NHS
Herefordshire and Worcestershire
Clinical Commissioning Group

Funding Arrangements for Use of Biological and Synthetic Mesh/Equivalents

July 2021

Commissioning Summary

NHS Herefordshire & Worcestershire CCG (also termed "the Commissioner" in this document): Following a review of the evidence and consideration of the local circumstances for use, Herefordshire and Worcestershire Clinical Commissioning Group **will separately fund** use of biological mesh for the following indications whilst it is listed as an exclusion from Payment by Results (PbR):

1. When used as part of eLAPE (extra-Levator Abdomino Perineal Excision of the rectum) reconstructive surgical technique for low rectal cancer to achieve wound closure.
2. When used in patients with cancer of the breast, ductal carcinoma in situ and those patients identified with the high risk BRCA gene, for single stage skin sparing mastectomy/reconstruction to avoid the need for a 2 stage operation involving mastectomy and reconstruction.

Further definition of the requirements for these indications is given in section 6.

Herefordshire and Worcestershire Clinical Commissioning Groups **will not separately fund** as an exclusion from PbR:

- Biological mesh when used for any other indications not listed above.
- Synthetic mesh* for any indications.
- Synthetic equivalents** to biological mesh.

Any identified new indications for use of biological mesh or synthetic equivalents requiring additional funding will require submission of a new technology request form for consideration by Herefordshire and Worcestershire Clinical Commissioning Policy Collaborative.

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Author(s)	Fiona Bates - Specialist Medicines and Clinical Policy Adviser Helen Bryant – Head of Acute Contracts
Directorate Responsible	Contracting
Directorate Lead	Ruth Lemiech – Director of Strategy
Ratified by	Herefordshire & Worcestershire Clinical Commissioning Executive Committee
Date Ratified	01/07/2020
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Date of Next Formal Review:	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: 12th July 2024
Target audience:	Patients, GPs, Optometrists, Secondary Care and Primary Care (Community) Providers, Independent Sector Providers
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Distribution:	GPs, Secondary Care & Primary Care (Community) Providers, Independent Sector Providers, CCG Internet Pages

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Version No	Description of change	Reason for Change	Author	Date
1.0 (WCCG's)	New Policy			February 2014
2.0 (WCCG's)	Minor Update	Review of increased evidence to support the findings for eLAPE since the initial review. No change in recommendations for Worcestershire CCGs. Review of evidence to consider biological mesh in breast reconstructive surgery. No change in recommendations. Incorporation of information in relation to titanium coated synthetic mesh. Reference to iBRA National UK prospective study of implant-based breast reconstruction; evidence update re-scheduled following publication of results in 2017.		October 2016

Version No	Description of change	Reason for Change	Author	Date
1.0 (H&WCCG)	Minor Update	Alignment of policy with Herefordshire to produce a single commissioning policy. Incorporating a brief update: - No change in recommendations - Included the results of the Biopex Study for eLAPE, NICE IPG 654 for stoma and the Biomesh Study Group recommendations for hernia		March 2020
1.1	Minor	Application of new commissioning policy template, no change to policy statement, no requirement to update Clinical Commissioning Executive Committee as Template already approved. Change of Executive Lead to Ruth Lemiech	Helen Bryant Jennie Hammond Helen Bryant	July 2021

Key individuals involved in developing the document:

Name	Designation	Version Reviewed
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Circulated to the following individuals/groups for comments:

Name	Date	Version Reviewed
Worcestershire CCGs Clinical Commissioning Policy Collaborative	Various	Version 1.0 and Version 2.0 (WCCGs)
Policy Alignment Task & Finish Group	24 March 2020	Version 1.0 (H&WCCG)
Herefordshire & Worcestershire Clinical Commissioning Groups - Joint Commissioning Committee	04 June 2020	Version 1.0 (H&WCCG)

Table of Contents

1. Definitions

1.1 **Exceptional** - refers to a person who demonstrates characteristics, which are highly unusual, uncommon or rare.

1.2 **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.

1.3 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 patient indicates that a decision regarding the commissioning of a **service development** or commissioning policy is required of the Commissioner.

1.4 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.

1.5 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.

1.6 The term "**where appropriate"** within this document means that clinical judgement is exercised in determining which aspects of the policy guidance can be applied to individual patients depending on their condition; ability to tolerate the listed treatment; and whether they have already undergone that treatment.

