 3 of the harmonisation of policies programme clinicians had been integral to the development of the policies from the beginning of the process. It could therefore be argued the proposed policy shared for public engagement was to some extent already informed from a local patient experience and outcomes perspective.

On behalf of Birmingham and Solihull CCG and Sandwell and West Birmingham CCG, a letter was sent by a specialist respiratory ventilation physiotherapist based at one of the acute NHS providers, inviting 20 patients using domiciliary NIV / CPAP to attend a meeting at the hospital to feedback on the non-invasive ventilation policies. Patients who were unable to attend due to travel difficulties were invited to inform the CCG so that transport could be provided for them. Two people followed up the invitation by telephone to find out more about the meeting, however they decided they would prefer not to attend. One person was calling on behalf of her father and explained that although he would not be able to attend, she would go through the information with him available online. A further telephone meeting was offered, should her father wish to feedback verbally. The other person calling, completed the questionnaire over the telephone with the engagement officer.

The actual meeting on Friday 4 October was attended by a patient with muscular dystrophy and her daughter (also the patient's full-time carer). The patient used non-invasive ventilation to help with her condition during the day and night.

The patient and carer told the interviewer that they strongly agreed with the policy for non-invasive ventilation for neuromuscular patients. This was because they felt the implementation of the policy would help GPs to refer patients for the correct treatment

promptly. The patient and carer felt the policy would raise awareness of the respiratory conditions associated with muscular dystrophy and provide guidance on when to refer patients into a specialist respiratory service.

As there is currently no policy available, the potential impact on patients is therefore minimal as the treatment will offered based on criteria. Of the 27 of the 49 people who provided responses to this policy, only 6 had actually received this treatment and their responses were mixed. There was a general agreement that people with respiratory issues should receive this treatment to improve their quality of life.

8. Summary of Analysis

Considering the evidence and engagement activity you listed above, please summarise the impact of your work:

The restriction of this policy will have an impact on those who would wish to receive the treatments, this must be balanced against the need to adhere to NICE guidelines and the clinical effectiveness evidence. The opportunity for any exceptional cases to be considered via IFR remains and will ensure treatment is available in an exceptional case where the CCG support the IFR.

9. Mitigations and Changes :

Please give an outline of what you are going to do, based on the gaps, challenges and opportunities you have identified in the summary of analysis section. This might include action(s) to mitigate against any actual or potential adverse impacts, reduce health inequalities, or promote social value. Identify the **recommendations** and any **changes** to the proposal arising from the equality analysis.

Consideration will need to be given to what additional support patients from a low socio economic background will require and how due regard can be given to reasonable adjustments in approach for disabled persons.

10. Contract Monitoring and Key Performance Indicators

Detail how and when the service will be monitored and what key equality performance indicators or reporting requirements will be included within the contract (refer to NHS Standard Contract SC12 and 13):

This policy is not linked to a contract however, prospective providers remain bound by their contracts with the CCG.

11. Procurement
Detail the key equality, health inequalities, human rights, and social value criteria that will be included as part of the procurement activity (to evaluate the providers ability to deliver the service in line with these areas):
N/A

12. Publication
How will you share the findings of the Equality Analysis? This can include: reports into committee or Governing Body, feedback to stakeholders including patients and the public, publication on the web pages. All Equality Analysis should be recommended for publication unless they are deemed to contain sensitive information.
Published on CCG website
Following approval all finalised Equality Analysis should be sent to the Communications and Engagement team for publication: bsol.comms@nhs.net

13. Sign Off		
The Equality Analysis will need to go through a process of **quality assurance** by the Senior Manager for Equality Diversity and Inclusion or the Manager for Equality Diversity and Inclusion prior to approval from the delegated committee		
	Name	**Date**
Quality Assured By:		
Which Committee will be considering the findings and signing off the EA?		
Minute number (to be inserted following presentation to committee)		

Please send to Balvinder Everitt or Michelle Dunne, Equality, Diversity and Inclusion for Quality Assurance.

Once you have committee sign off, please send to Caroline Higgs, Communications & Engagement Team for publication: bsol.comms@nhs.net

Equality Analysis

(Health Inequalities, Human Rights, Social Value)

Policy for Subacromial Pain in Adults.

Before completing this equality analysis it is recommended that you:

- ✓ Contact your equality and diversity lead for advice and support
- ✓ Take time to read the accompanying policy and guidance document on how to complete an equality analysis

1. Background			
EA Title	Policy for Subacromial Pain in Adults.		
EA Author	David King	**Team**	Equality and Diversity Team
Date Started	13/08/2019	**Date Completed**	4/12/2019
EA Version	4	**Reviewed by E&D**	
What are the intended outcomes of this work? Include outline of objectives and function aims			

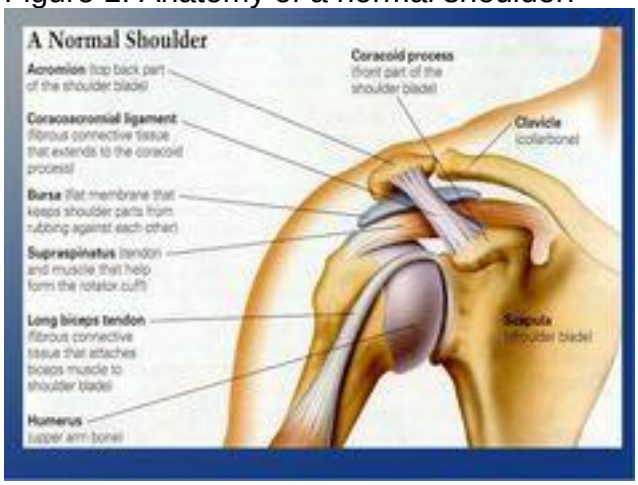
Sub-acromial Pain in Adults

Rotator cuff disease (wear and tear of the rotator cuff tendons) is thought to be a continuum ranging from shoulder impingement syndrome (SIS) through to partial and then full thickness rotator cuff tears [1]. It is one of the most common causes of non-traumatic shoulder pain which presents in primary care and is a normal part of aging [2].

The rotator cuff tendons hold the shoulder joint in place and allow people to lift the arm and reach overhead. When the arm is lifted, the rotator cuff tendon passes through a narrow space at the top of the shoulder, known as the sub-acromial space. The illustration of a healthy shoulder joint below (Figure 1) shows the relationship of tendons, ligaments, soft tissue and bony anatomy of the sub-acromial space.

Arthroscopic sub-acromial decompression is a surgical procedure that involves decompressing the sub-acromial space by removing bone spurs and soft tissue arthroscopically.

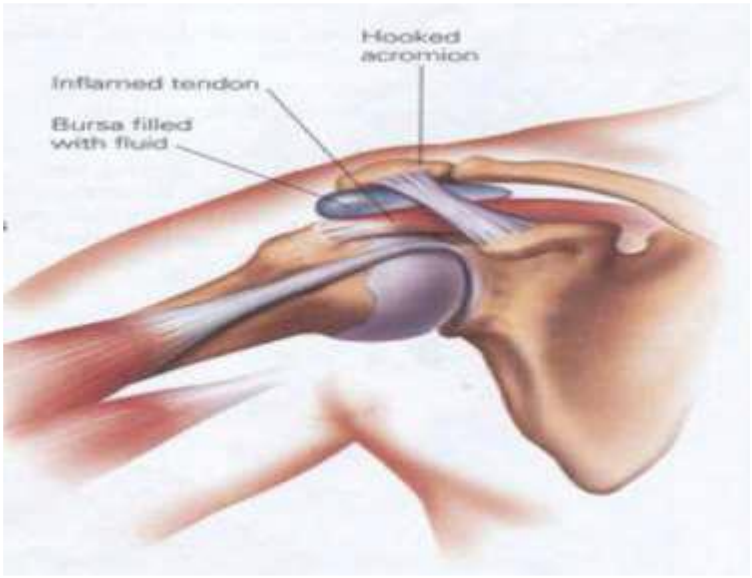
Figure 1: Anatomy of a normal shoulder.



