Commissioning Policy

Funding Arrangements for Use of Biological and Synthetic Mesh/Equivalents

February 2014

This commissioning policy has been endorsed by and applies to patients within:
NHS Redditch & Bromsgrove Clinical Commissioning Group (CCG)
NHS South Worcestershire Clinical Commissioning Group (CCG)
NHS Wyre Forest Clinical Commissioning Group (CCG)

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Equality & Diversity Impact Assessment	February 2014

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Circulated to the following individuals/groups for comments

Name	Designation
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Review and Amendment Log

Version No	Type of Change	Date	Description of change

Table of Contents

SUMMARY

Following a review of the evidence and consideration of the local circumstances for use, Worcestershire Clinical Commissioning Groups **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 AbdominoPerineal 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.

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

- Biological mesh when used for complex abdominal wall hernia repair or closure of laparostomy, until further clarity is provided with respect to patient type, surgical techniques and procedure codes.
- 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 Worcestershire Clinical Commissioning Policy Collaborative.

* Synthetic mesh does not meet the criteria for consideration as an exclusion from PbR; the costs associated with use are therefore contained within tariff rates for given procedures.
**This wording included within 2014/15 PbR exclusions is intended to allow for the possibility that there are synthetic materials in use which may represent a similar disproportionate cost as biological mesh.

1. Definitions

1.1 **Exceptional clinical circumstances** are clinical circumstances pertaining to a particular patient, which can properly be described as exceptional. This will usually involve a comparison with other patients with the same clinical condition and at the same stage of development of that clinical condition and refer to features of the particular patient which make that patient out of the ordinary, unusual or special compared to other patients in that cohort. It can also refer to a clinical condition which is so rare that the clinical condition can, in itself, be considered exceptional. That will only usually be the case if the NHS commissioning body has no policy which provides for the treatment to be provided to patients with that rare medical condition.

1.2 *A* **Similar Patient** refers to the existence of a patient within the patient population 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. When the treatment meets the regional criteria for supra-CCG policy making, then the similar patient may be in another CCG with which the Primary Care Trust collaborates. The existence of one or more similar patients indicates that a policy position is required of the Primary Care Trust.

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 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 Primary Care Trust agrees to fund outside of the annual commissioning round. 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 should be considered in line with all other Worcestershire 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 relates to use of biological and synthetic mesh and equivalents during identified surgery undertaken at all provider trusts.

2.3 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.

2.4 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.

2.5 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.

2.6 Beyond the four indications 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. NHS principles have been applied in the agreement of this policy.

3.2. 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.

3.3. 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."

3.4. 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.

3.5. 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.

3.6. **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. 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%.

3.7. **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.

3.8. **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.

3.9. **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) have published Joint Guidelines for "Acellular Dermal Matrix (ADM) assisted breast reconstruction procedures". 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

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).

5. Evidence for Use

5.1. Reconstructive Breast Surgery

There are no randomised controlled trials for breast reconstruction using ADM but there have been a number of systematic/evidence reviews undertaken 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 there has been further evidence published; these studies have 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.

5.2. eLAPE reconstructive surgical technique for low rectal cancer

The evidence is not sufficiently robust to support either one surgical technique over another or one closure method over another.

eLAPE vs APE - Standard abdominoperineal excision (APE) of the rectum and anus for low rectal cancer is associated with a higher rate of circumferential resection margin (CRM) involvement and intraoperative perforation (IOP), leading to higher local disease recurrence rates and potentially poorer survival, compared with anterior resection for higher rectal tumours. A change to operative surgery has been recommended and investigated in the form of observational studies and case-controlled studies. These studies, although limited have demonstrated comparable short term outcomes (30-day complications, re-admission and length of stay) and quality of life. In addition eLAPE has been associated with less CRM involvement and IOP than standard surgery, although it appears there could be increased perineal wound complications. However there is no direct evidence that eLAPE improves longer term outcomes in terms of survival.

Closure method for eLAPE ie. flap vs BM - There are no randomised controlled trials but 2 systematic reviews involving small comparative trials and cohort studies have been identified. It is unclear in terms of outcomes from the available evidence whether flap or biological mesh is the optimum closure method; the main concern within the literature relates to increased wound complications and subsequent use of additional healing aids eg. vacuum assisted closure. It is uncertain whether this relates to eLAPE procedure generally or one or both of the wound closure methods reported. It is hoped that the LOREC wound registry will provide further clarity on this when it reports in 2015.