1.7 **Biologic and Synthetic Mesh** are forms of surgical mesh, a loosely woven sheet of either synthetic or biological materials, used as either a permanent or temporary support for organs and other tissue during surgery.

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: www.herefordshireandworcestershireccg.nhs.uk

2.2 This policy applies to all patients for whom Herefordshire & Worcestershire CCG has responsibility including:

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

2.3 The clinical responsibility for applying this policy to a presenting patient rests with the clinician who is responsible for the patient at that point in the treatment pathway and should be done in consideration of the patient's individual clinical circumstances, their place on the management pathway and following discussion with the patient.

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 the intervention or is not considered clinically suitable for the intervention . Such patients should be discharged without the intervention.

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.

2.7 This policy relates to use of biological and synthetic mesh and equivalents during identified surgery undertaken at all provider trusts.

2.8 Surgical mesh is a loosely woven sheet which is used as either a permanent or temporary support for organs and other tissue during surgery. The meshes are available in both inorganic (synthetic) and biological materials and are used in a variety of surgeries. Composite meshes are also available with a synthetic inner and biological outer. More recently synthetic meshes with titanium coating have been developed to enhance biocompatibility; for the purpose of breast reconstruction surgery these products are available in larger sizes.

2.9 Biologic mesh development resulted from a search for a biomaterial that addresses the problems associated with permanent synthetic mesh, including chronic inflammation and foreign body reaction, stiffness and fibrosis, and mesh infection. Biological Mesh is made from human or animal dermis or porcine small intestinal submucosa and there are many different products available. Each product differs in composition, porosity, weave,

configuration and material nature, thus making it difficult to directly compare the different products available.

2.10 The theoretical advantage of biologic mesh over synthetic mesh is appealing and over the last decade biologic mesh has been used in a variety of indications. The presence of contamination limits the applicability of permanent synthetic mesh and biological mesh is being used for this purpose or for placement in open wounds as a staged closure in complex abdominal wall reconstruction. There is limited data across all indications for use and a particular lack of comparable data between products. However, the lack of suitable alternatives has made biologic mesh attractive for contaminated field surgery.

2.11 Beyond the four indications originally identified by Worcestershire Acute Hospitals Trust (WAHT) (see background) there is a raft of further evidence for use in other indications eg. vaginal wall prolapse, a variety of hernia repair techniques, mucogingival surgery, urethroplasty. These indications have not been assessed at the current time.

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 Herefordshire & Worcestershire 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 to a particular patient's clinical condition or is related to the anticipated benefits to be derived from a proposed form of treatment.

3.3 NHS England/Improvement launched their Evidenced Based Interventions (EBI) programme in 2018 which aims to ensure that interventions routinely available on the NHS are evidence-based and appropriate. Adoption of published EBI guidance is mandated in the NHS standard contract; commissioners have the freedom to implement criteria with local variations, provided that the decision to adopt varying criteria reflects the requirement to have regard to the national guidance. Where EBI guidance is available, this has been accommodated within the policy criteria.

3.4 In April 2012, Biological Mesh became excluded from PbR tariff. This is because of the variable and often high cost associated with its use; the product can range in cost from £750 to in excess of £10,000 per patient, depending on intended use, size of wound and product choice. All items listed as PbR exclusions are subject to locally agreed payments taking into consideration existing tariff charges.

3.5 The terms of the tariff exclusion for biological mesh were updated for 2014/15 to read: "biological mesh, including synthetic equivalents". The Pricing Team at Montior.gov.uk have clarified their intentions: "Our intention in the wording used in the 2014/15 National Tariff was to allow for the possibility that there are synthetic materials in use which may represent a similar disproportionate cost as biological mesh. It was not our intention to cover any materials that are routinely used and are relatively low cost. We would expect providers and commissioners to take a sensible approach to discussions around reimbursement for items not reimbursed through tariff prices, and act in the best interests of patients and the wider health economy."

3.6 For a device to be considered as an exclusion from PbR it must meet all 3 of the following criteria:

I. high cost and represent a disproportionate cost relative to the relevant HRG
II. used in a subset of cases within an HRG and/or used in a subset of providers delivering services under a specific HRG
III. relatively high cost in terms of volume and cost.