Source: Orthopaedic Surgeons of Long Island Association.
Retrieved from http://www.orthomd.com/procedures/impingement_syndrome.html

Previously it was thought that sub acromial pain occurs when the top of the tendon rubs or catches on the acromion and the sub-acromial bursa, however more recent studies have shown that between 76-91% of rotator cuff tears occur within the tendon or on the 'under-side' of the tendon. There has been shown to be poor correlation between acromial shape and pain. Furthermore, rotator cuff tears can continue to develop post sub-acromial decompression. To this end subacromial decompression surgery is no longer recommended routinely in any clinical circumstances.

Figure 2: Anatomy of a shoulder affected by shoulder impingement syndrome



The main problem in shoulder impingement syndrome is of pain in the top and outer side of the shoulder, which is worse when the arm is raised overhead [1]. Pain is associated with dysfunction, affecting usual activities of daily living, sporting activities and ability to work full time. Patients often report a significant reduction in terms of health-related quality of life [3].

Shoulder impingement will often improve in a few weeks or months, especially with prescribed shoulder exercises.

Arthroscopic Sub-acromial Decompression.

The term 'arthroscopic' describes any surgical procedure which is performed using surgical instruments inserted through a small 'keyhole' incision and an endoscope inserted via a separate incision to visualise the area.

Arthroscopic shoulder surgery is not one single surgical procedure; rather it refers to a wide range of procedures to different parts of the shoulder anatomy. These may repair damaged cartilage or torn tendons, remove loose fragments of bone or cartilage, drain excess fluid, or release adhesions.

Arthroscopic sub-acromial decompression (ASD) is the most common surgical procedure in patients with shoulder impingement syndrome (SIS) [3]. The standard procedure is antero-inferior acromioplasty, i.e. the resection of bone spurs under the

lateral third of the acromion, as well as the excision of the coracoacromial ligament and the sub-acromial bursa. If a partial or small full-thickness tear of the rotator cuff is present, it may be mildly debrided or left alone [3].

Evidence Review

Shoulder Impingement Syndrome

Three randomised controlled trials were identified and reviewed, which compared ASD to conservative treatment for patients with SIS (at 24 months in two of the trials and 12 months only in the CSAW RCT). Patients with partial thickness rotator cuff tears were not excluded from these RCTs. The key differences between the study design were that Ketola et al [7] compared ASD plus physiotherapy to physiotherapy alone [7], whereas in the FIMPACT [6] and CSAW [4] RCTs, there were three treatment arms. Both FIMPACT and CSAW included ASD plus physiotherapy and diagnostic arthroscopy plus physiotherapy as two of the three arms. However, in the UK based multicentre RCT known as CSAW, the third arm was no treatment at all, whereas in the FIMPACT RCT, the non-operative third arm was a home exercise regime as well as 15 hysiotherapy visits.

ASD plus physiotherapy versus diagnostic arthroscopy plus physiotherapy. There was no clinically significant difference between ASD plus physiotherapy treatment compared to diagnostic (sham) arthroscopy plus physiotherapy at either 12-month follow-up in the CSAW RCT [4] or at 24 months (FIMPACT RCT) [6]. This was consistent for all of the outcomes measured: OSS, Constant score, pain, depression and anxiety, quality of life, simple shoulder test,15D and patient satisfaction.

ASD plus physiotherapy versus no treatment: Although small statistical differences were seen in favour of ASD followed by up to four sessions of physiotherapy, there were no clinically important differences for any outcomes measured at 12 months compared to no treatment at all [4].

ASD plus physiotherapy versus physiotherapy therapy only: There were no clinically important differences reported between these two treatment groups at 24-month follow-up [6,7] even though the physiotherapy protocol for the FIMPACT RCT was for 15 sessions (compared to just one post-operative session for those being treated with ASD). Both the ASD plus PT and PT only groups in the RCT by Ketola et al [7] had a similar number of physiotherapy sessions (6 and 7 sessions respectively). Within each treatment group, all three trials showed clinically significant improvements at 12 or 24 months, when compared to baseline for the OSS, the Constant score and for pain [4,6,7].

These RCTs showed that ASD for SIS was no more effective than physiotherapy alone or no treatment at achieving clinically important differences at 12 months and 24 months (OSS, Constant Score and pain). In addition, all three treatment groups

achieved clinically important improvements over time compared to baseline. This suggests that the natural history of non-traumatic shoulder impingement syndrome, which has previously failed conservative treatment, is for the painful and disabling symptoms to resolve without intervention.

Supraspinatus Tear

There was one single RCT where 180 patients with a supraspinatus tear were treated with arthroscopic acromioplasty and physiotherapy, or tendon repair, acromioplasty and physiotherapy and the outcomes were compared to patients who had 10 sessions of physiotherapy alone. All the patients followed the same physiotherapy plan. There were no between group differences in the Constant score at 12 months. Although the ASD was performed concomitantly with repair of the supraspinatus tendon, the results are consistent with the results of the RCTs which assessed the effectiveness of ASD for the management of shoulder impingement syndrome.

Cost Effectiveness

No studies generalisable to the NHS were found which measured the cost effectiveness of ASD compared to conservative treatment in patients with subacromial shoulder pain.

Who will be affected by this work? e.g. staff, patients, service users, partner organisations etc.

Patients who would wish to access this approach**.**

Eligibility Criteria

Due to the lack of evidence for the clinical effectiveness of arthroscopic shoulder decompression (ASD) compared to conservative treatment, ASD patients with sub-acromial pain is not routinely commissioned.

N.B. **Acute Severe Shoulder Pain**

- Any shoulder ‘red flags’ identified during primary care assessment need urgent secondary care referral. A suspected infected joint needs same day emergency referral.
- An unreduced dislocation needs same day emergency referral.
- Suspected tumour and malignancy will need urgent referral following the local 2-week cancer referral pathway.
- An acute cuff tear as a result of a traumatic event needs urgent referral and ideally should be seen in the next available outpatient clinic.

- Acute calcific tendinopathy is not a red flag, it is severely painful, often mimicking malignant pain and usually necessitates an early secondary care referral for more interventional treatment.
- It should also be noted that patients with subacromial shoulder pain in which the symptoms and signs suggest a more systemic inflammatory joint disease, should be considered as a 'rheumatological red flag'.
- Any new inflammatory oligo or polyarthritis, with symptoms of inflammation in several joints, should be referred urgently (following local rheumatology referral pathways) because time is of the essence with these diseases and a prompt diagnosis with early commencement of disease modifying drugs where appropriate is essential.

This means the CCG will **only** fund the treatment if an Individual Funding Request (IFR) application proves exceptional clinical need and that is supported by the CCG.

Activity data:

Number of procedures	BSOL	Sandwell
	217	90

Number of procedures undertaken overall and by CCG

Due to limited data collection by the providers service activity data is available by headcount only not protected characteristic.
The Joint Strategic Needs Assessments for Birmingham, Solihull and Sandwell are available via the links below.

Sandwell

Birmingham

Solihull

2. Research

What evidence have you identified and considered? This can include national research, surveys, reports, NICE guidelines, focus groups, pilot activity evaluations, clinical experts or working groups, JSNA or other equality analyses.

