

# HTG10165 Surgical mesh for treatment of non-primary ventral hernias – Existing Use Assessment

## Final Protocol

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Protocol of Peninsula Technology Assessment Group (PenTAG; University of Exeter)  
External Assessment Group who are assessing [Surgical mesh for treatment of primary  
ventral hernia \(GID-HTE10080\)](#) in parallel.

# 1. Decision problem

Table 1 summarises the decision problem to be addressed in this assessment. Further detail on each element can be found in the published scope for the assessment.

**Table 1. Summary table of the decision problem**

Item	Description	EAG comments
<b>Population(s)</b>	<p>Use of surgical mesh for repair of non-primary hernias in adults. If evidence is available, the following subgroups will be considered:</p> <ul style="list-style-type: none"> <li>• Type of non-primary hernia:               <ul style="list-style-type: none"> <li>○ Incisional</li> <li>○ Parastomal</li> </ul> </li> <li>• Contamination status (e.g. VHWG grades 1,2 and 3)</li> <li>• Surgical urgency:               <ul style="list-style-type: none"> <li>○ Elective surgery</li> <li>○ Emergency surgery</li> </ul> </li> </ul>	<p>Evidence exclusively in primary hernia will be summarised in <a href="#">HTE10080</a>. The EAG may apply a threshold to evidence in a mixed population (primary and non-primary) to determine which assessment they are most relevant to.</p> <p>Due to potential differences in outcomes, the EAG may consider evidence separately for laparoscopic, robotic and open procedures, if evidence permits.</p>
<b>Intervention(s)</b>	<p>Surgical mesh for ventral hernia available for purchase in the NHS including:</p> <ul style="list-style-type: none"> <li>• Synthetic mesh</li> <li>• Biological mesh</li> <li>• Hybrid mesh</li> </ul> <p>These surgical meshes should meet basic technology requirements and have one or more additional or innovative features.</p>	<p>21 manufacturers are listed on <a href="#">NHS Supply Chain (Appendix A)</a>. On NHS Supply Chain the mesh divided into 4 product categories: synthetic mesh, biological mesh, specialist mesh, fixation devices; the EAG assume that fixation devices are not within the scope of this assessment. NICE will check with each manufacturer whether each surgical mesh is indicated for non-primary ventral hernia.</p> <p>A list of key features (and definitions) was discussed with experts at the scoping workshop. NICE will request that companies classify the features for each of their mesh products available on NHS Supply Chain. At the scoping workshop key clinical outcomes of recurrence, infection and pain were identified. The EAG will liaise with clinical experts to determine</p>

		<p>which innovative features contribute to those outcomes. This approach is consistent with the approach applied to other existing use assessments (formerly known as late stage assessment, for example <a href="#">bed frames for adults in acute settings, HTG759</a>)</p>
<b>Comparators</b>	<p>Comparisons may be made between interventions. Comparators will be considered relevant to the assessment if the value of innovative features is able to be assessed.</p>	<p>The EAG may consider the most appropriate mesh comparator for each subgroup as appropriate, for example the one most frequently used.</p>
<b>Setting</b>	<p>Secondary or tertiary care setting</p>	
<b>Outcomes eligible for inclusion</b> (organised by outcome type)	<p>Intermediate outcomes:</p> <ul style="list-style-type: none"> <li>• Postoperative pain</li> <li>• Postoperative complications</li> <li>• Readmission within 30 to 90 days</li> <li>• Time to return to normal activities</li> </ul> <p>Clinical outcomes:</p> <ul style="list-style-type: none"> <li>• Surgical site occurrence (SSO) <ul style="list-style-type: none"> <li>○ Surgical site infection</li> <li>○ Seroma</li> <li>○ Hematoma</li> <li>○ Wound dehiscence</li> <li>○ Skin or soft tissue necrosis</li> <li>○ Cellulitis</li> <li>○ Chronic wound</li> </ul> </li> <li>• Hernia recurrence</li> <li>• Mesh related complications: <ul style="list-style-type: none"> <li>○ Mesh infection</li> <li>○ Chronic pain</li> <li>○ Chronic foreign body sensation</li> </ul> </li> </ul>	<p>The EAG may work with clinical experts, the NICE team, stakeholder and the teams involved with the concurrent assessment for surgical mesh for primary ventral hernias (HTE10080) to identify key outcomes.</p>