3.7 Worcestershire Acute Hospital Trust (WAHT) reported use of biological mesh in the following areas and requested funding from Commissioners:

- reconstructive breast surgery
- eLAPE reconstructive surgical technique for low rectal cancer
- complex abdominal wall hernia repair
- closure of laparostomy.

3.8 **Breast reconstruction:** The mesh is used to enhance the pectoralis major muscle deficiencies at the breasts lower pole; achieving complete coverage at the breast lower pole with one piece of mesh. This allows a breast implant to be placed immediately,

rather than an expander, saving the patient many outpatient visits for expansion and a second operation to exchange the expander for the implant. Using biological mesh, this technique is only suitable for a subset of women with BMI < 30 and small to moderate size breasts (usually A/B cup and minimal breast ptosis). This is due to the size of the mesh that can be used and the availability of sufficient intact skin to achieve adequate skin coverage/closure. The proportion of all patients undergoing mastectomy and breast reconstruction that would be eligible for reconstruction with ADM is in the order of 10%. Titanium coated mesh allows immediate implant breast reconstruction surgery in a larger cohort of women with small to large breasts. However, the overall rate of mastectomy is declining, with current rates at 25-30% (previously around 50%).

3.9 **eLAPE reconstructive surgery for low rectal cancer:** In 2010, there was a general shift in the management of low rectal cancer from the traditional method of surgery – AbdominoPerineal Excision (APE) to the eLAPE procedure. The more extensive nature of eLAPE surgery leads to reduced circumferential resection margins (CRM) and reduced intraoperative perforation (IOP), both indicators of improved outcomes for cancer patients, and this prompted the shift to eLAPE surgery. APE surgery is less extensive and allows for primary closure to be undertaken. The extensive nature of eLAPE surgery means that primary closure is rarely feasible and closure must be undertaken using either a biological mesh or flap repair. In the absence of suitable plastic surgeons to undertake the flap repair and in the knowledge of a reduced operative time associated with use of biological mesh, local surgeons who were consulted in reviewing the evidence for this policy, chose the latter option.

3.10 **Complex abdominal wall hernia repair:** A small number of patients with complex abdominal wall hernias, often huge, multiple and recurrent are unsuitable for conventional open or laparoscopic repair using the normal mesh, primarily because they frequently undergo a concurrent bowel operation such as reversal of Hartmann's (re-joining of large bowel following previous emergency surgery and colostomy formation) increasing the risk of infections.

3.11 **Closure of laparostomy:** These are rare operations where biological mesh is used for delayed abdominal closure following an emergency abdominal operation necessitating the leaving of an open abdomen (where primary closure with sutures is not feasible or advisable eg. Following major abdominal trauma or intra-abdominal catastrophe). These patients are often critically ill.

4. Relevant National Guidance and Facts

4.1 There is no national guidance in relation to use of biological or synthetic mesh.

4.2 For use of biological mesh during breast reconstructive surgery: the Association of Breast Surgery (ABS) and the British Association of Plastic, Reconstructive and Aesthetic Surgeons (BAPRAS) published Joint Guidelines for "Acellular Dermal Matrix (ADM) assisted breast reconstruction procedures" in 2012. The guidelines outline the:

- Requirements for ADM assisted implant reconstruction (including MDT agreement)
- Clinical Indications (including immediate, delayed, reconstruction, cancer and risk reduction)
- Patient Selection (including limitations with regard to BMI and breast size)
- Cautions for use (including radiotherapy, smoking status and breast size)
- Quality/audit issues (prospective audit recommended and target standards set)
- Other organisational requirements

These guidelines are being updated during 2020. The guidelines are expected to be a general overview of most recent evidence from a clinical perspective and will be issued nationally. They will cover appropriate clinical indications for the use of ADM and evidence on how to minimise complication rates.

In the meantime, the ABS position on ADM use for IBBRs is that each breast service using these products should obtain fully informed consent from each patient prior to their use and should follow currently published guidelines unless there is a compelling clinical reason not to do so. Outcomes should be regularly audited.

4.3 For use of biological mesh associated with the eLAPE procedure: the National Cancer Action Team supported the establishment of the LOREC (Low Rectal Cancer) National Development Programme. This programme sought to provide training for surgeons in undertaking the eLAPE procedure and set up a "wound registry" to monitor outcomes in terms of wound healing with the different closure methods (one of the concerns following such extensive surgery).

