NHS
Cheshire and Merseyside

Clinical Commissioning Policy

CMICB_Clin108
Rectal prolapse (internal or external), surgical management

Category 2 Intervention - Only routinely commissioned when specific criteria are met

Contents

Last Reviewed: March 2024

This policy statement will be reviewed 5 years from the date of the last review unless new evidence or technology is available sooner.

1. Policy statement

1.1 Patients with pelvic floor symptoms could have an underlying bowel pathology or malignancy which should be excluded prior to starting conservative management.

1.2 Patients presenting with rectal prolapse and/or associated symptoms (e.g., obstructed defaecation syndrome) should be given a reasonable period of conservative treatment which includes diet, biofeedback, laxatives, and pelvic floor retraining.

1.3 If conservative treatment is unsuccessful, referral can be made to a multidisciplinary team (which is recognised and accredited in the management of these patients) for a surgical opinion.

2. Exclusions

2.1 None.

3. Core Eligibility Criteria

3.1 There are several circumstances where a patient may meet a 'core eligibility criterion' which means they are eligible to be referred for this procedure or treatment, regardless of whether they meet the policy statement criteria, or the procedure or treatment is not routinely commissioned.

3.2 These core clinical eligibility criteria are as follows:

- Any patient who needs 'urgent' treatment will always be treated.
- All NICE Technology Appraisals Guidance (TAG), for patients that meet all the eligible criteria listed in a NICE TAG will receive treatment.
- In cancer care (including but not limited to skin, head and neck, breast and sarcoma) any lesion that has features suspicious of malignancy, must be referred to an appropriate specialist for urgent assessment under the 2-week rule.
  NOTE: Funding for all solid and haematological cancers are now the responsibility of NHS England.
- Reconstructive surgery post cancer or trauma including burns.
- Congenital deformities: Operations on congenital anomalies of the face and skull are usually routinely commissioned by the NHS. Some conditions are considered highly specialised and are commissioned in the UK through the National Specialised Commissioning Advisory Group (NSCAG). As the incidence of some cranio-facial congenital anomalies is small and the treatment complex, specialised teams, working in designated centres and subject to national audit, should carry out such procedures.
- Tissue degenerative conditions requiring reconstruction and/or restoring function e.g. leg ulcers, dehisced surgical wounds, necrotising fasciitis.
- For patients expressing gender incongruence, further information can be also be found in the current ICB gender incongruence policy and within the NHS England gender services programme - https://www.england.nhs.uk/commissioning/spec-services/npc-crg/gender-dysphoria-clinical-programme/

4. Rationale behind the policy statement

4.1 This policy statement is consistent with NICE guidance and other published literature.

5. Summary of evidence review and references

5.1 The current Cheshire CCG policy on rectopexy is based on two references. The first contains a broken (unobtainable) link to a Bristol CCG policy, published in 2016, and the 2nd was a very general article on rectal prolapse. Because of the general lack of underpinning evidence, a rapid review of the literature was performed limited to the last 3 – 4 years.

5.2 Rectal prolapse may occur externally when the bowel protrudes through the anus or internally when the bowel pushes against one of the internal structures, most commonly the vagina in women. Although not life-threatening, the disorder can be very distressing and demoralising and the symptoms could include discomfort, pain, constipation, difficulty in evacuation (obstructed defecation syndrome) and discharge of mucus or blood. In women, this could also be associated with painful intercourse, lower back pain and urinary dysfunction.[1] Further, the protrusion of the anterior rectal wall through the posterior wall of the vagina is termed a rectocele and the prevalence of this in women over the age of 50, is estimated to be 30 – 50%.[2]

5.3 Conservative treatment is generally recommended for most patients, and this includes pelvic floor exercises and advice to improve defaecatory habits in order to reduce constipation and improve incontinence. These are often termed biofeedback or pelvic floor retraining. When conservative management has failed, the indication for surgery depends on the intensity of symptoms and the resulting deterioration in quality-of-life.[1]

5.4 Two main surgical approaches can be utilised, abdominal (laparoscopic) or perineal. Laparoscopic posterior suture rectopexy used to be preferred whereas laparoscopic ventral mesh rectopexy is now more common. Techniques for the perineal approach include Delorme's and Altemeier's rectosigmoidectomy [3] Although over 100 abdominal and perineal procedures are available [4] , there doesn't seem to be a consensus in the literature regarding the best technique(s). [2,5] However, recurrence is significantly lower in laparoscopic patients compared to perineal [6] or suture rectopexy [7,8] Ventral mesh rectopexy is gaining ground although more robust RCTs are required.[9]

5.5 Surgery -related adverse effects, although serious are infrequent.[1] In a case series of 2, 203 patients, there were 2 (<1%) reports of death and 45 reports (2%) of mesh erosion. Rare cases of intra-abdominal bleeding, infection and pain have also been reported.[10] Patient selection is thought to be key in optimising post-operative outcomes.[11]