Research/Publications	**Working Groups**	**Clinical Experts**

Guidance

1. NHS choices. Shoulder Pain. https://www.nhs.uk/conditions/shoulder-pain/
2. Artus M, Holt T and Rees J. The painful shoulder: an update on assessment, treatment, and referral. British Journal of General Practice. 2014;64(626), e593-e595.
3. Chipchase LS, O'Connor DA, Costi JJ, Krishnan J (2000) Shoulder impingement syndrome: preoperative health status. J Shoulder Elbow Surg 9:12–15
4. Beard DJ, Rees JL, Cook JA CSAW Study Group et al. Arthroscopic subacromial decompression for subacromial shoulder pain (CSAW): a multicentre, pragmatic, parallel group, placebo-controlled, three-group, randomised surgical trial. Lancet 2018;391:329-38.
5. Linsell L, Dawson J, Zondervan K, Rose P, Randall T, Fitzpatrick R, Carr A. Prevalence and incidence of adults consulting for shoulder conditions in UK primary care; patterns of diagnosis and referral. Rheumatology (Oxford). 2006;45(2):215-21.
6. Paavola M, Malmivaara A, Taimela S et al. Subacromial decompression versus diagnostic arthroscopy for shoulder impingement: randomised, placebo surgery controlled clinical trial. BMJ 2018;362:k2860
7. Ketola S, Lehtinen J, Arnala I, et al. Does arthroscopic acromioplasty provide any additional value in the treatment of shoulder impingement syndrome? a two-year randomised controlled trial. J Bone Joint Surg Br 2009;91:1326-34
8. Ketola S, Lehtinen J, Rousi T et al. Which patients do not recover from shoulder impingement syndrome, either with operative treatment or with non-operative treatment? Subgroup analysis involving 140 patients at 2 and 5 years in a randomised study. Acta Orthop 2015;86:641-46
9. Ketola S, Lehtinen J, Elo P et al. No difference in long-term development of rotator cuff rupture and muscle volumes in impingement patients with or without decompression. Acta Orthop 2016;87(4):351-55
10. Ketola S, Lehtinen J, Arnala I. Arthroscopic decompression not recommended in the treatment of rotator cuff tendinpathy. Bone Joint J 2017;99-B:799-805
11. Kukkonen J, Joukainen A, Lehtinen J et al. Treatment of non-traumatic rotator cuff tears. Bone Joint J 2014;96-B:75-81
12. Longo UG, Vasta S, Maffulli N, Denaro V. Scoring systems for the functional assessment of patients with rotator cuff pathology Sports Med Arthrosc Rev. 2011;19(3):310-20.doi: 10.1097/JSA.0b013e31820af9b6.
13. Christiansen DH1, Frost P, Falla D, Haahr JP, Frich LH, Svendsen SW. Responsiveness and Minimal Clinically Important Change: A Comparison Between Shoulder Outcome Measures. J Orthop Sports Phys Ther. 2015 Aug;45(8):620-5.
14. Constant CR, Murley AH. A clinical method of functional assessment of the shoulder. Clin Orthop Relat Res 1987;214:160–164

15. Mathieson S, LinC. PainDETECT Questionnaire Clinimetrics. Journal of Physiotherapy 2013 Vol. 59
16. Stern AF. Questionnaire Review: The Hospitals Anxiety and Depression Score. Occupational Medicine 2014;64:393–394
17. EuroQol Research Foundation 2018. EQ-5D Instruments. https://euroqol.org/eq-5d-instruments/. Accessed 19.11.2018
18. National Clinical Coding Standards OPCS-4 (2017) - NHS Digitalhttps://hscic.kahootz.com/gf2.ti/f/762498/27837541.1/.../-/NCCSOPCS42017.pdf
19. McCormack HM, Horne DJ, Sheather S. Clinical applications of visual analogue scales: a critical review. Psychol Med 1988;18:1007–1019
20. Beard D, Rees J, Rombach I et al. The CSAW Study (Can Shoulder Arthroscopy Work?)—a placebo-controlled surgical intervention trial assessing the clinical and cost effectiveness of arthroscopic subacromial decompression for shoulder pain: study protocol for a randomised controlled trial.Trials. 2015; 16: 210
21. Kukkonen J, Kauko T, Vahlberg T et al Investigating minimal clinically important difference for Constant score in patients undergoing rotator cuff surgery. J Shoulder Elbow Surg 2013;22:1650–1655
22. Salaffi F, Stancati A, Silvestri CA et al. Minimal clinically important changes in chronic musculoskeletal pain intensity measured on a numerical rating scale. Eur JPain 2004;8:283-91
23. Beard DJ, Carr AJ, Cook JA et al. Can Shoulder Arthroscopy Work? (CSAW) trial –Authors' reply. Lancet. July 28, 2018.
24. Kulkarnhi, R. et al. 2015) Sub-acromial Shoulder pain: BESS/BOA Patient Care Pathways.http://www.bess.org.uk/media/Research%20Committee/National%20Guidelines/Subacromial%20Shoulder%20Pain.pdf
25. NHS. Shoulder impingement. https://www.nhs.uk/conditions/shoulder-impingement-syndrome/

3. Impact and Evidence:

In the following boxes detail the findings and impact identified (positive or negative) within the research detailed above; this should also include any identified health inequalities which exist in relation to this work.

Age: Describe age related impact and evidence. This can include safeguarding, consent and welfare issues:

Age range data is not available for the profile of patients requesting the procedure. Some link may be identified between older patients and increased instances of joint pain, particularly in relation to Osteoarthritis.

As the treatment has been not routinely commissioned, those who meet the criteria will be able to access treatment, who are the group who are deemed to benefit most. It is expected that patients not eligible would receive more suitable alternative treatment.

3. Impact and Evidence:
Disability: Describe disability related impact and evidence. This can include attitudinal, physical, communication and social barriers as well as mental health/ learning disabilities, cognitive impairments:
As with age pain is itself a life limiting condition and is commonly found as a co morbidity with other conditions. It has not been shown that restricting this treatment will impact on this group negatively since the treatment has not been shown to offer significant benefit. The CCG recognises its obligations to meet the needs of disabled people. The overall intention for this policy since it is NRC is for conservative management to be offered to all patients, but due regard will be given to the CCG's obligations to disabled people.
Gender reassignment (including transgender): Describe any impact and evidence on transgender people. This can include issues such as privacy of data and harassment:
No impact identified
Marriage and civil partnership: Describe any impact and evidence in relation to marriage and civil partnership. This can include working arrangements, part-time working, and caring responsibilities:
No impact identified
Pregnancy and maternity: Describe any impact and evidence on pregnancy and maternity. This can include working arrangements, part-time working, and caring responsibilities:
No impact identified on the basis of available data.
Race: Describe race related impact and evidence**.** This can include information on different ethnic groups, Roma gypsies, Irish travellers, nationalities, cultures, and language barriers:
No impact identified
Religion or belief: Describe any religion, belief or no belief impact and evidence. This can include dietary needs, consent and end of life issues:
No impact identified
Sex: Describe any impact and evidence on men and women. This could include access to services and employment:
No impact identified
Sexual orientation: Describe any impact and evidence on heterosexual people as well as lesbian, gay and bisexual people. This could include access to services and employment, attitudinal and social barriers:
No impact identified
Carers: Describe any impact and evidence on part-time working, shift-patterns, general caring responsibilities:

3. Impact and Evidence:
No impact identified
Other disadvantaged groups: Describe any impact and evidence on groups experiencing disadvantage and barriers to access and outcomes. This can include lower socio-economic status, resident status (migrants, asylum seekers), homeless, looked after children, single parent households, victims of domestic abuse, victims of drugs / alcohol abuse: (This list is not exhaustive)
No impact identified

4. Health Inequalities	Yes/No	Evidence
Could health inequalities be created or persist by the proposals?	No	This condition is not linked to any identified health inequality
Is there any impact for groups or communities living in particular geographical areas?	No	No impact identified
Is there any impact for groups or communities affected by unemployment, lower educational attainment, low income, or poor access to green spaces?	No	No impact identified
How will you ensure the proposals reduce health inequalities?		
This condition is not linked to any identified health inequality		

5. FREDA Principles/ Human Rights	Question	Response
Fairness – Fair and equal access to services	How will this respect a person's entitlement to access this service?	Yes, this decision has been made in line with clinical recommendation
Respect – right to have private and family life respected	How will the person's right to respect for private and family life, confidentiality and consent be upheld?	No evidence of impact for this policy
Equality – right not to be discriminated against based on your protected characteristics	How will this process ensure that people are not discriminated against and have their needs met and identified?	No discrimination identified
	How will this affect a person's right to freedom of thought, conscience and religion?	N/A
Dignity – the right not to be treated in a degrading way	How will you ensure that individuals are not being	Policy will be applied with due regard to this consideration.

	treated in an inhuman or degrading way?	
Autonomy – right to respect for private & family life; being able to make informed decisions and choices	How will individuals have the opportunity to be involved in discussions and decisions about their own healthcare?	An individual can discuss the impact with their GP and has the option for an IFR request to be made
Right to **Life**	Will or could it affect someone's right to life? How?	No evidence of impact for this policy
Right to **Liberty**	Will or could someone be deprived of their liberty? How?	No evidence of impact for this policy

6. Social Value

Consider how you might use the opportunity to improve health and reduce health inequalities and so achieve wider public benefits, through action on the social determinants of health.