4.4 NICE IPG 654 June 2019 Reinforcement of a permanent stoma with a synthetic or biological mesh to prevent a parastomal hernia. The evidence shows there are serious but well-recognised complications and the procedure should not be used unless special arrangements are in place for clinical governance, consent and audit or research.

5. Evidence Review

5.1. Reconstructive Breast Surgery

The original evidence review in 2013 did not identify any randomised controlled trials for breast reconstruction using ADM but there were a number of systematic/evidence reviews published during 2010/11:

- The systematic review by Ho et al concludes that ADM-assisted breast reconstruction is associated with higher risk of seroma, infection and reconstructive failure compared with prosthetic based reconstruction using traditional musculofascial flaps. ADM assisted reconstruction is associated with a lower rate of capsular contracture.
- The review by Nguyen et al concludes that all perceived advantages of ADM in breast reconstruction are either anecdotal or inconsistent. The only consistent evidence related to a decreased incidence of capsular contracture (but with limited long-term follow-up).

Since these reviews further published studies sought to refine patient selection (breast size, weight) and surgical technique (drain and dressing use) with a view to improving outcomes and have demonstrated at least comparable outcomes to reconstruction without the use of ADM.

In 2014, a UK base National audit of the practice and outcomes of Implant Breast Reconstruction was set up with patient enrolment and data collection to June 2016. The audit aims are to:

1. Define current practice of implant-based breast reconstruction in the UK
2. Evaluate clinical and patient reported outcomes of implant-based breast reconstruction
3. Determine the feasibility of future evaluation in a clinical trial or registry
4. Generate new guidelines for implant-based breast reconstruction iBRA Study Group on behalf of the National Surgical Research Collaborative

A brief evidence update in December 2019 identified the results of the UK based prospective iBRA cohort study and a number of published randomised control trials. Overall the studies presented a mixed picture in relation to the clinical effectiveness, cost effectiveness and safety of ADM within breast reconstruction surgery. It is important to note however that the quality of each study was not critically appraised during the brief evidence update.

Some of the issues raised relate to the complication rates associated with immediate reconstruction vs two-stage reconstruction, regardless of whether mesh is used. Most studies reference that immediate implant-based reconstruction with mesh is widely used both nationally and internationally. In addition, many cite the inherent challenges of conducting high quality and suitably powered randomised controlled trials to investigate this topic.

In 2018, the BMJ published the following article – “Does the addition of mesh improve outcomes in implant based breast reconstruction after mastectomy for breast cancer?”. Whilst published before some of the more recent studies identified above, the article concluded that there remains a “lack of high quality evidence comparing clinical and patient reported outcomes with mesh assisted immediate and traditional breast reconstruction”, with this arising from the low quality of existing evidence due to small studies, methodological limitations and risks of bias. This

article recommended that in light of the uncertainty surrounding this procedure, clinicians should ensure patients are fully informed that:

- there is limited short and long term safety and patient reported outcome data for mesh assisted IBBR
- surgeons may have limited experience with the technique.

5.2. eLAPE reconstructive surgical technique for low rectal cancer

Local review in 2014 of the eLAPE technique found the evidence was not robust enough to support either Abdominoperineal Excision (APE) or Extralevator Abdomino Perineal Excision (eLAPE) over the other. eLAPE had been introduced to practice because it had been thought to lower CRM rates and IOP rates. Increased rates of both CRM and IOP contribute to increased local recurrence rates. This review also raised some concerns about increased perineal wound complications with eLAPE. A further literature review was completed, in 2016, with inclusion of 5 recent meta-analyses comparing APE to eLAPE alongside the LOREC wound registry results.

APE vs eLAPE - Evidence consistently showed lower IOP rates with eLAPE. CRM positivity rates were also reduced with eLAPE, however, this was not statistically significant. Despite this, local recurrence rates were lower with the eLAPE technique than with APE. The time periods for local recurrence were mostly unspecified. Previous concerns of increased perineal wound complications associated with the eLAPE technique have not been confirmed. Current literature shows similar rates of perineal complications (including infection) between both eLAPE and APE techniques. A much stronger association is seen between neoadjuvant radiotherapy and perineal wound problems, independent of the type of surgery performed.

