Commissioning Policy

NHS Redditch and Bromsgrove Clinical Commissioning Group

NHS South Worcestershire Clinical Commissioning Group

NHS Wyre Forest Clinical Commissioning Group

Hernia Repair in Adults (18 years and over)

June 2017

This policy applies to patients for whom the following Clinical Commissioning Groups are responsible:

- NHS South Worcestershire Clinical Commissioning Group (CCG)
- NHS Redditch & Bromsgrove Clinical Commissioning Group (CCG)
- NHS Wyre Forest Clinical Commissioning Group (CCG)

Collectively referred to as the Worcestershire CCGs

COMMISSIONING SUMMARY

Worcestershire CCGs (also termed "the Commissioner" in this document) endorses the NHS funded management of inguinal, femoral, umbilical, and incisional hernias in accordance with the following criteria:

Inguinal: Surgery is only supported when **one** of the following criteria is met:

- A history of incarceration, or real difficulty reducing the hernia;
- A hernia that is increasing in size month on month;
- Pain or discomfort sufficient to interfere with activities of daily living;
- An inguino-scrotal hernia;
- A strangulated hernia (emergency surgery);
- A recurrence to a previously treated hernia.

Femoral: All suspected femoral hernias should be referred to secondary care due to the increased risk of incarceration/strangulation

Umbilical: Surgery is only supported when **one** of the following criteria is met:

- Pain or discomfort sufficient to interfere with activities of daily living;
- A hernia that is increasing in size month on month;
- To avoid incarceration or strangulation of the bowel.

Incisional: Surgery is only supported when **both** of the following criteria are met:

- Pain or discomfort sufficient to interfere with activities of daily living;
- Appropriate conservative management has been tried first e.g. weight reduction where appropriate

Note: Further detail regarding these referral/treatment criteria in adults (18yrs+) is provided in section 6 of this policy.

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Document Details:

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Ratified by (name and date of Committee):	Clinical Senate – February 2013 1st April 2013 – this policy was formally adopted by: NHS South Worcestershire Clinical Commissioning Group NHS Redditch & Bromsgrove Clinical Commissioning Group NHS Wyre Forest Clinical Commissioning Group
Date issued:	April 2013, Reissued June 2017
Internal Review Date:	Documents will be reviewed as a minimum every 3 years. However, earlier revisions to the policy may be made in light of published updates to local and national evidence of effectiveness and cost effectiveness and/or recommendations and guidelines from local, national and international clinical professional bodies. Date to Initiate Review: June 2020
Lead Executive/Director:	Chris Emerson, Head of Commissioning & Service Redesign
Name of originator/author:	Original Version - Mr Stuart Bourne, Public Health Consultant Updates - Mrs Helen Bryant and Mrs Fiona Bates
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Distribution:	NHS Trusts, Independent Providers, CCGs, GP's, patients, Public & Patient Involvement Forum
Equality & Diversity Impact Assessment	March 2012, scrutinised June 2012 Updated March 2017

Key individuals involved in developing the document:

Name	Designation	Version Reviewed
Mr Stuart Bourne	Public Health Consultant, NHSW	V 1.0
Mr Martin Wadley	Consultant Surgeon, WAHT	V 1.0
Mr Anthony Perry	Consultant Surgeon, WAHT	V 1.0
Dr Guy Busher	GP, Malvern Health Centre	V 1.0

Circulated to the following individuals/groups for comments:

Name	Date	Version Reviewed
Clinical Commissioning Policy Collaborative, which includes: GPs, Commissioners, Medicines Commissioning, Public Health, Patient and Public Representatives	Various in line with meeting schedule and workstream	All versions
Elective Care Clinical Review Group	Various in line with meeting schedule and workstream	V1.3

Version Control:

Version No	Type of Change	Date	Description of change
V1.0	Policy Initiation	Apr 12	Original Policy Development
V1.2	Minor changes to layout	Feb 13	Changes to reflect changes to responsible commissioning arrangements only.
V1.3	Minor changes to layout	Feb 17	Updated onto new commissioning policy template for completeness.

Table of Contents

1. Definitions

1.1 **Exceptional clinical circumstances** are clinical circumstances pertaining to a particular patient, which can properly be described as exceptional, when compared to the clinical circumstances of other patients with the same clinical condition and at the same stage of development of that condition (i.e. similar patients). A patient with **exceptional clinical circumstances** will have clinical features or characteristics which differentiate that patient from other patients in that cohort and result in that patient being likely to obtain significantly greater clinical benefit (than those other patients) from the intervention for which funding is sought.