	<ul style="list-style-type: none"> <li>○ Mesh migration</li> <li>○ Mesh shrinkage or contraction</li> <li>○ Mesh failure</li> <li>○ Erosion into bowel or other organs</li> <li>○ Fistula formation</li> <li>○ Adhesion to bowel</li> </ul> <ul style="list-style-type: none"> <li>● Long term morbidity</li> <li>● Bowel function</li> <li>● Sexual function (e.g. pain during sex)</li> <li>● Fertility outcomes</li> <li>● Reoperation or reintervention</li> <li>● Ileus/bowel obstruction</li> </ul> <p>Patient-reported outcomes:</p> <ul style="list-style-type: none"> <li>● Health-related quality of life</li> <li>● Pain and discomfort</li> <li>● Numbness</li> <li>● Impact on mental health</li> <li>● Satisfaction</li> <li>● Body image</li> <li>● Cosmetic outcome</li> <li>● Impact on daily life</li> </ul> <p>Cost and resource use:</p> <ul style="list-style-type: none"> <li>● Cost of surgical mesh</li> <li>● Cost of fixation materials</li> <li>● Staff training cost</li> <li>● Imaging cost</li> <li>● Operating room time including staff time and anaesthesia cost</li> <li>● Cost of surgical approach</li> <li>● Hospitalisation and perioperative resource use (length of hospital stay, readmission rates, emergency department)</li> </ul>	
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	<p>visit, medication and postoperative imaging)</p> <ul style="list-style-type: none"> <li>• Cost of treating mesh related complication including treatment of SSI or SSO, infection, mesh removal, management of adhesion or erosion</li> <li>• Cost of treating recurrence</li> <li>• Monitoring costs and follow-up visits</li> </ul> <p>User preference and non-clinical outcome measures will be based on the prioritisation of outcomes as part of the user preference assessment.</p>	
<p><b>Economic analysis</b></p>	<p>A health economic model will be developed comprising a cost utility or cost-comparison analysis. Costs will be considered from an NHS and Personal Social Services perspective.</p> <p>Sensitivity and scenario analysis should be undertaken to address the relative effect of parameter or structural uncertainty on results.</p> <p>The time horizon should be long enough to reflect all important differences in costs or outcomes between the technologies being compared.</p>	

## 1.1 Objectives

The purpose of this assessment is to identify evidence for the effectiveness of innovative features of surgical mesh for non-primary ventral hernia repair in the NHS to identify which features are associated with benefits and provide value for money for the NHS. The outcome of this assessment may support NHS procurement and commission decisions. This assessment will try to address the following research questions:

- Do differences in clinical and cost-effectiveness between alternative surgical meshes for treatment of non-primary hernias justify the price variation?
- Are there other factors that can inform decisions about which surgical mesh to purchase?

The assessment will include a systematic search for published evidence that enables evaluation of the efficacy or effectiveness of additional or innovative features of (above that of standard) surgical mesh. Where available, this may be supplemented by real-world evidence sources and evidence provided by the companies. Evidence that is relevant to the decision problem for this assessment (that is it represents the relevant population, interventions, outcomes, settings and is considered of suitable quality) will be extracted and appraised by the EAG. The EAG will also develop an economic model to provide an assessment of the cost-effectiveness of the features of the technologies in scope. The EAG will undertake a User Preference Assessment to determine what other factors inform decision-making about the technology or technologies to use. The findings of this assessment are intended to be used by adults having non-primary ventral hernia repair, healthcare professionals supporting them, and commissioners, to inform decisions about the procurement and selection of surgical mesh in practice.