Marmot Policy Objective	**What actions are you able to build into the procurement activity and/or contract to achieve wider public benefits?**
Enable all people to have control over their lives and maximise their capabilities	None
Create fair employment and good work for all	None
Create and develop health and sustainable places and communities	None
Strengthen the role and impact of ill-health prevention	None

7. Engagement, Involvement and Consultation

If relevant, please state what engagement activity has been undertaken and the date and with which protected groups:

Engagement Activity	**Protected Characteristic/ Group/ Community**	**Date**

For each engagement activity, please state the key feedback and how this will shape policy / service decisions (E.g. patient told us …. So we will …):

As part of the process further targeted engagement is planned with representative groups from among Birmingham and Solihull Patients. In addition, it has been identified that patient and clinician information is key in ensuring that the harmonised treatment policies review delivers effective outcomes. To this end an information briefing sheets on each procedure will be developed to give more information on the procedure, eligibility criteria and signposting to further information sources, such as NHS Choices. These information sheets are also designed to help facilitate discussions between GPs and patients. Information briefing sheets have already been tested and uploaded onto the GP systems for the first 45 harmonised treatment policies for Birmingham and Solihull. Due regard will

be given to both the accessible information standard and the potential need to translate such leaflets into relevant local languages.

The engagement team used every possible route throughout the engagement period to encourage people to feedback on the proposed policy. Unfortunately, despite the wide communication undertaken through all communication and engagement channels available, 49 questionnaires were completed online and there was no interest from stakeholders, patients and the public to attend any of the five stakeholder events arranged. As a result, the events were cancelled, and the engagement team looked at other routes to encourage engagement with patients directly. A possible reason for the general lack of interest and feedback from stakeholders, patients and the public is most likely because this clinical treatments policy either widening the scope of the current service provision, providing policies to protect the current service provision or the intervention is for somewhat rare conditions.

Also, in phase 3 of the harmonisation of policies programme clinicians had been integral to the development of the policies from the beginning of the process. It could therefore be argued the proposed policy shared for public engagement was to some extent already informed from a local patient experience and outcomes perspective.

The potential impact on patients was therefore minimal as the treatment is offered based on specific criteria. Feedback suggested that the decision should to offer this treatment is between the doctor and patient, based on individual circumstances and needs.

8. Summary of Analysis

Considering the evidence and engagement activity you listed above, please summarise the impact of your work:

The restriction of surgery or conservative management will have limited impact on those who would wish to receive the treatments, this must be balanced against the need to adhere to clinical effectiveness evidence. The opportunity for any exceptional cases to be considered via IFR remains and will ensure treatment is available in an exceptional case.

9. Mitigations and Changes

Please give an outline of what you are going to do, based on the gaps, challenges and opportunities you have identified in the summary of analysis section. This might include action(s) to mitigate against any actual or potential adverse impacts, reduce health inequalities, or promote social value. Identify the **recommendations** and any **changes** to the proposal arising from the equality analysis.

The CCG will need to review the impact on disabled patients of the operation of this policy and whether further exploration of suitable treatments is required.

10. Contract Monitoring and Key Performance Indicators

Detail how and when the service will be monitored and what key equality performance indicators or reporting requirements will be included within the contract (refer to NHS Standard Contract SC12 and 13):

This policy is not linked to a contract however, prospective providers remain bound by their contracts with the CCG.

11. Procurement

Detail the key equality, health inequalities, human rights, and social value criteria that will be included as part of the procurement activity (to evaluate the providers ability to deliver the service in line with these areas):
N/A

12. Publication

How will you share the findings of the Equality Analysis? This can include: reports into committee or Governing Body, feedback to stakeholders including patients and the public, publication on the web pages. All Equality Analysis should be recommended for publication unless they are deemed to contain sensitive information.
Publication on the CCG's website.
Following approval all finalised Equality Analysis should be sent to the Communications and Engagement team for publication: bsol.comms@nhs.net

13. Sign Off

The Equality Analysis will need to go through a process of **quality assurance** by the Senior Manager for Equality and Diversity, Senior Manager for Assurance and Compliance or Equality and Human Rights Manager **and** signed-off by a delegated committee

	Name	Date
Quality Assured By:		
Which Committee will be considering the findings and signing off the EA?		
Minute number (to be inserted following presentation to committee)		

Please send to Balvinder Everitt or Michelle Dunne, Equality, Diversity and Inclusion for Quality Assurance.

Once you have committee sign off, please send to Caroline Higgs, Communications & Engagement Team for publication: bsol.comms@nhs.net

Equality Analysis

(Health Inequalities, Human Rights, Social Value)

Image Guided High Volume Intra-Articular Injections

Before completing this equality analysis it is recommended that you:

- ✓ Contact your equality and diversity lead for advice and support
- ✓ Take time to read the accompanying policy and guidance document on how to complete an equality analysis

NHS Birmingham and Solihull Clinical Commissioning Group
NHS Sandwell and West Birmingham Clinical Commissioning Group

1. Background

EA Title	Image Guided High Volume Intra-Articular Injections		
EA Author	David King	**Team**	Equality and Diversity
Date Started	13/08/2019	**Date Completed**	4/12/2019
EA Version	4	**Reviewed by E&D**	

What are the intended outcomes of this work? Include outline of objectives and function aims

Joint Pain
Pain in the joints affects millions of people worldwide. The causes of joint pain are numerous. Joint pain can be related to osteoarthritis or inflammatory joint disorders such as rheumatoid arthritis and psoriatic arthritis. Joint pain can also be as a result of traumatic injury, joint surgery or crystal deposition in the joints such as gout or chondrocalcinosis. Other causes of joint pain include sports injuries, general sprains and strains, frozen or unstable shoulder, and bleeding into joint spaces caused by torn ligaments.

Depending on the individual, pain might be felt in the joint or in the muscles around the joint. Depending on the cause the pain may be diffuse and constant, occurring at rest or while moving. Despite the wide range of underlying conditions and symptoms, joint pain of different aetiology may share similar mechanisms, manifestations, and potential treatments.

Image Guided High Volume Intra-Articular Injections
Treatment of joint pain consists of both pharmacologic and non-pharmacologic modalities. First-line therapy generally includes analgesia and physiotherapy. If these fail, intraarticular steroid injection may be considered.

Hydrodilatation (HD) also known as arthrographic capsular distension or distension arthrography is a procedure where a high volume injection of saline solution and/or steroids or air is given into the joint usually into the glenohumeral (shoulder) joint. HD is generally carried out with a mixture of contrast medium, long acting anaesthetics, steroids, saline or air. However, because of the inherent compressibility of air, the procedure is more difficult than when saline is used. Dependent upon the contracted state of the joint capsule, HD usually occurs with an injection of between 10ml and 55ml of normal saline.

The procedure is performed under imaging guidance, using fluoroscopy, ultrasound or Computed Tomography (CT). HD is felt to provide benefit via two mechanisms: manual stretching of the capsule and thus disruption of adhesions that might be limiting the movements of the glenohumeral joint and causing pain and disability which are characteristic of adhesive capsulitis; and the introduction of cortisone, which provides a potent anti-inflammatory effect and thus prevents further recurrence of adhesion. The risk of complications is thought to be low.

1. Background

Clinical Evidence Review

From the evidence reviewed, there is no clear benefit of treatment for joint pain with an image-guided high volume intra-articular injection.

Evidence from two systematic reviews of Randomised Controlled Trials (RCTS) comparing hydrodilatation with corticosteroids, and corticosteroid injection only, is conflicting. The systematic review (with meta-analysis) by Saltychev et al (2018) reported that hydrodilatation with corticosteroids has only a small, clinically insignificant effect for pain and Range Of Movement (ROM) (seven RCTs) when treating adhesive capsulitis. Conversely, Catapano et al (2018) reported that the intervention is likely to be effective. However, this conclusion was based on the results from two of five RCTs and three of five RCTs which reported improvements in pain scores and range of movement respectively. The evidence is therefore at best inconsistent. No long term results were reported. Both authors report that the included RCTs were of moderate quality.

Evidence from one small RCT suggests that arthrographic capsular release is associated with a higher Oxford Shoulder Score (OSS) than hydrodilatation at six months follow-up. It is not known for how long this effect is likely to be sustained (Gallacher 2018). In addition, the study may not have been sufficiently powered to show any meaningful differences. The pain scores were reported by the patients who were not blinded to their treatment, this could have introduced bias. It is also unclear whether the ROM assessors were blinded to the treatments.

Who will be affected by this work? e.g. staff, patients, service users, partner organisations etc.