1.2 A **Similar Patient** is a patient who is likely to be in the same or similar clinical circumstances as the requesting patient and who could reasonably be expected to benefit from the requested treatment to the same or a similar degree. The existence of more than one similar patients indicates that a decision regarding the commissioning of a **service development** or commissioning policy is required of the Commissioner.

1.3 An **individual funding request (IFR)** is a request received from a provider or a patient with explicit support from a clinician, which seeks exceptional funding for a single identified patient for a specific treatment.

1.4 An **in-year service development** is any aspect of healthcare, other than one which is the subject of a successful individual funding request, which the Commissioner agrees to fund outside of the annual commissioning round. Such unplanned investment decisions should only be made in exceptional circumstances because, unless they can be funded through disinvestment, they will have to be funded as a result of either delaying or aborting other planned developments.

2. Scope of policy

2.1 This policy is part of a suite of locally endorsed Commissioning Policies. Copies of these Commissioning Policies are available on the following website address: http://www.redditchandbromsgroveccg.nhs.uk/about-us/strategies-policies-and-procedures/commissioning-ifr/

2.2 This policy applies to all patients for whom the Worcestershire CCGs have responsibility including:

- People provided with primary medical services by GP practices which are members of any one of the CCGs and
- People usually resident in any of the areas covered by the CCG's and not provided with primary medical services by any CCG.

2.3 There are many different types of hernia; those that are covered in this policy include inguinal, femoral, ventral (including incisional) and umbilical hernias.

2.4 Where a patient's clinical presentation does not clearly meet the requirements for secondary care referral within the context of this policy, and where a GP is uncertain or concerned about the appropriate treatment/management pathway, referral for Advice & Guidance should be considered as an alternative to a referral for clinical assessment.

2.5 There may be occasions when a GP referral is made for specialist assessment which appears to meet the policy requirements, but which on specialist clinical examination either does not meet the clinical criteria for surgery or is not considered clinically suitable for surgery. Such patients should be discharged without surgery.

2.6 For patients who do not fall within the eligibility criteria set out in the policy but where there is demonstrable evidence that the patient has exceptional clinical circumstances, an Individual Funding Request may be submitted for consideration. The referring clinician should consult the Commissioner's "Operational Policy for Individual Funding Requests" document for further guidance on this process.

For a definition of the term "exceptional clinical circumstances", please refer to the Definitions section of this document.

3. Background

3.1. The NHS Constitution, which details the principles and values that guide the NHS, has been applied in the agreement of this policy.

3.2. NHS Redditch & Bromsgrove Clinical Commissioning Group, NHS South Worcestershire Clinical Commissioning Group and NHS Wyre Forest Clinical Commissioning Group consider all lives of all patients whom they serve to be of equal value and, in making decisions about funding treatment for patients, will seek not to discriminate on the grounds of sex, age, sexual orientation, ethnicity, educational level, employment, marital status, religion or disability except where a difference in the treatment options made available to patients is directly related a particular patient's clinical condition or is related to the anticipated benefits to be derived from a proposed form of treatment.

3.3. A hernia is defined as a protrusion of a sac or peritoneum, often containing intestine or other abdominal contents, from its proper cavity through a weakness in the abdominal wall. They usually present as a lump, and patients often experience pain or discomfort that can limit daily activities and the ability to work.1,2 In addition, hernias can present as a surgical emergency should the bowel strangulate or become obstructed due to the hernia.

3.4. There are many different types of hernia including inguinal, femoral, incisional (and ventral) and umbilical.

3.5. An **inguinal** hernia is a protrusion of the contents of the abdominal cavity or preperitoneal fat through a defect in the inguinal area. Indirect hernias follow the inguinal canal, whereas direct hernias usually occur due to a defect or weakness in the transversalis fascia area of the Hesselbach triangle. 98% occur in men due to the vulnerability of the male anatomy.[1], [2]

3.6. **Femoral** hernias follow the tract below the inguinal ligament through the femoral canal, and account for less than 10% of all groin hernias. However, due to the small size of this space through which they protrude, they frequently become incarcerated or strangulated1 with 40% presenting as emergencies[3]. The incidence of femoral hernias is higher in women than men, with a ratio of 4:1.