5.6 As mentioned above, ventral mesh rectopexy has emerged as one of the most effective procedures. However, there are international concerns regarding its mesh-related complications following rectopexy. [12] In the UK, these concerns are amplified by the controversy due to synthetic mesh used in women for the treatment of uterine prolapse, a treatment which was paused in 2018 until certain criteria had been satisfied [13] This "pause" was subsequently extended in March 2019. [14] At the time of writing, the pause seems to be continuing until there are sufficient accredited surgeons suitably trained to remove any troublesome mesh.[15]

5.7 More specifically, concerning mesh for rectopexy, the Pelvic Floor Society on behalf of the Association of Coloproctology of Great Britain and Ireland have issued a position statement. This states that the available evidence suggests that mesh morbidity for ventral mesh rectopexy (VMR) is far lower than that seen in trans-vaginal procedures and lower than that observed following abdominal pelvic procedures for urogenital prolapse. Therefore, VMR should be performed by adequately trained surgeons who work within a multidisciplinary team (MDT) framework. Within this, it is mandatory to discuss all patients considered for surgery at an MDT meeting. The Society also states that a move towards accreditation of UK units performing VMR will improve performance and outcomes in the long term.[16]

5.8 Meanwhile, there is existing national guidance from the National Institute for Health and Care Excellence (NICE) on 2 of these procedures. The first is interventional procedures guidance (IPG) on laparoscopic ventral mesh rectopexy for internal rectal prolapse, IPG 618, published in 2018. [1] Special arrangements for clinical governance and consent are required because of the limited data on efficacy and safety. This recommendation stems from the well-recognised, serious but infrequent complications.

5.9 IPG 618 stipulates that patient selection should be done by a pelvic floor multidisciplinary team which should include a surgeon, urogynaecologist, radiologist, nurse specialist, physiotherapist, pelvic floor physiologist and when appropriate, a gastroenterologist. Unsurprisingly, the surgery should only be performed by surgeons who are trained and experienced in laparoscopic pelvic floor surgery. There are also requirements regarding patient information, selection & outcomes and also recording of clinical data.

5.10 The 2nd guidance is IPG 351 on stapled transanal rectal resection for obstructed defecation syndrome, published in 2010.[17] Stapled transanal rectal resection (STARR) is a procedure carried out through the anus and involves resection (removal) of a portion of the rectum which is then joined together using a specialist stapling device. Although IPG 351 suggests that normal arrangements for clinical governance etc. are required, the procedure should only be carried out in units specialised in the investigation and management of pelvic floor disorders. Similarly, patient selection and management should involve an MDT. To this extent, IPGs 618 & 351 are consistent in their approach that these patients should be selected and managed by a highly specialised team. It is also explicit in both guidelines that a managed period of conservative treatment should be tried before consideration of surgery.

5.11 Patients with rectal prolapse (and associated conditions), therefore, require special consideration and management to determine which procedures (if any) are appropriate. Factors to consider will include the choice between the perineal or laparoscopic approach which in turn will be driven by the patients' age, gender, symptoms and underlying pathology. Clearly, it is entirely appropriate that this choice should be made by a specialist unit.

5.12 Finally, none of the neighbouring CCGs (Mersey, Shropshire, North Staffordshire & Greater Manchester) currently include a policy for rectopexy in their clinical policy documents.

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6. Advice and Guidance

6.1 **Aim and Objectives**

- This policy aims to ensure a common set of criteria for treatments and procedures across the region. This is intended to reduce variation of access to NHS services in different areas and allow fair and equitable treatment for all patients.

- This policy relates to the commissioning of interventions which optimise clinical effectiveness and represent value for money.

- This document is part of a suite of policies which the Integrated Care Board (ICB) uses to drive its commissioning of healthcare. Each policy is a separate public document in its own right but should be considered alongside all the other policies in the suite as well as the core principles outlined.

- At the time of publication, the evidence presented per procedure/treatment was the most current available.

- The main objective for having healthcare commissioning policies is to ensure that:
  - Patients receive appropriate health treatments
  - Treatments with no or a very limited evidence base are not used; and
  - Treatments with minimal health gain are restricted.

- Owing to the nature of clinical commissioning policies, it is necessary to refer to the biological sex of patients on occasion. When the terms ‘men’ and ‘women’ are used in this document (unless otherwise specified), this refers to biological sex. It is acknowledged that this may not necessarily be the gender to which individual patients identify.