Closure methods (biological mesh vs flap) – Limited evidence is available. It has shown increased late wound morbidity with flap closure compared with both mesh closure and primary closure without mesh. No difference in perineal wound infection rates has been found between the use of biological mesh and flap closure. However, flap closure often requires involvement of a plastic surgical team which creates a higher provider cost and tariff rate.

The 5 meta-analyses used consisted of fairly low quality evidence; one RCT and many observational studies and registries. Randomisation was not used in most of the studies and therefore, the results may have been affected by the clinicians' choice of procedure for each patient. There was not a clear group of patients that were preferentially being allocated to eLAPE. This is likely because there is no formal guidance currently. Prospective RCTs are required in this area especially concerning the use of biological mesh. The BIOPEX study is underway which is aiming to evaluate the effectiveness of biological mesh in eLAPE surgery. Further data is required on the longer term effects (disease free survival rates, overall survival rates and local recurrence rates) of eLAPE.

An update to the policy in 2020 identified the outcomes of the Biopex Study which looked at the effect of biological mesh closure on perineal wound healing after eLAPE. Uncomplicated perineal wound healing rate at 30 days was 66% after primary closure which did not significantly differ from 63% after biological mesh closure. A significantly lower 1 year perineal hernia rate after biological mesh closure was seen as a secondary finding, this needs longer follow-up to determine its clinical relevance.

5.3. **Complex abdominal wall hernia repair and closure of laparostomy**

The evidence for use in the proposed indications is not clear, with too many variables in terms of the patient type and biological mesh used to draw conclusions.

- Many of the studies are retrospective series or prospective uncontrolled studies performed on small cohorts; with methodology poorly described and time to recurrence (for hernias) often missing. There is some evidence of reduced recurrence rates but there is a lack of clarity regarding the distinction between incisional hernias and CAWR within published studies.
- A great number of different meshes have been investigated which somewhat “muddies” the outcomes, as the focus of many of the studies is a comparison of products used. Some studies have investigated different areas of surgical placement. Further the majority of published studies in this area have involved "clean" wounds, yet it is understood that the optimum use of BM would be in an "unclean" environment. All these variations within the literature make it difficult to form any firm conclusions.
- From a number of reviews it does appear that recurrence rates are greater with allograft acellular dermal matrix (eg Alloderm) compared with xenograft type products.
- Porcine acellular dermal matrix (PADM) has been compared with synthetic mesh in a review of a prospective database of all open ventral hernia repairs. The review demonstrated comparable results between the 2 groups (in terms of surgical site infection (SSI), recurrence rates and mesh explanation. The PADM group had a significantly longer length of stay (average 7 days vs 4 days) and were more likely to be readmitted within 90 days of surgery. However the PADM group were clearly higher risk with significantly higher ventral wall hernia grading and higher prior SSI.
- The evidence is not overwhelmingly in support of BM over synthetic mesh, with the majority of studies concluding that further longer term comparative studies are necessary.
- Cumulative data from the “BioMesh Study Group”, composed of invited surgeons with a special interest in surgical meshes, did not support the use of biologic mesh over synthetic mesh. There is an urgent need for high standard comparative studies in well-defined patient populations.

5.4. **Reinforcement of a permanent stoma**

- A review of the literature consisted of 2 systematic reviews and meta-analyses, 3 randomised controlled trials, 2 non-randomised comparative studies and 1 case series. It found that evidence on the efficacy is limited in quantity and quality and that there were serious but well recognised complications.

6. Patient Eligibility

6.1 Breast Reconstruction Surgery

Acellular dermal matrix (biological mesh) will be funded as an exclusion from PbR where all the following circumstances are met:

- For patients with cancer of the breast, ductal carcinoma in situ and those patients identified with the high risk BRCA gene
- For single stage skin sparing mastectomy/reconstruction to avoid the need for a 2 stage operation involving mastectomy and reconstruction
- Identified procedure code B276 - Skin sparing mastectomy mapping to HRG code JA16Z
- Regular audit of outcomes is undertaken in accordance with the recommendations of the joint guidelines of the ABS and BAPRAS; with an absolute requirement for implant loss < 10%
- Fully informed patient consent is obtained prior to use, providing an explanation of available safety and outcome data, and the experience of the surgeon in undertaking the technique
- Other recommendations of national guidelines in relation to breast reconstruction surgery are followed.