3.7. **Incisional** hernias are iatrogenic, with protrusion through a defect caused during surgery. They account for 80%[4] of ventral hernias, and may arise from 3-11% of all laparotomies, rising to >23% should wound infection occur. Other predisposing factors include diabetes, smoking and obesity. Again, they can give rise to symptoms such as discomfort or pain

3.8. **Umbilical** hernias are very common in infants and young children, especially in babies born prematurely. An umbilical hernia appears as a painless lump in or near the navel (belly button). It may get bigger when laughing, coughing, crying or going to the toilet and may shrink when relaxing or lying down. In many cases, the umbilical hernia goes back in and the muscles reseal before the child's first birthday. Umbilical hernias can also develop in adults. Without treatment, the hernia will probably get worse over time.

3.9. Approximate frequencies for each type of hernia are:

Inguinal:	70 - 75%
Femoral:	17%
Umbilical:	3 - 8.5%
Rarer form:	1-2% (epigastric/incisional)

4. Relevant National Guidance and Facts

4.1 A trial carried out by Fitzgibbons[6] randomised 720 men to watchful waiting vs surgical repair of their inguinal hernia. Primary outcomes were pain limiting activities and their 'physical component score'. It was found that results for these outcomes were similar between watchful waiting and surgical repair at 2 years. Although a relatively high proportion of the watchful waiting group (23%) crossed over to operative repair of the hernia (usually due to pain), there was no difference in post op complications between this group and those allocated initially to repair. Only one watchful waiting patient experience acute hernia incarceration within 2 years, with a second experiencing this at 4 years. The authors therefore concluded that watchful waiting is an acceptable option in minimally symptomatic inguinal hernias, and that in effect surgery was delayed rather than avoided. They also concluded that delaying surgical repair until symptoms increase is safe because acute incarcerations occur rarely and there was no increase in operative complications. This approach is also advocated by the BMJ clinical evidence team[8]. Furthermore, in a response to the article by Fitzgibbons, Flum[7] agrees with this position and reiterates the benefits of watchful waiting where clinically appropriate

4.2 Furthermore, the Danish hernia database[9] recommend surgical repair in the presence of symptoms affecting daily life. In addition, they advise surgical repair in women due to the higher risk of strangulation. However, in men with minimal or absent symptoms, a watchful waiting approach is recommended.

4.3 There is also evidence from the European Hernia society[10] supporting this recommendation and advocating a watchful waiting approach for those who are asymptomatic or minimally symptomatic. However, they recommend that those who are symptomatic should be considered for elective surgery. This approach is also in line with recommendations from other Commissioners such as Buckinghamshire, Oxfordshire, West Essex and Westminster.

4.4 However, there are some conflicts in the studies looking at watchful waiting compared to early placement on the list for elective surgery. For example, Primatesta[11] looked at the incidence of elective and emergency surgery, readmission and mortality, finding that patients who underwent emergency repair were older, had higher emergency readmission rates than electives, and significantly elevated postoperative mortality rates, and they therefore advised that elective repair of inguinal hernia should be undertaken soon after diagnosis to minimise the risk of adverse outcomes. However, in the study carried out by Fitzgibbons, patients were operated on once their symptoms (i.e. pain) increased, rather than the decision being made to delay surgery until strangulation occurred and an emergency procedure was carried out.

4.5 The case is different for femoral surgery. Femoral hernias account for less than 10% of groin hernias[3] but 40% of these present as emergencies with incarceration or strangulation. Also, femoral hernias are more common in women (ratio 4:1) in contrast to inguinal hernias which have a higher incidence in men. Therefore, we have recommended that femoral hernias should be referred for specialist assessment, and that clinicians should note that these hernias are more common in women. This view is supported by the Danish hernia database.

4.6 Incisional hernias represent approximately 80% of ventral hernias[11], and are more common in people who have experienced wound complications or infections post operatively. Friedrich et al recommend conservative management such as weight reduction to relieve symptoms, and that surgery should be carried outi n those who are symptomatic and conservative management has given no benefit. The most

common complaint is pain, with on 12% presenting acutely with incarceration or strangulation. Courtney[12] found that only one third of incisional hernias became symptomatic and required repair. The Society for Surgery of the Alimentary Tract[13] advise that incisional hernias occur in 3-13% of primary abdominal incisions, although recurrence rates can be quite high at 25-50%, with risk factors for hernias being wound infections, obesity, diabetes and smoking. They advised that reasons for repairing incisional hernias would include relieving symptoms, to prevent gradual enlargement over time, and to avoid incarceration and strangulation of bowel. Therefore these latter recommendations have formed the basis of our criteria for referrals and treatment for umbilical and incisional hernias.