The EAG acknowledges the [Existing Use Assessment for surgical mesh for treatment of primary ventral hernias \(HTE10080\)](#) is ongoing at the time of this assessment for primary ventral hernias. The EAG may consider collaborative approaches with NICE and other EAG(s) to ensure that conclusions are complementary, streamlined and beneficial for committee decision-making. For example, where innovative features are agreed and defined in collaboration with experts, the EAG will consider alignment for this assessment across topics, or data pooling across some outcomes.

## **2. Technology**

NICE will review the list of hernia mesh technologies identified from the [Existing Use Assessment for surgical mesh for treatment of primary ventral hernias \(HTE10080\)](#)

topic and will check with each manufacturer that they can be used in non-primary (incisional or parastomal) hernia.

The EAG will review the standard request for information forms and instructions for use submitted by each company to NICE for each technology within scope to develop a technology summary. Due to the volume of mesh products available, a matrix of innovative features will only be generated for meshes which can be used in non-primary hernia where comparative evidence has been identified (see section 3 evidence review). Any missing or incomplete information may be supplemented by information found in the public domain, for example from company websites, as appropriate. To try and ensure that guidance reflects on-label product use, indications and contraindications listed in each technology's instructions for use will be considered and any evidence identified which has been undertaken in a contraindicated population (either exclusively or where results are reported for a mixed population) will be excluded by the EAG. The EAG will summarise information on each technology using information provided by the Companies, company website and information held in the public domain (for example, NHS Supply Chain). Technology summary tables may be sent to each company for review to ensure accuracy of content. The EAG will create a matrix outlining the proposed mechanism of action through which each mesh feature is expected to influence the outcomes of interest will be developed and validated by clinical experts. This matrix will be used to aid understanding of the relationship between additional features and their estimated impact on quality of life and costs.

### **3. Evidence review methods**

The purpose of the evidence review is to identify the most relevant evidence relating to the decision problem. The EAG will use methods in line with the [NICE HealthTech programme manual](#). The EAG will conduct 3 literature searches that will aim to identify relevant 1) systematic reviews, 2) clinical evidence, and 3) economic evaluations of surgical mesh and innovative features for treating non-primary hernias. To focus on evidence that is most relevant to the decision problem, each literature search will have an appropriate filter applied. The EAG will consider use of digital tools to rank studies in order of relevance to minimise the chances of missing a relevant study within a broader literature search of studies with non-controlled

comparative design. The EAG may prioritise key studies, based on the hierarchy of evidence, date or sample size or other classification method, and outcomes as guided by advice from clinical experts, where appropriate.

Systematic literature searches conducted by the EAG will be supplemented by information provided by the companies. The EAG will consider including unpublished comparative studies provided by the Companies, provided they meet the decision problem and other eligibility criteria outlined within this protocol. Any studies submitted by Companies which are excluded by the EAG will have reasons for exclusion documented in the EAG report.

The EAG may also consider any non-primary hernia mesh evidence excluded from the primary hernia topic and noted to be of potential relevance to this topic.

### **Inclusion criteria**

The inclusion and exclusion criteria for the clinical evidence are outlined in Table 2. These criteria have been informed by the NICE scope, discussion with the NICE team, feedback from stakeholders to this assessment given in the scoping workshop. Furthermore, feedback from the NICE team, EAG and stakeholders involved in the coinciding topic involving surgical mesh for primary hernias has been considered in the approach to the evidence base. The EAG may liaise with clinical and patient experts to prioritise the list outcomes prior to data extraction.

**Table 2. Inclusion and exclusion criteria**

	Inclusion Criteria	Exclusion Criteria
Population	Use of surgical mesh for repair of non-primary hernias in adults.	Primary ventral hernia repair, other hernia sites.
Intervention	<p>Surgical mesh for ventral hernia available for purchase in the NHS including:</p> <ul style="list-style-type: none"> <li>• Synthetic mesh</li> <li>• Biological mesh</li> <li>• Hybrid mesh</li> </ul> <p>These surgical meshes should meet basic technology requirements and have one or more additional or innovative features.</p>	Mesh not available for purchase on NHS Supply Chain.