These criteria will be reviewed/updated on publication of new evidence in the form of relevant trial data or national audit outcomes.

Reporting requirements and funding arrangements are detailed in Appendix 1.

6.2 eLAPE Reconstructive Surgery for Low Rectal Cancer

Biological mesh for this surgical technique will be funded as an exclusion from PbR where all the following circumstances are met:

- Patient has low rectal cancer with a diagnosis of C19X (rectosigmoid junction) or C20X (rectum)
- Patients with anal cancer diagnosis (C210 or C211) are excluded as NHSE is the responsible commissioner.
- Identified procedure code H331 – Abdominoperineal excision of rectum mapping to HRG FZ08A/B

These criteria will be reviewed/updated on publication of new evidence in the form of relevant trial data or national audit outcomes.

Reporting requirements and funding arrangements are detailed in Appendix 1.

6.3 Complex Abdominal Wall Hernia Repair & Closure of Laparostomy

Given the uncertainties in the literature regarding evidence and circumstances for use, biological mesh for use in complex abdominal wall hernia repair and closure of laparostomy is not funded as a PbR exclusion at the current time.

Further clarification is required in relation to

- when it is appropriate to use BM and how this will be determined ie. which patient types/characteristics.
- when it is considered inappropriate to use synthetic mesh.
- anticipated patient numbers, surgical techniques (including procedure codes) and associated costs by CCG.

6.4 Other indications for use of Biological Mesh

No other indications for use of biological mesh outside of these indications will be funded as a PbR exclusion.

Any identified new indications for use require submission of a new technology request form for consideration by the Clinical Commissioning Policy Collaboration.

6.5 Synthetic Mesh and Synthetic Equivalents

Synthetic mesh does not meet the criteria for consideration as an exclusion from PbR; the costs associated with use are considered to be contained within tariff rates for given procedures. Synthetic mesh will not be funded by commissioners as an exclusion to PbR.

At the current time, Worcestershire CCPC has not received a formal application for use of any synthetic equivalents to biological mesh. Consequently commissioners do not currently provide any funding for synthetic equivalents as an exclusion to PbR.

7. Supporting Documents

- NHS Herefordshire & Worcestershire: Individual Funding Request Operating Procedure
- NHS Herefordshire & Worcestershire: Prioritisation Framework for the Commissioning of Healthcare Services
- WM01 – Ethical Framework
- WM02 – Orphan Drugs
- WM03 – Patients Leaving Industry Sponsored Trials
- WM05 – NICE Guidance
- WM07 – Choice
- WM08 – In Year Service Developments
- WM09 – Individual Funding Requests (to be read with local process document)
- WM10 – Patients Leaving Non Commercially Funded Trials
- WM11 – Patients Leaving a CCG Funded Trial
- WM12 – Patients Changing Responsible Commissioner
- WM13 – NHS Private Interface
- WM14 – Experimental Treatments
- WM15 – Trial of Treatment
- NHS Constitution, updated 27th July 2015
- Worcestershire CCPC: Report to Worcestershire CCG Clinical Executive Teams. Biological Mesh for Use during Surgery. February 2014
- Worcestershire CCPC Report: Review of existing policy for the use of biological mesh during extra-levator abdominoperineal excision of rectum (eLAPE) surgery. July 2016
- Herefordshire and Worcestershire Policy Alignment Task and Finish Group: Brief evidence update – Biological mesh for reconstructive breast surgery. December 2019
- Implant Based Reconstruction Audit: A National Audit of the Practice and Outcomes of Implant Breast Reconstruction. iBRA Study Group on behalf of the National Surgical Research Collaborative. Study Protocol Version 7. 20th March 2014
- NICE IPG 654 June 2019: Reinforcement of a permanent stoma with a synthetic or biological mesh to prevent a parastomal hernia.

8. Appendices

Reporting Requirements and Funding Arrangements

Commissioner funded Biological Mesh as a PbR exclusion

1. Reporting Requirements – All Approved Indications

Date	Purchaser Code	Pseudonymised Patient Number	Gender	Procedure	Procedure Code	Diagnosis Code	HRG Code	Site Name	Mesh Used	Cost of Mesh

This information should be provided quarterly for validation purposes. Without this level of data Commissioners will be unable to authorise charges for biological mesh.