5. Patient Eligibility

5.1 Inguinal:
For asymptomatic or minimally symptomatic hernias, the Commissioner advocates watchful waiting.

Surgical treatment should only be offered when one of the following criteria is met:

- A history of incarceration, or real difficulty reducing the hernia;
- A hernia that is increasing in size month on month;
- Pain or discomfort sufficient to interfere with activities of daily living;
- An inguino-scrotal hernia;
- A strangulated hernia (emergency surgery);
- A recurrence to a previously treated hernia.

Older patients should have the symptoms clearly explained so that they can present promptly for referral if pain worsens or hernia size increases. Emergency repair carries an elevated mortality risk and emergency repair becomes more common as patient age increases. Prompt referral is therefore important for patients beyond 65yrs of age to reduce the risks associated with emergency surgery.

5.2 Femoral:
All suspected femoral hernias should be referred to secondary care due to the increased risk of incarceration/strangulation

5.3 Umbilical:
Surgical treatment should only be offered when one of the following criteria is met:

- Pain or discomfort sufficient to interfere with activities of daily living;
- A hernia that is increasing in size month on month;
- To avoid incarceration or strangulation of the bowel.

5.4 Incisional:
Surgical treatment should only be offered when both of the following criteria are met:

- Pain or discomfort sufficient to interfere with activities of daily living;
- Appropriate conservative management has been tried first e.g. weight reduction where appropriate

5.5 Activity carried out in relation to this policy will be monitored through the following procedures codes:

OPCS codes:

•	Umbilical Hernia	T24.1 – T24.9
•	Recurrent Umbilical Hernia	T97.1 – T97.9
•	Femoral Hernia	T22.1 – T 22.9
•	Recurrent Femoral Hernia	T23.1 – T23.9

Where activity exceeds an appropriate benchmark (e.g. the regional average procedure rate), a retrospective casenote audit may be instigated in secondary care to confirm compliance with this policy.

6. Supporting Documents

- Worcestershire CCGs: Operational Policy for Individual Funding Requests
- Worcestershire CCGs: Prioritisation Framework for the Commissioning of Healthcare Services
- NHS England: Ethical Framework for Priority Setting Resource Allocation
- NHS England: Individual Funding Requests
- NHS Constitution, updated 27th July 2015

Evidence Review References:

1. http://emedicine.medscape.com/article/775630-overview#a0104 (accessed 6th June 2011)
2. NICE guidelines: TA83 (Sept 2004) – Laparoscopic surgery for hernia
3. McIntosh, Hutchinson, Roberts, Withers (2000). Evidence based management of groin hernia in primary care - a systematic review. Family Practice; 17:442-447
4. Friedrich, Muller-Riemenschneider, Roll, Kulp, Vauth, Greiner, Willich and von der Schulenbury (2008). Health Technology Assessment of laparoscopic compared to conventional surgery with and without mesh for incisional hernia repair regarding safety, efficacy and cost-effectiveness. GMS Health Technology Assessment ; 7/4: Doc 01
5. Dabbas (2011) Frequency of abdominal wall hernias: is classical teaching out of date. JRSM Short Reports: 2/5; 5
6. Fitzgibbons (2006); Watchful waiting versus repair of inguial hernia in minimally symptomatic men, a randomised controlled trial. JAMA: 295; 285-292
7. Flum (2006) : The asymptomatic hernia: If it's not broken don't fix it. JAMA: 295; 249
8. BMJ clinical evidence on Inguinal Hernias; Chos, Purkayastha, Anthanasiou, Tekkis and Darzi.
9. Rosenberg (2011). Danish hernia database recommendations for management of inguinal and femoral hernias in adults. Danish Medical Bulletin; 58/2: C4243
10. Simons et al. European hernia society guidelines: Treatment of inguinal hernia in adult patients. Hernia, 2009: 13(4): 343–403.
11. Primatesta, Goldacre. Inguinal Hernia repair: incidence of elective and emergency surgery, readmission and mortality (1996). International Journal of Epidemiology; 25/4: 835-839
12. Courtney, Lee, Wilson and O'Dwyer (2003). Ventral hernia repair: a study of current practice. Hernia; 7:44-46
13. Surgery for Society on the Alimentary tract patient care guidelines(2004). Surgical repair of incisional hernia. Journal of Gastrointestinal surgery; 8/3: 369-70