Eligibility Criteria:

Due to the limited quality of evidence of clinical and cost effectiveness for image-guided high volume intra-articular injections compared to alternative treatment options, this intervention is Not Routinely Commissioned.

This means the CCG will **only** fund the treatment if an Individual Funding Request (IFR) application proves exceptional clinical need and that is supported by the CCG.

Number of procedures undertaken overall and by CCG – data not available.

	BSOL	Sandwell
	Activity data on this procedure is not available from the providers	

1. Background

Due to limited data collection by the providers information on the protected characteristics of patients who have received the procedure is not available and is thus shown as patient headcount only.

Population data for the Birmingham Solihull and Sandwell and West Birmingham areas can be found via the following links.

2. Research

What evidence have you identified and considered? This can include national research, surveys, reports, NICE guidelines, focus groups, pilot activity evaluations, clinical experts or working groups, JSNA or other equality analyses.

Research/Publications	Working Groups	Clinical Experts
Guidance 1. International Association for the Study of Pain (IASP). Treating people with joint pain. Global year against pain in the joint 2016; Fact sheet no 1. https://s3.amazonaws.com/rdcmsiasp/ files/production/public/Content/ContentFolders/GlobalYearAgainstPain2/2016/FactSheets/English/1.%20Patients%20and%20Joint%20Pain.pdf Last accessed 15 October 2018 2. NHS Choices [online] https://www.nhs.uk/conditions/joint-pain/ Last accessed 15 October 2018 3. Gallacher S, Beazley JC et al. A randomized controlled trial of arthroscopic capsular release versus hydrodilatation in the treatment of primary frozen shoulder. Journal of Shoulder & Elbow Surgery. 2018 Aug; 27(8):1401-6. 4. Neogi T. Joint pain epidemiology. Global year against pain in the joint 2016; Fact sheet no 11. https://s3.amazonaws.com/rdcmsiasp/files/production/public/Content/ContentFolders/GlobalYearAgainstPain2/2016/FactSheets/English/11.%20Joint%20Pain%20Epidemiology.pdf Last accessed 15 October 2018 5. Duncan R, Francis RM et al. Prevalence of arthritis and joint pain in the oldest old: findings from the Newcastle 85+ Study. Age and Aging 2011; 40(6):752-5. 6. Georgiannos D, Markopoulos G et al. Adhesive Capsulitis of the Shoulder. Is there Consensus Regarding the Treatment? A		

2. Research

Comprehensive Review. The open orthopaedics journal. [Review]. 2017; 11:65-76. 7. Buchbinder R, Green S et al. Arthrographic distension for adhesive capsulitis (frozen shoulder). Cochrane Database of Systematic Reviews 2008, Issue 1. Art. No.: CD007005. 8. Saltychev M, Laimi K et al. Effectiveness of Hydrodilatation in Adhesive Capsulitis of Shoulder: A Systematic Review and Meta-Analysis. Scandinavian Journal of Surgery: SJS. 2018:1457496918772367. 9. Catapano M, Mittal N et al. Hydrodilatation with Corticosteroid for the Treatment of Adhesive Capsulitis: A Systematic Review. Pm & R. [Review]. 2018; 10(6):623-35. 10. Maund E, Craig D et al. Management of frozen shoulder: a systematic review and cost-effectiveness analysis. Health Technology Assessment (Winchester, England). [Research Support, Non-U.S. Gov't Review]. 2012; 16(11):1-264.		

3. Impact and Evidence:

In the following boxes detail the findings and impact identified (positive or negative) within the research detailed above; this should also include any identified health inequalities which exist in relation to this work.

Age: Describe age related impact and evidence. This can include safeguarding, consent and welfare issues:

Age range data is not available for the profile of patients requesting the procedure. Some link may be identified between older patients and increased instances of joint pain, particularly in relation to arthritis.

As the treatment has not been shown to demonstrate significant benefits the impact on this group will be more around a perception of not being able to access a treatment. It is expected that patients would receive more suitable alternative treatment.

Disability: Describe disability related impact and evidence. This can include attitudinal, physical, communication and social barriers as well as mental health/ learning disabilities, cognitive impairments:

3. Impact and Evidence:

As with age pain is itself a life limiting condition and is commonly found as a co morbidity with other conditions. It has not been shown the restricting this condition will impact on this group negatively.

Gender reassignment (including transgender): Describe any impact and evidence on transgender people. This can include issues such as privacy of data and harassment:

No impact identified

Marriage and civil partnership: Describe any impact and evidence in relation to marriage and civil partnership. This can include working arrangements, part-time working, and caring responsibilities:

No impact identified

Pregnancy and maternity: Describe any impact and evidence on pregnancy and maternity. This can include working arrangements, part-time working, and caring responsibilities:

No impact identified on the basis of available data.

Race: Describe race related impact and evidence**.** This can include information on different ethnic groups, Roma gypsies, Irish travellers, nationalities, cultures, and language barriers:

No impact identified

Religion or belief: Describe any religion, belief or no belief impact and evidence. This can include dietary needs, consent and end of life issues:

No impact identified

Sex: Describe any impact and evidence on men and women. This could include access to services and employment:

No impact identified

Sexual orientation: Describe any impact and evidence on heterosexual people as well as lesbian, gay and bisexual people. This could include access to services and employment, attitudinal and social barriers:

No impact identified

Carers: Describe any impact and evidence on part-time working, shift-patterns, general caring responsibilities:

No impact identified

Other disadvantaged groups: Describe any impact and evidence on groups experiencing disadvantage and barriers to access and outcomes. This can include lower socio-economic status, resident status (migrants, asylum seekers), homeless, looked after children, single parent households, victims of domestic abuse, victims of drugs / alcohol abuse: (This list is not exhaustive)

3. Impact and Evidence:
No impact identified

4. Health Inequalities	Yes/No	Evidence
Could health inequalities be created or persist by the proposals?	No	This condition is not linked to any identified health inequality
Is there any impact for groups or communities living in particular geographical areas?	No	No impact identified
Is there any impact for groups or communities affected by unemployment, lower educational attainment, low income, or poor access to green spaces?	No	No impact identified
How will you ensure the proposals reduce health inequalities? This condition is not linked to any identified health inequality.		

5. FREDA Principles/ Human Rights	Question	Response
Fairness – Fair and equal access to services	How will this respect a person's entitlement to access this service?	Yes, this decision has been made in line with clinical recommendation
Respect – right to have private and family life respected	How will the person's right to respect for private and family life, confidentiality and consent be upheld?	No evidence of impact for this policy
Equality – right not to be discriminated against based on your protected characteristics	How will this process ensure that people are not discriminated against and have their needs met and identified?	No discrimination identified
	How will this affect a person's right to freedom of thought, conscience and religion?	N/A
Dignity – the right not to be treated in a degrading way	How will you ensure that individuals are not being treated in an inhuman or degrading way?	Policy will be applied with due regard to this consideration.
Autonomy – right to respect for private & family life; being able to make informed decisions and choices	How will individuals have the opportunity to be involved in discussions and decisions about their own healthcare?	An individual can discuss the impact with their GP and has the option for an IFR request to be made

5. FREDA Principles/ Human Rights	Question	Response
Right to **Life**	Will or could it affect someone's right to life? How?	No evidence of impact for this policy
Right to **Liberty**	Will or could someone be deprived of their liberty? How?	No evidence of impact for this policy

6. Social Value

Consider how you might use the opportunity to improve health and reduce health inequalities and so achieve wider public benefits, through action on the social determinants of health.

Marmot Policy Objective	What actions are you able to build into the procurement activity and/or contract to achieve wider public benefits?
Enable all people to have control over their lives and maximise their capabilities	None
Create fair employment and good work for all	None
Create and develop health and sustainable places and communities	None
Strengthen the role and impact of ill-health prevention	None

7. Engagement, Involvement and Consultation

If relevant, please state what engagement activity has been undertaken and the date and with which protected groups:

Engagement Activity	Protected Characteristic/ Group/ Community	Date

For each engagement activity, please state the key feedback and how this will shape policy / service decisions (E.g. patient told us …. So we will …..):

As part of the process further targeted engagement is planned with representative groups from among Birmingham and Solihull Patients and Sandwell and West Birmingham CCG. In addition, it has been identified that patient and clinician information is key in ensuring that the harmonised treatment policies review delivers effective outcomes. To this end an information briefing sheets on each procedure will be developed to give more information on the procedure, eligibility criteria and signposting to further information sources, such as NHS Choices. These information sheets are also designed to help facilitate discussions between GPs and patients. Information briefing sheets have already been tested and uploaded for the Phase 1 and Phase 2 harmonised treatment policies for Birmingham and Solihull CCG and Sandwell and West Birmingham CCG. Due regard will be given to both the accessible information standard and the potential need to translate such leaflets into relevant local languages.