2. Funding Arrangements

Biological mesh will be funded in accordance with surgical requirements and current prices of the most economical product.

3. Additional points to note:

- The Provider will notify the Commissioner if expenditure forecasts suggest expenditure to be >10% of planned levels; investigating these to reduce CCG financial risk.
- Where the chosen biological mesh of animal origin is considered to be unacceptable for a patient because of their religion/belief, an alternative, acceptable biological mesh product should be sourced and will be funded by commissioners where they meet the defined criteria for funding.

9. Equality Impact Assessment

Equality Statement

9.1. All public bodies have a statutory duty under the Equality Act 2010 to set out arrangements to assess and consult on how their policies and functions impact on race equality. This obligation has been increased to include equality and human rights with regard to disability, age, gender, sexual orientation, gender reassignment and religion.

9.2. HWCCG endeavours to challenge discrimination, promote equality, respect human rights, and aims to design and implement services, policies and measures that meet the diverse needs of our service, and population, ensuring that none are placed at a disadvantage over others.

9.3. All staff are expected to deliver services and provide care in a manner which respects the individuality of patients and their Carer's and as such treat them and members of the workforce respectfully, regardless of age, gender, race, ethnicity, religion/belief, disability and sexual orientation.

9.4. Providers are expected to use the appropriate interpreting, translating or preferred method of communication for those who have language and/or other communication needs. CCG staff and Providers will need to assess that the policy is applied fairly and equitably for all groups covered under the Equality Act 2010 and that they are implementing the Accessible Information Standard and have considered health inequalities.

9.5. HWCCG must meet its statutory duty to reduce inequalities of access and outcomes, as set out in the NHS Act 2006 (as amended). As a result, the CCG aims to design and implement policy documents that seek to reduce any inequalities that already arise or may arise from any new policy. Therefore, the CCG will consciously consider the extent to which any policy reduces inequalities of access and outcomes.

9.6. Any change to this policy will require a conscious effort from the HWCCG to actively consider the impact that this will have on any Protected group(s) and act due diligently. Where an impact on any of the Equality groups is realised after the implementation of this policy, HWCCG and the Providers, will seek to minimise such an impact and simultaneously carry out a full review.

9.7. HWCCG aims to design and implement policy documents that meet the diverse needs of our services, population and workforce, ensuring that none are placed at a disadvantage over others. It takes into account current UK legislative requirements, including the Equality Act 2010 and the Human Rights Act 1998, and promotes equal opportunities for all. This document has been designed to ensure that no-one

receives less favourable treatment due to their personal circumstances, i.e. the protected characteristics of their age, disability, sex, gender reassignment, sexual orientation, marriage and civil partnership, race, religion or belief, pregnancy and maternity. Appropriate consideration has also been given to gender identity, socio-economic status, immigration status and the principles of the Human Rights Act.

Organisation	NHS Herefordshire & Worcestershire Clinical Commissioning Group		
Department	Contracting	Name of lead person	Fiona Bates and Helen Bryant
Name of Policy being assessed	Funding Arrangements for Biological and Synthetic Mesh		
Aims of this Policy	To identify when it is appropriate to fund biological mesh outside of PbR		
Date of EIA	07/02/2014, 24/10/2016 Updated May 2021	Other partners/stakeholders involved	Herefordshire & Worcestershire Policy Alignment Task & Finish Group Clinical Commissioning Policy Collaborative (CCPC)
Who will be affected by this Policy?	Patients and Surgeons wishing to use Mesh		
Did the Policy require Engagement or Consultation?	No		

Equality Group	**Potential Positive Impact**	**Potential Neutral Impact**	**Potential Negative Impact**	**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**
Age	Y			The risk of breast cancer increases with age and therefore this intervention is more likely to be offered to older women but is available to women of any age who fulfil the criteria. Low rectal cancer also occurs more commonly later in life with the majority diagnosed over the age of 50.