6.2 Core Principles

- Commissioning decisions by ICB Commissioners are made in accordance with the commissioning principles set out as follows:

  - Commissioners require clear evidence of clinical effectiveness before NHS resources are invested in the treatment.
  - Commissioners require clear evidence of cost effectiveness before NHS resources are invested in the treatment.
  - Commissioners will consider the extent to which the individual or patient group will gain a benefit from the treatment.
  - Commissioners will balance the needs of an individual patient against the benefit which could be gained by alternative investment possibilities to meet the needs of the community.
  - Commissioners will consider all relevant national standards and consider all proper and authoritative guidance.
  - Where a treatment is approved Commissioners will respect patient choice as to where a treatment is delivered, in accordance with the 'NHS Choice' framework.
  - Commissioning decisions will give 'due regard' to promote equality and uphold human rights. Decision making will follow robust procedures to ensure that decisions are fair and are made within legislative frameworks.

6.3 Individual Funding Requests (Clinical Exceptionality Funding)

- If any patients are excluded from this policy, for whatever reason, the clinician has the option to make an application for clinical exceptionality. However, the clinician must make a robust case to the Panel to confirm their patient is distinct from all the other patients who might be excluded from the designated policy.

- The ICB will consider clinical exceptions to this policy in accordance with the Individual Funding Request (IFR) Governance Framework consisting of: IFR Decision Making Policy; and IFR Management Policy available on the C&M ICB website: https://www.cheshireandmerseyside.nhs.uk/your-health/individual-funding-requests-ifr/

6.4 Cosmetic Surgery

- Cosmetic surgery is often carried out to change a person's appearance to achieve what a person perceives to be a more desirable look.

- Cosmetic surgery/treatments are regarded as procedures of low clinical priority and therefore not routinely commissioned by the ICB Commissioner.

- A summary of Cosmetic Surgery is provided by NHS Choices. Weblink: http://www.nhs.uk/conditions/Cosmetic-surgery/Pages/Introduction.aspx and http://www.nhs.uk/Conditions/Cosmetic-surgery/Pages/Procedures.aspx

6.5 Diagnostic Procedures

- Diagnostic procedures to be performed with the sole purpose of determining whether or not a restricted procedure is feasible should not be carried out unless the eligibility criteria are met, or approval has been given by the ICB or GP (as set out in the approval process of the patients responsible ICB) or as agreed by the IFR Panel as a clinically exceptional case.

- Where a General Practitioner/Optometrist/Dentist requests only an opinion the patient should not be placed on a waiting list or treated, but the opinion given and the patient returned to the care of the General Practitioner/Optometrist/Dentist, in order for them to make a decision on future treatment.

6.6 **Clinical Trials**

- The ICB will not fund continuation of treatment commenced as part of a clinical trial. This is in line with the Medicines for Human Use (Clinical Trials) Regulations 2004 and the Declaration of Helsinki which stipulates that the responsibility for ensuring a clear exit strategy from a trial, and that those benefiting from treatment will have ongoing access to it, lies with those conducting the trial. This responsibility lies with the trial initiators indefinitely.

7. Monitoring and Review

7.1 This policy remains in force until it is superseded by a revised policy or by mandatory NICE guidance or other national directive relating to this intervention, or to alternative treatments for the same condition.

7.2 This policy can only be considered valid when viewed via the ICB website or ICB staff intranet. If this document is printed into hard copy or saved to another location, you must check that the version number on your copy matches that of the one published.

7.3 This policy may be subject to continued monitoring using a mix of the following approaches:
- Prior approval process
- Post activity monitoring through routine data
- Post activity monitoring through case note audits

7.4 This policy will be kept under regular review, to ensure that it reflects developments in the evidence base regarding effectiveness and value.

8. Quality and Equality Analysis

8.1 Quality and Equality Impact Analyses have been undertaken for this policy at the time of its review.

9. Clinical Coding

9.1 **Office of Population Censuses and Surveys (OPCS)**

H35 Fixation of rectum for prolapse OR
H41.5 Perianal resection of rectum using staples
Either in primary position, with or without the ICD 10 codes.

9.2 **International classification of diseases (ICD-10)**

K62.3 Rectal prolapse OR
K56.1 Intussusception OR
N81.6 Rectocele

Document Control

Ref:	CMICB_Clin108 – Rectal prolapse (internal or external), surgical management
Version:	1
Supersedes:	Previous Clinical Commissioning Group (CCG) Policies
Author (inc Job Title):	Consultant in Public Health, NHS Midlands and Lancashire
Ratified by: **(Name of responsible Committee)**	ICB Board
Cross reference to other Policies/Guidance	N/A
Date Ratified:	March 2024
Date Published and where (Intranet or Website):	March 2024 - (Website)
Review date:	March 2029
Target audience:	All Cheshire & Merseyside ICB staff and provider organisations

Version History
Version 1 – March 2024 – Policy ratified by NHS Cheshire & Merseyside ICB