7. Engagement, Involvement and Consultation

The engagement team used every possible route throughout the engagement period to encourage people to feedback on the proposed policy. Unfortunately, despite the wide communication undertaken through all communication and engagement channels available, 49 questionnaires were completed online and there was no interest from stakeholders, patients and the public to attend any of the proposed stakeholder events arranged across the footprint of Birmingham, Solihull, Sandwell and West Birmingham. As a result, the events were cancelled, and the engagement team looked at other routes to encourage engagement with patients directly. A possible reason for the general lack of interest and feedback from stakeholders, patients and the public is most likely because this clinical treatments policy either widening the scope of the current service provision, providing policies to protect the current service provision or the intervention is for somewhat rare conditions.

Also, in phase 3 of the harmonisation of policies programme clinicians had been integral to the development of the policies from the beginning of the process. It Therefore the proposed policy shared for public engagement was to some extent already informed from a local patient experience and outcomes perspective.

Feedback received form patients who have accessed this service commented that the treatment was 'highly effective'. However over 30% of the comments received refer to not enough clinical evidence in ascertaining whether they agree or disagree with the proposed change due to ongoing clinical study. It was felt until this was available, the decision to offer the treatment should be between the GP and the patient.

8. Summary of Analysis

Considering the evidence and engagement activity you listed above, please summarise the impact of your work:

The restriction of this policy will have limited impact on those who would wish to receive the treatments, this must be balanced against the need to adhere to the clinical effectiveness evidence. The opportunity for any exceptional cases to be considered via IFR remains and will ensure treatment is available in an exceptional case.

9. Mitigations and Changes :

Please give an outline of what you are going to do, based on the gaps, challenges and opportunities you have identified in the summary of analysis section. This might include action(s) to mitigate against any actual or potential adverse impacts, reduce health inequalities, or promote social value. Identify the **recommendations** and any **changes** to the proposal arising from the equality analysis.

None required

10. Contract Monitoring and Key Performance Indicators

Detail how and when the service will be monitored and what key equality performance indicators or reporting requirements will be included within the contract (refer to NHS Standard Contract SC12 and 13):
This policy is not linked to a contract however, prospective providers remain bound by their contracts with the CCG.

11. Procurement

Detail the key equality, health inequalities, human rights, and social value criteria that will be included as part of the procurement activity (to evaluate the providers ability to deliver the service in line with these areas):
N/A

12. Publication

How will you share the findings of the Equality Analysis? This can include: reports into committee or Governing Body, feedback to stakeholders including patients and the public, publication on the web pages. All Equality Analysis should be recommended for publication unless they are deemed to contain sensitive information.
Publication on the CCG's website.
Following approval all finalised Equality Analysis should be sent to the Communications and Engagement team for publication: bsol.comms@nhs.net

13. Sign Off

The Equality Analysis will need to go through a process of **quality assurance** by the Senior Manager for Equality and Diversity, Senior Manager for Assurance and Compliance or Equality and Human Rights Manager **and** signed-off by a delegated committee

	Name	**Date**
Quality Assured By:		
Which Committee will be considering the findings and signing off the EA?		

Minute number (to be inserted following presentation to committee)		

Please send to Balvinder Everitt or Michelle Dunne, Equality, Diversity and Inclusion for Quality Assurance.

Once you have committee sign off, please send to Caroline Higgs, Communications & Engagement Team for publication: bsol.comms@nhs.net

Equality Analysis

(Health Inequalities, Human Rights, Social Value)

Policy for the use of Non-Cosmetic Body Contouring Surgery

Before completing this equality analysis it is recommended that you:

- ✓ Contact your equality and diversity lead for advice and support
- ✓ Take time to read the accompanying policy and guidance document on how to complete an equality analysis

NHS Birmingham and Solihull Clinical Commissioning Group
NHS Sandwell and West Birmingham Clinical Commissioning Group

1. Background			
EA Title	Policy for the use of Non-Cosmetic Body Contouring Surgery		
EA Author	David King	**Team**	Equality and Diversity
Date Started	September 2019	**Date Completed**	4/12/2019
EA Version	4	**Reviewed by E&D**	

What are the intended outcomes of this work? Include outline of objectives and function aims

Body Contouring Surgery

The Surgical Procedures included in Body Contouring

- Full abdominoplasty

For patients who have significant skin laxity, excess fat and separation of the muscles, a classic tummy tuck is the most common procedure. Performed under general anaesthetic, this operation can require patients to be in hospital for two or three days.

During the operation, an incision is made from hip to hip and around the umbilicus. The excess skin and fat is excised from the umbilicus to just above the pubic hair. The muscles above and below the umbilicus are tightened. The skin is then sewn up to give a circular scar around the umbilicus and a long scar across the lower abdomen. Although this operation leaves a large scar, it does provide the greatest improvement in abdominal shape.

Patients who are thinking about becoming pregnant should not undergo this procedure and should wait until they are sure they are not having any more children. All the skin and fat below the umbilicus can be removed in a standard abdominoplasty. This results in a scar across the lower abdomen and a scar around the umbilicus.

- Mini abdominoplasty

For patients with only a small amount of excess skin a lesser abdominoplasty might be appropriate. A general anaesthetic is still needed.

During the operating, a wedge of skin and fat is excised from the lower tummy leaving a horizontal scar above the pubic hair. Sometimes the muscles will also be tightened. No scar is left around the umbilicus, which may be stretched slightly to become a different shape.
A mini abdominoplasty will give a smaller effect than a full abdominoplasty.

- Extended abdominoplasty

Surplus skin and fat of the loins and back are removed at the same time as the abdomen.

1. Background

- Endoscopic abdominoplasty

Tightens the muscles of the abdominal wall. Skin is not removed but liposuction can be carried out at the same time.

- Apronectomy (Panniculectomy)

An Apronectomy is a modified mini-abdominoplasty, mainly for patients who have a large excess of skin and fat hanging down over the pubic area and only the surplus skin and fat is removed. A modification to an abdominoplasty might also be necessary when the patient has problems with scars from previous operations.

A panniculus is excess adipose tissue hanging downward from the abdomen and resembles an "apron of skin" overlying the front of the pelvic girdle. A large panniculus can interfere with normal activities such as walking, and lead to serious medical problems. The heavy overhanging tissue can cause chronic skin inflammation under the flap, and subsequently, skin breakdown and infection.

The panniculus hanging below the symphysis pubis when the individual is standing normally can cause significant functional impairment and other complications such as intertrigo.

- Arm reduction and lift (Brachioplasty)

Brachioplasty, or upper arm reduction or arm lift is a surgical procedure which removes and tightens loose skin and excess fat in the upper arm. It is usually performed under a general anaesthetic. The surgeon makes a long incision between the elbow and axilla. Segments of skin and fat are removed and the remaining skin and tissue lifted resulting in a tight, smooth look.

- Buttock and/or Thigh lift (Thighplasty)

Thighplasty is aesthetic reshaping surgery with the removal of excess skin and fat. Buttock or thigh lift surgery is performed to lift the excess skin to firm and tighten the skin around the buttocks and/or thighs. Liposuction may also be performed during this procedure. Sometimes a buttock lift is combined with this procedure.

- Liposuction / Liposculpture / Suction Assisted Lipectomy

Liposuction is also known as liposculpture or suction assisted lipectomy. It is a technique most commonly performed to remove unwanted fat deposits. Liposuction can be performed on other areas of the body, including the neck, arms, tummy, loins, thighs, inner side of the knees and the ankles.

1. Background

Evidence Review

The results from the search strategy found 3 systematic reviews, 1 economic systematic review and 4 clinical trials & guidance which directly informed 'Body Contouring' in reference to the effectiveness measurable by physical, physiological, and/or qualitative patient reported outcomes.