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Disability		Y		The policy provides guidance on the clinical presentation of an individual who should be considered for NHS funded surgery including biological or a synthetic equivalent mesh. The decision to treat should not be impacted on by the fact that the individual has a disability.
Gender Reassignment		Y		The policy provides guidance on the clinical presentation of an individual who should be considered for NHS funded surgery including biological or a synthetic equivalent mesh. The decision to treat should not be impacted on by the fact that the individual has entered onto (or completed, at any stage) an NHS funded Gender Reassignment treatment pathway.
Marriage & Civil Partnerships		Y		The policy provides guidance on the clinical presentation of an individual who should be considered for NHS funded surgery including biological or a synthetic equivalent mesh. The decision to treat should not be impacted on by the fact that the individual is married or is within a civil partnership.
Pregnancy & Maternity		Y		The policy provides guidance on the clinical presentation of an individual who should be considered for NHS funded surgery including biological or a synthetic equivalent mesh. The decision to treat may be impacted by the fact that the individual is pregnant, but that would be a clinical decision made by the treating specialist and should be discussed as part of the consultation.
Race including Travelling Communities		Y		The policy provides guidance on the clinical presentation of an individual who should be considered for NHS funded surgery including biological or a synthetic equivalent mesh. The decision to treat should not be impacted on by which race or community the patient is part of. It is important to note that, should a biological mesh be considered most appropriate to aid in the surgical treatment of an individual, and that mesh be unacceptable for use as part of that individual's culture, then an alternative source should be identified and funded.
Religion & Belief	Y			Biological mesh is often from animal origin. The product used locally is denatured pig intestine and has been accepted for use by the Muslim Council, this is referenced in a

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				document produced by the World Health Organisation in July 2001. Anecdotal reports from requests for use via local rabbi suggest that the Jewish Community also accept use of this product. There is no evidence supporting use in the Rastafarian community. Should the chosen biological mesh be unacceptable for use because of a patients religion/belief an alternative product would be sourced and funded that is acceptable to the patient.
Sex	Y			The indication for breast reconstruction relates to females only Low rectal cancer occurs in both males and females; the difference that occurs relates to the extent of surgery undertaken which is influenced by the lower anatomy and presence of pelvic floor in a female. This warrants using a larger piece of mesh in females over males.
Sexual Orientation		Y		The policy provides guidance on the clinical presentation of an individual who should be considered for NHS funded surgery including biological or a synthetic equivalent mesh. The decision to treat should not be impacted on by the individual's sexual orientation.
Carers		Y		The policy provides guidance on the clinical presentation of an individual who should be considered for NHS funded surgery including biological or a synthetic equivalent mesh. The decision to treat should not be impacted on by whether the individual is a carer.
Care Leavers		Y		The policy provides guidance on the clinical presentation of an individual who should be considered for NHS funded surgery including biological or a synthetic equivalent mesh. The decision to treat should not be impacted on by whether the individual is a care leaver.
Homeless	Y			This is linked to socio/economic deprivation, which is detailed below.
Socio/Economic Deprivation	Y			There are associations between social deprivation and risk factors for all cancers and thus it is possible that patients from socially deprived backgrounds are more likely to require access.
Other Vulnerable and Disadvantaged Groups		Y		The CCG is not aware of any other vulnerable and disadvantaged groups that are not already covered by other equality groups identified within the EIA.

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				However, the policy provides guidance on the clinical presentation of an individual who should be considered for NHS funded surgery including biological or a synthetic equivalent mesh, their clinical presentation should be the deciding factor in use of mesh within a surgical procedure.
Health Inequalities		Y		In producing the policy, the commissioner's intention was to provide clear clinical information to patients and their responsible clinician, therefore improving the option for equitable access to treatment for clinically eligible patients.
Does this policy impact on an individual's Human Rights?		Y		The CCG policy does not seek to impact on an individual's human rights.

Equality Impact Assessment Action Plan

Equality Group	Risk Identified	Action required to reduce/eliminate negative impact	How will you measure the outcome/impact	Timescale	Lead
Sex	Breast reconstruction in females	Whilst breast cancer is not exclusive to females, it rarely occurs in males and where it does, males would not require reconstruction and would not therefore need use of biological mesh – no action	-	-	-
	eLAPE surgery for low rectal cancer	Differential funding according to size of biological mesh required linked to gender anatomy – no action, all receive mesh required	-	-	-
Age	Breast cancer Low rectal cancer	Occurs more frequently with increasing age but biological mesh is available to all within scope of policy.	-	-	-
Socio/Economic Deprivation Homelessness	Cancer	Social deprivation increases the risk factors associated with cancer and may influence those presenting. Nevertheless this does not affect who can access use of biological mesh within the scope of the policy.	-	-	-