7. Equality Impact Assessment

Organisation	NHS Redditch & Bromsgrove CCG, NHS South Worcestershire CCG, NHS Wyre Forest CCG		
Department	Contracting	Name of lead person	Fiona Bates & Helen Bryant
Piece of work being assessed	Hernia Commissioning Policy		
Aims of this piece of work	To provide guidance for patients and clinicians in both primary and secondary care on the process for clinical management of individuals with hernias of different types and the clinical criteria required for NHS funded interventions to surgically manage the condition		
Date of EIA	3rd March 2017	Other partners/stakeholders involved	Clinical Commissioning Policy Collaborative
Who will be affected by this piece of work?	Individuals who have a non-emergency related hernia and wish to have surgery to correct this.		

Single Equality Scheme Strand	**Baseline data and research on the population that this piece of work will affect.** What is available? E.g. population data, service user data. What does it show? Are there any gaps? Use both quantitative data and qualitative data where possible. **Include consultation with service users wherever possible**	**Is there likely to be a differential impact?** Yes, no, unknown
Gender	There are many different forms of hernia; of those covered by the policy: • Inguinal hernias – 98% of these occur in men due to the vulnerability of the male anatomy. • Femoral hernias – 80% (4:1) of these occur in women. 40% of femoral hernias present as emergencies, therefore the pathway for femoral hernias is direct referral to for a specialist assessment[1] • Incisional hernias - these are more common in people who have experienced wound complications or post-surgical complications.	No

[1] Danish Hernia Database supported recommendation

Single Equality Scheme Strand	**Baseline data and research on the population that this piece of work will affect.** What is available? E.g. population data, service user data. What does it show? Are there any gaps? Use both quantitative data and qualitative data where possible. **Include consultation with service users wherever possible**	**Is there likely to be a differential impact?** Yes, no, unknown
	• Umbilical hernias – between 3 and 8% of hernias are umbilical and predominantly occur in males. This CCG policy does not differentiate between the gender of the presenting patient but rather on their clinical presentation and will treat all patients equally in that respect.	
Race	In 2011, The Office of National Statistics noted that 95.7% of Worcestershire's population classified themselves as "White" (including 0.6% White Irish, 0.2% White Gypsy or Irish Traveller). 2.4% of the population classified themselves as "Asian or Asian British" and 0.4% "Black or Black British". This CCG policy applies to any patient wishing to receive surgical treatment for a hernia regardless of race.	No
Disability	In 2011, The Office of National Statistics noted that 8.1% of Worcestershire's population classified themselves as "having long term health problems or disabilities such that their day to day activities are affected a lot". No data is available to determine the ability breakdown of people who present to the NHS to consider (or receive) corrective surgery for hernias. Given the CCG policy concentrates on the clinical presentation of the patient's hernia condition the expectation would be that a patient with one or multiple disabilities would be considered for surgery using the same clinical criteria.	No
Religion/ belief	There is no available evidence regarding the breakdown of the UK population who have received corrective hernia surgery by their religion/beliefs. This CCG policy applies to any patient wishing to receive corrective hernia surgery regardless of religion/belief.	No
Sexual orientation	There is no available evidence regarding the breakdown of the UK population who have received corrective hernia surgery by their sexual orientation. This CCG policy applies to any patient wishing to receive corrective hernia surgery regardless of the sexual orientation of the patient.	No
Age	The policy is only applicable to adult patients, the treatment pathway for children presenting with hernias is not considered as part of this policy.	No

Single Equality Scheme Strand	**Baseline data and research on the population that this piece of work will affect.** What is available? E.g. population data, service user data. What does it show? Are there any gaps? Use both quantitative data and qualitative data where possible. **Include consultation with service users wherever possible**	**Is there likely to be a differential impact?** Yes, no, unknown
Social deprivation	There is no published information that indicates whether people from socially deprived backgrounds are more or less likely to present for consideration of a hernia.	No
Carers	The Office of National Statistics 2011 Census noted that 11.3% of Worcestershire population provide unpaid care. Therefore, it may be reasonable to assume that a proportion of that small population group may also be part of the population group affected by hernias but this will have no impact on patient management in accordance with this policy.	No
Human rights	The local commissioning policy would not seek to affect a patient's human rights.	No

Equality Impact Assessment Action Plan

Strand	**Issue**	**Action required**	**How will you measure the outcome/impact**	**Timescale**	**Lead**