The BAPRAS UK Commissioning Guide 2017 highlights an expert interpretation of various papers to inform NICE and clinical commissioners in the UK health care sector. All results highlighted in the evidence review are also utilised within the commissioning guide.

The 'BODY-Q' systematic review is strong evidence to support the method in measuring the effectiveness of body contouring from patient-reported outcomes (PRO. 'BODY-Q' method is the framework of the BODY-Q scales, presented below, is comprised of three overarching themes as follows: 1) Appearance; 2) Health-Related Quality of Life; and 3) Patient Experience. Under these domains, there are 18 independently functioning scales that measure important COI. In addition to the 18 scales, there is 1 obesity-specific symptom checklist.

Due to the statistically significant health improvement benefits both in relation to QoL and clinical outcomes of more than 30%, and that the evidence has demonstrated the potential of removal of excess skin to prevent both 1st and 2nd prevention of future illness such as mobility, QoL concerns, infection, lymphoedema and other illnesses, it was deemed within certain clinical circumstances that excess skin removal could be an effective surgical intervention.

Who will be affected by this work? e.g. staff, patients, service users, partner organisations etc.

Eligibility Criteria: Restricted

Removal of excess skin is commissioned in the following clinical circumstances:
The patient is 18 or over at the time of application.

AND

The patient has lost at least 50% of their original excess weight and maintained their weight for at least two years, both of which have been recorded and documented by a clinician in the patient's medical notes.

AND the patient has one of the following:

- Skin folds are causing severe functional impairment which is impacting on the patient's ability to carry out activities of daily living.

1. Background

OR

- Recurrent skin infections in the skin folds which fail to resolve, despite appropriate medical treatment for at least 6 months.

Definition

Body mass index (BMI) A measure for human body shape based on an individual's weight and height. BMI = body weight in kilograms / height in meters squared

Excess body weight Calculation of change of BMI relative to a maximum normal BMI of 25kg/m2

Massive weight loss Loss of 50% or more excess body weight

BODY-Q The Patient-Reported Outcome Instrument for Weight Loss and Body Contouring Treatments

N.B. Functional impairment is defined as preventing activities of daily living to be undertaken independently, i.e. sleeping; eating; walking.

Funding is for procedures to remove excess skin from an area of the body, which is causing functional impairment / recurrent skin infections. Procedures to aid weight loss or muscle tightening e.g. full abdominoplasty are not commissioned under this policy.

Investigations for suspected or proven malignancy are outside the scope of this policy and should be treated in line with the relevant cancer pathway.

Other procedures **which are not included** within the Body Contouring Surgery policy are:

- Breast Surgery
- Liposuction
- Cosmetic Surgery

This means **(for patients who DO NOT meet the above criteria)** the CCG will **only** fund the treatment if an Individual Funding Request (IFR) application proves exceptional clinical need and that is supported by the CCG

Number of procedures undertaken overall and by CCG

	BSOL	Sandwell
	1	0

1. Background

Due to limited data collection by the providers service activity data is available by headcount only not protected characteristic.
The Joint Strategic Needs Assessments for Birmingham, Solihull and Sandwell are available via the links below.

- Sandwell
- Birmingham
- Solihull

2. Research

What evidence have you identified and considered? This can include national research, surveys, reports, NICE guidelines, focus groups, pilot activity evaluations, clinical experts or working groups, JSNA or other equality analyses.

Research/Publications	Working Groups	Clinical Experts
Guidance [1] British Association of Plastic Reconstructive and Aesthetic Surgeons (BAPRAS), Royal College of Surgeons: UK Commissioning Guide: Massive Weight Loss Body Contouring, 2017. http://www.bapras.org.uk/docs/default-source/commissioning-and-policy/2017--draft-for-consultation--body-contouring-surgery-commissioning.pdf?sfvrsn=0 [2] Measuring Quality of Life and Patient Satisfaction After Body Contouring: A Systematic Review of Patient-Reported Outcome Measures, Patrick L. Reavey et al, Aesthetic Surgery Journal September 2011 vol. 31 no. 7 807-813 https://academic.oup.com/asj/article/31/7/807/176334 [3] Recommendations on the most suitable quality-of-life measurement instruments for bariatric and body contouring surgery: a systematic review. C.E.E. de Vries, et al. – https://www.ncbi.nlm.nih.gov/pubmed/29883059 [4] Quality of life among adults following bariatric and body contouring surgery: a systematic review. J. Gilmartin, et al. JBI Database of Systematic Reviews and Implementation Reports November 2016 vol.14 no.11 240-270 https://journals.lww.com/jbisrir/Abstract/2016/11000/Quality_of_life_among_adults_following_bariatric.16.aspx		

2. Research

[5] Diverse approaches to the health economic evaluation of bariatric surgery: a comprehensive systematic review. J.A. Campbel, et al. https://www.ncbi.nlm.nih.gov/pubmed/27383557

[6] Body image and quality of life in patients with and without body contouring surgery following bariatric surgery: a comparison of pre- and post-surgery groups. M. de Zwaan, et al - https://www.frontiersin.org/articles/10.3389/fpsyg.2014.01310/full

[7] The impact of reconstructive procedures following bariatric surgery onpatient well-being and quality of life. Van der Beek ES, et al. - https://www.ncbi.nlm.nih.gov/pubmed/19688408

[8] The BODY-Q: A Patient-Reported Outcome Instrument for Weight Loss and Body Contouring Treatments. A.F. Klassen, et al. - https://www.ncbi.nlm.nih.gov/pubmed/27200241

[9] Body-Q User Manual, Royal College of Surgeons - https://tinyurl.com/y53b9xmn

[10] Body Image and Quality of Life in Post Massive Weight Loss Body Contouring Patients. AY. Song, et al. - https://www.ncbi.nlm.nih.gov/pubmed/17030974

[11] Mukherjee,S.,Kamat,S.,Adegbola,S.,andAgrawal,S.(2014). Funding for post-bariatric body contouring (bariplastic) surgery in England: a post code lottery. Plast.Surg.Int. 2014:153194. doi:10.1155/2014/153194 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3980931/

[12] NHS Digital: Statistics on Obesity, Physical Activity and Diet - England, 2018 [PAS] https://digital.nhs.uk/data-and-information/publications/statistical/statistics-on-obesity-physical-activity-and-diet/statistics-on-obesity-physical-activity-and-diet-england-2018

3. Impact and Evidence:

In the following boxes detail the findings and impact identified (positive or negative) within the research detailed above; this should also include any identified health inequalities which exist in relation to this work.

Age: Describe age related impact and evidence. This can include safeguarding, consent and welfare issues:

Age range data is not available for the profile of patients requesting the procedure. Some link may be identified between obesity, reduced mobility and the occurrence of the condition if it's a genetic disorder.

Disability: Describe disability related impact and evidence. This can include attitudinal, physical, communication and social barriers as well as mental health/ learning disabilities, cognitive impairments:

As with age obesity is itself a life limiting condition and is commonly found as a co morbidity with other conditions. It has not been shown that restricting this treatment will impact on this group negatively since those who would benefit and are eligible can access surgery.

It is noted that exercise may be more difficult / impossible for patients with some conditions which reduce mobility. In such case the approach would give due regard to reasonable adjustments.

There may be an impact on patients experiencing significant mental health difficulties resulting in a functional impairment related to body image. However, the CCGs have a number of policies (Cosmetic Policy 2017) for body contouring related to body image - to improve the patient's physical appearance, which would include the cohort of patients described above. The currently revised policy was developed following a number of IFRs from clinicians, where the patient was so physically disabled by the size and weight of their excess skin folds or were having numerous hospital admissions due to the recurrent skin infections, that surgery would be the most beneficial outcome for these patients. This cohort of patient was not included in the 2017 policies. Therefore, the evidence review reviewed the physical impact of the removal of the excess skin on improving activities of daily living, not the impact on the patient's mental health as this was already covered by existing CCG policies. Whilst there is undoubtedly a cohort of patients who experience a mental health impact from their body image, this cohort of patients would fall under the already commissioned cosmetic surgery policy 2017.

