### Treatment
The use of Biological and Synthetic Mesh/Equivalents in surgery

### Indication
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.

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.

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.

### Background
Biological Mesh is currently 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 £8,500 per patient, depending on intended use, size of wound and product choice. All items listed as PbR exclusions are subject to locally agree payments taking into consideration existing tariff charges.

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.

University Hospital Coventry and Warwickshire (UHCW) reported use of biological mesh in the following areas and requested funding from Commissioners:
- reconstructive breast surgery
Coventry and Rugby Clinical Commissioning Group

Mesh policy

June 2016

- eLAPE reconstructive surgical technique for low rectal cancer
- complex and recurrent hernia repairs
- stoma creation and closure
- complex colorectal surgical procedures

Commissioning position

Following a review of the evidence and consideration of the local circumstances for use, Coventry and Rugby 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 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.

Coventry and Rugby Clinical Commissioning Group 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.
- 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 Individual Funding Request for consideration

* 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 2015/16 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.

Documents which have informed this policy

1. Worcestershire CCGs’ Commissioning Policy on Funding Arrangements for Use of Biological and Synthetic Mesh/Equivalents
2. Thames Valley Priorities Committee Commissioning Policy Statement. Policy No. 255 (TVPC 14) Biological Mesh
3. Thames Valley Priorities Committee policy proposal: Biological Mesh

References

- Literature Review: WCC 2016: The Use of Biological Mesh in Abdominal Hernia repair

Equality Impact

See EIA attached
## VERSION CONTROL

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<tr>
<td>Date ratified</td>
<td>13th July 2016</td>
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<td>Name of originator/author</td>
<td>Joint CCG Clinical Commissioning Policy Development Group</td>
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<td>14th July 2016</td>
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<td>Review date</td>
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**EQUALITY ANALYSIS FORM**

<table>
<thead>
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<th>TITLE (service/ plan/ project/ policy/ decision):</th>
<th>The use of Biological and Synthetic Mesh/Equivalents in surgery</th>
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<tr>
<td>AUTHOR / LEAD:</td>
<td>EIA Lead</td>
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<tr>
<td>DATE ANALYSIS UNDERTAKEN:</td>
<td>June 2016</td>
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**STAGE 1: SCREENING FOR ADVERSE IMPACTS (X PLEASE CHECK):**

<table>
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<th>Age</th>
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<tr>
<td>Sexual Orientation</td>
<td>Carers (inc. young carer’s)</td>
<td>Sex (men &amp; women)</td>
<td>Gender Reassignment/ Transgender</td>
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<td>Race/ Ethnicity</td>
<td>Pregnancy, Maternity, Perinatal</td>
<td>Multiple Social Deprivation</td>
<td>Human Rights (FREDA) fairness, respect, equality, dignity &amp; autonomy</td>
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**Describe any potential or known adverse impacts or barriers for protected/ vulnerable groups:** (if there are no known adverse impacts, please state who has been involved in the screening and explain how you have reached this conclusion, then move to Stage 6 sign off)

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Since CCGs operate within finite budgetary constraints the policy detailed in this document make explicit the need for the CCG to prioritise resources and provide interventions with the greatest proven health gain.
The intention is to ensure equity and fairness in respect of access to NHS funding for interventions and to ensure that interventions are provided within the context of the needs of the overall population and the evidence of clinical and cost effectiveness.

The impact of this policy has been considered against all protected characteristics and human rights principles; the review identified the protected characteristics of age (particularly older people, though not limited to) and disability as most likely to be affected by the policy. No restrictions in terms of age were identified in the policy review. The policy provides a consistent clinically based criteria for decision making, benefitting patients within the CCG area by providing consistency and equity of service provision. The policy provides an avenue through the 'Individual Funding Requests' policy to seek funding in exceptional clinical circumstances. No potential or known adverse impacts or barriers for protected and/or vulnerable groups were identified.

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<th>ROLE</th>
<th>NAME</th>
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<tr>
<td>Chief Clinical Officer</td>
<td>Steve Allen</td>
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Guidance:

A summary guidance sheet can be found overleaf.
### STAGE 1: Screening
This stage involves an initial analysis of any adverse impacts or potential adverse impacts for protected groups. The author should draw on their knowledge and experience of the service/plan/policy/project decision and the people that are affected. It is therefore beneficial to seek the views of a range of people at this early stage. E.g. you may wish to involve the E&D Manager or relevant working group. You should consider the following when undertaking screening:

- Is there a higher prevalence of any group(s) in relation to the prevalent conditions?
- Are there any concerns about the participation of any group(s) in the service or any aspect of the service?
- Are there any known barriers or potential barriers to access for any group?

You will need to record your explanation of any adverse impacts or no impacts. If adverse impacts or potential adverse impacts are identified you will need to complete the rest of the impact assessment. Defining the scope of your Equality Analysis (EA) will help to establish the specific aspects of the service/plan/policy/project decision that require further examination.

*seeing things through an equality lens*

### STAGE 2: Data and Information
This stage involves looking at the available data for the service/plan/policy/project decision and any of the equality groups that have been identified. It is known that equality data may be limited so it is acceptable to use proxy data. The following quantitative and qualitative data and feedback can be used:

- Joint Strategic Needs Assessment
- National data/trends
- Integrated Plan
- LCN Profile Data Sets
- Existing equality consultation feedback
- Service participation and outcomes data
- Patient feedback
- Complaints
- Public involvement feedback
- Demographic profile data
- Service reviews and QOF data

New consultation is not always necessary, especially when there is existing feedback from target groups. Speak to the Public Involvement Team and the E&D manager about any existing consultation feedback. Record the findings of your analysis of data, information, and feedback and what it has told you about the service and how it can be improved for the adversely impacted groups. Be succinct - use bullet points if you can. Attach any additional information to the EA or record in the Supplementary Notes section below.

### STAGE 3: Critical Challenge
This stage asks you to critically consider the service/plan/policy/project decision and how equality considerations are being taken into account. Some of the questions may not be applicable.

If the assessment relates to a commissioned service consider whether any improvements can be made through the design of the service or monitoring of the contract.

Record any explanations or evidence in relation to your response.

### STAGE 4: Changes
This stage asks you to record any changes you will make to the service design/plan/policy/project decision to improve access for the adversely impacted group(s), and outcomes for patients and the patient experience. This may include enhancements to existing care pathways or protocols for how things are done. Any changes should be realistic and feasible.

ANY CHANGES NEED TO BE REFLECTED IN THE DOCUMENTED SPECIFICATION / POLICY / PLAN

### STAGE 5: Monitoring and Evaluation
This stage asks you to consider how the changes that have been identified will be monitored in the contract/plan/policy. Specifically state what will be recorded in the contract/plan/policy and whether there is any associated key performance indicator. How will you know the change or proposals are working?

### STAGE 6: Sign-Off
The completed Equality Analysis form should be sent to the Equality and Diversity manager for Sign-off, and then presented to the appropriate Chief Officer/Governing Body Member, and where relevant the Business Case Panel.