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 explantation. 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.

6. Commissioning Policy

6.1 NHS Redditch & Bromsgrove Clinical Commissioning Group, NHS South Worcestershire Clinical Commissioning Group and NHS Wyre Forest Clinical Commissioning Group (termed "the Commissioners") consider all lives of all patients whom it serves 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 the patient's clinical condition or is related to the anticipated benefits to be derived from a proposed form of treatment.

6.2 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%.
- Other recommendations of the joint guidelines 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.

6.3 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
- Regular audit of outcomes is undertaken, including participation in the LOREC wound registry.

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.

6.4 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.

6.5 Other indications for use of Biological Mesh

No other indications for use of biological mesh outwith 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.

6.6 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, it is not apparent that there are any synthetic equivalents to biological mesh in use in Worcestershire. Consequently commissioners will not provide any funding for synthetic equivalents as an exclusion to PbR.

7. Clinically Exceptional Circumstances

6.1 If there is demonstrable evidence of a patient's clinically exceptional circumstances, the referring practitioner should refer to the Commissioner's "Operational Policy for Individual Funding Requests" document for further guidance on the process for consideration.

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

8. References

- CCPC: Report to Worcestershire CCG Clinical Executive Teams. Biological Mesh for Use during Surgery. February 2014

9. Documents Which Have Informed This Policy

- Worcestershire CCGs: Operational Policy for Individual Funding Requests
- Worcestershire CCGs: Prioritisation Framework for the Commissioning of Healthcare Services
- West Midlands Strategic Group Commissioning Policy 1: Guiding principles and considerations to underpin priority setting and resource allocation within collaborative commissioning arrangements
- West Midlands Strategic Group Commissioning Policy 4: Use of cost-effectiveness, value for money and cost effectiveness thresholds
- West Midlands Strategic Group Commissioning Policy 16: Prior Approval
- West Midlands Strategic Group Commissioning Policy 9: Individual funding requests

Appendix 1

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 (currently Biodesign)*:

Breast Reconstruction	Biodesign 6-layer tissue graft		7 x 20cm	£625 + VAT per breast	equating to £750 per breast
eLAPE surgical procedure	Biodesign Hernia Graft	male	10 x 10cm	£780 + VAT	equating to £936
		female	13 x 15cm	£1,550 + VAT	equating to £1,860

* Subject to price or product choice change. This requires discussion with commissioners in advance of any changes made.

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.
- There is currently no activity involving use of biological mesh provided at The Alexandra Hospital, Redditch. Commissioners require a minimum period of 3 months' notice if this situation is likely to change.
- Procedure codes identified are not exclusive to use of biological mesh.
- 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.

NHS Redditch and Bromsgrove Clinical Commissioning Group

NHS South Worcestershire Clinical Commissioning Group

NHS Wyre Forest Clinical Commissioning Group

Equality Impact Assessment

Organisation: Worcestershire Clinical Commissioning Groups

Department: Commissioning

Name of lead person: Fiona Bates

Piece of work being assessed: Funding Arrangements for Biological and Synthetic mesh

Aims of this piece of work: To identify when it is appropriate to fund biological mesh outside of PbR

Date of EIA: 7/2/2014

Other partners/stakeholders involved: WHAT, Public Health

Who will be affected by this piece of work? Patients and Surgeons

Single Equality Scheme Strand	**Baseline data and research on the population that this piece of work will affect.** What is available? Eg 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	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.	Yes Yes
Race	No issues	No
Disability	No issues	No
Religion/ belief	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 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.	No
Sexual orientation	No issues	No
Age	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.	Yes Yes
Social deprivation	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.	Yes
Carers	No issues	
Human rights	Will this piece of work affect anyone's human rights?	No

Equality Impact Assessment Action Plan

Strand	Issue	Action required	How will you measure the outcome/impact	Timescale	Lead
Gender	Breast reconstruction in females eLAPE surgery for low rectal cancer	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 Differential funding according to size of biological mesh required linked to gender anatomy – no action, all receive mesh required	N/A N/A	- -	- -
Age	Breast cancer Low rectal cancer	Occurs more frequently with increasing age but biological mesh is available to all within scope of policy.	N/A	-	-
Social Deprivation	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.	N/A	-	-