Gender reassignment (including transgender): Describe any impact and evidence on transgender people. This can include issues such as privacy of data and harassment:

3. Impact and Evidence:
No impact identified
Marriage and civil partnership: Describe any impact and evidence in relation to marriage and civil partnership. This can include working arrangements, part-time working, and caring responsibilities: No impact identified
Pregnancy and maternity: Describe any impact and evidence on pregnancy and maternity. This can include working arrangements, part-time working, and caring responsibilities: No impact identified Due to the surgical procedures involved within some of the body contouring techniques across the stomach area such as the full abdominoplasty, it is not advisable to have surgery for patients who are thinking about becoming pregnant. Also, if condition has arisen from a genetic disorder such as lymphoedema, there may be a link to conditions worsening at the time of hormone changings such as pregnancy.
Race: Describe race related impact and evidence**.** This can include information on different ethnic groups, Roma gypsies, Irish travellers, nationalities, cultures, and language barriers: No impact identified
Religion or belief: Describe any religion, belief or no belief impact and evidence. This can include dietary needs, consent and end of life issues: No impact identified
Sex: Describe any impact and evidence on men and women. This could include access to services and employment: No impact identified
Sexual orientation: Describe any impact and evidence on heterosexual people as well as lesbian, gay and bisexual people. This could include access to services and employment, attitudinal and social barriers:

3. Impact and Evidence:
No impact identified
Carers: Describe any impact and evidence on part-time working, shift-patterns, general caring responsibilities: No impact identified
Other disadvantaged groups: Describe any impact and evidence on groups experiencing disadvantage and barriers to access and outcomes. This can include lower socio-economic status, resident status (migrants, asylum seekers), homeless, looked after children, single parent households, victims of domestic abuse, victims of drugs / alcohol abuse: (This list is not exhaustive) No impact identified

4. Health Inequalities	Yes/No	Evidence
Could health inequalities be created or persist by the proposals?	No	This condition could be linked to a health inequality due to the prevalence of obesity. As the surgical procedures remain available it is not anticipated that a health inequality will be made worse.
Is there any impact for groups or communities living in particular geographical areas?	Yes	A limited link between obesity and areas of high deprivation has been made.
Is there any impact for groups or communities affected by unemployment, lower educational attainment, low income, or poor access to green spaces?	Yes	The ability to access better diet and exercise may be reduced for those in low socio economic

4. Health Inequalities	Yes/No	Evidence
		groups. Due regard to this will need to be given in supporting such patients.

How will you ensure the proposals reduce health inequalities?

The intention of the policy is to support patients who have managed to maintain their weight for at least two years and where they have lost at least 50% of their original excess weight. Through the procedure the quality of life for all patients can be improved.

5. FREDA Principles/ Human Rights	Question	Response
Fairness – Fair and equal access to services	How will this respect a person's entitlement to access this service?	Yes, this decision has been made in line with clinical recommendation and NICE
Respect – right to have private and family life respected	How will the person's right to respect for private and family life, confidentiality and consent be upheld?	No evidence of impact for this policy
Equality – right not to be discriminated against based on your protected characteristics	How will this process ensure that people are not discriminated against and have their needs met and identified?	No discrimination identified
	How will this affect a person's right to freedom of thought, conscience and religion?	N/A
Dignity – the right not to be treated in a degrading way	How will you ensure that individuals are not being treated in an inhuman or degrading way?	Policy will be applied with due Regard to this consideration.
Autonomy – right to respect for private & family life; being able to make informed decisions and choices	How will individuals have the opportunity to be involved in discussions and decisions about their own healthcare?	An individual can discuss the impact with their GP and has the option for an IFR request to be made
Right to **Life**	Will or could it affect someone's right to life? How?	No evidence of impact for this policy
Right to **Liberty**	Will or could someone be deprived of their liberty? How?	No evidence of impact for this policy

6. Social Value

Consider how you might use the opportunity to improve health and reduce health inequalities and so achieve wider public benefits, through action on the social determinants of health.

Marmot Policy Objective	What actions are you able to build into the procurement activity and/or contract to achieve wider public benefits?
Enable all people to have control over their lives and maximise their capabilities	None
Create fair employment and good work for all	None
Create and develop health and sustainable places and communities	None
Strengthen the role and impact of ill-health prevention	None

7. Engagement, Involvement and Consultation

If relevant, please state what engagement activity has been undertaken and the date and with which protected groups:

Engagement Activity	Protected Characteristic/ Group/ Community	Date

For each engagement activity, please state the key feedback and how this will shape policy / service decisions (E.g. patient told us …. So we will …..):

As part of the process further targeted engagement was planned with representative groups from among Sandwell, Birmingham and Solihull Patients. In addition, it has been identified that patient and clinician information is key in ensuring that the harmonised treatment policies review delivers effective outcomes. To this end an information briefing leaflet on each procedure has been developed to give more information on the procedure, eligibility criteria and signposting to further information sources, such as NHS Choices. These information leaflets are also designed to help facilitate discussions between GPs and patients. Information briefing leaflets have already been tested for the Pjase 1 and Phase 2 Harmonised Clinical Treatment Policy Projects for Birmingham and Solihull CCG and Sandwell and West Birmingham CCGs. Due regard will be given to both the accessible information standard and the potential need to translate such leaflets into relevant local languages.

The engagement team used every possible route throughout the engagement period to encourage people to feedback on the proposed policy. Unfortunately, despite the wide communication undertaken through all communication and engagement channels available, 49 questionnaires were completed online and there was no interest from stakeholders, patients and the public to attend any of the five stakeholder events arranged. As a result, the events were cancelled, and the engagement team looked at other routes to encourage engagement with patients directly. A possible reason for the lack feedback from stakeholders, patients and the public is most likely because this clinical treatments policy is widening the scope of the current service provision.

7. Engagement, Involvement and Consultation

Also, in phase 3 of the harmonisation of policies programme clinicians had been integral to the development of the policies from the beginning of the process. It could therefore be argued the proposed policy shared for public engagement was to some extent already informed from a local patient experience and outcomes perspective.

The potential impact on patients is minimal and feedback from approximately 59% of responders either strongly agree or agree to the proposed eligibility criteria for this draft policy. Additional comments are also in favour of this policy and also relate to supporting patients at the early stages of obesity to prevent them reaching advance stages. There was wide ranging clinical support for this policy.

8. Summary of Analysis

Considering the evidence and engagement activity you listed above, please summarise the impact of your work:

The restriction of this policy will have limited impact on those who would wish to receive the treatments, this must be balanced against the need to adhere to the clinical effectiveness evidence, overall health improvements in relation to quality of life for the patient and clinical outcomes.

The opportunity for any exceptional cases to be considered via IFR remains and will ensure treatment is available in a clinically exceptional case.

9. Mitigations and Changes :

Please give an outline of what you are going to do, based on the gaps, challenges and opportunities you have identified in the summary of analysis section. This might include action(s) to mitigate against any actual or potential adverse impacts, reduce health inequalities, or promote social value. Identify the **recommendations** and any **changes** to the proposal arising from the equality analysis.

Consideration will need to be given to what additional support patients from a low socio economic background will require and how due regard can be given to reasonable adjustments in approach for disabled persons.

10. Contract Monitoring and Key Performance Indicators

Detail how and when the service will be monitored and what key equality performance indicators or reporting requirements will be included within the contract (refer to NHS Standard Contract SC12 and 13):

This policy is not linked to a contract however, prospective providers remain bound by their contracts with the CCG.

11. Procurement

Detail the key equality, health inequalities, human rights, and social value criteria that will be included as part of the procurement activity (to evaluate the providers ability to deliver the service in line with these areas):
N/A

12. Publication

How will you share the findings of the Equality Analysis? This can include: reports into committee or Governing Body, feedback to stakeholders including patients and the public, publication on the web pages. All Equality Analysis should be recommended for publication unless they are deemed to contain sensitive information.
Publication on the CCG's website.
Following approval all finalised Equality Analysis should be sent to the Communications and Engagement team for publication: bsol.comms@nhs.net

13. Sign Off

The Equality Analysis will need to go through a process of **quality assurance** by the Senior Manager for Equality Diversity and Inclusion or the Manager for Equality Diversity and Inclusion prior to approval from the delegated committee

	Name	Date
Quality Assured By:		

Which Committee will be considering the findings and signing off the EA?		
Minute number (to be inserted following presentation to committee)		

Please send to Balvinder Everitt or Michelle Dunne, Equality, Diversity and Inclusion for Quality Assurance.

Once you have committee sign off, please send to Caroline Higgs, Communications & Engagement Team for publication: bsol.comms@nhs.net