	Inclusion Criteria	Exclusion Criteria
Comparators	Comparisons may be made between interventions. Comparators will be considered relevant to the assessment if the value of innovative features is able to be assessed.	Mesh not available for purchase on NHS Supply Chain.
Setting	Secondary and tertiary care settings.	None.
Outcomes	<p>Intermediate outcomes:</p> <ul style="list-style-type: none"> <li>• Postoperative pain</li> <li>• Postoperative complications</li> <li>• Readmission within 30 to 90 days</li> <li>• Time to return to normal activities</li> </ul> <p>Clinical outcomes:</p> <ul style="list-style-type: none"> <li>• Surgical site occurrence (SSO) <ul style="list-style-type: none"> <li>○ Surgical site infection</li> <li>○ Seroma</li> <li>○ Hematoma</li> <li>○ Wound dehiscence</li> <li>○ Skin or soft tissue necrosis</li> <li>○ Cellulitis</li> <li>○ Chronic wound</li> </ul> </li> <li>• Hernia recurrence</li> <li>• Mesh related complications: <ul style="list-style-type: none"> <li>○ Mesh infection</li> <li>○ Chronic pain</li> <li>○ Chronic foreign body sensation</li> <li>○ Mesh migration</li> <li>○ Mesh shrinkage or contraction</li> <li>○ Mesh failure</li> <li>○ Erosion into bowel or other organs</li> </ul> </li> </ul>	Studies not reporting any outcomes in scope.

	Inclusion Criteria	Exclusion Criteria
	<ul style="list-style-type: none"> <li>○ Fistula formation</li> <li>○ Adhesion to bowel</li> <li>● Long term morbidity</li> <li>● Bowel function</li> <li>● Sexual function (e.g. pain during sex)</li> <li>● Fertility outcomes</li> <li>● Reoperation or reintervention</li> <li>● Ileus/bowel obstruction</li> </ul> <p>Patient-reported outcomes:</p> <ul style="list-style-type: none"> <li>● Health-related quality of life</li> <li>● Pain and discomfort</li> <li>● Numbness</li> <li>● Impact on mental health</li> <li>● Satisfaction</li> <li>● Body image</li> <li>● Cosmetic outcome</li> <li>● Impact on daily life</li> </ul> <p>Cost and resource use:</p> <ul style="list-style-type: none"> <li>● Cost of surgical mesh</li> <li>● Cost of fixation materials</li> <li>● Staff training cost</li> <li>● Imaging cost</li> <li>● Operating room time including staff time and anaesthesia cost</li> <li>● Cost of surgical approach</li> <li>● Hospitalisation and perioperative resource use (length of hospital stay, readmission rates, emergency department visit, medication and postoperative imaging)</li> <li>● Cost of treating mesh related complication including treatment of SSI or SSO, infection, mesh</li> </ul>	

	Inclusion Criteria	Exclusion Criteria
	<p>removal, management of adhesion or erosion</p> <ul style="list-style-type: none"> <li>• Cost of treating recurrence</li> <li>• Monitoring costs and follow-up visits</li> </ul> <p>User preference and non-clinical outcome measures will be based on the prioritisation of outcomes as part of the user preference assessment.</p>	
Study design	<p>Any comparative studies (including RCTs, cohorts, before and after studies).</p> <p>Systematic reviews and meta-analyses which include comparative studies.</p>	Non-comparative studies (such as single-arm studies).
Language	English language only.	Studies unavailable in English.

### 3.1 Search strategy

Separate literature searches will be carried out for clinical and cost-effectiveness evidence. The EAG will develop literature searches which will be informed by published systematic reviews in the topic area and the literature review conducted by PenTAG External Assessment Group within the ongoing primary hernia assessment ([HTE10080](#)).

#### 3.1.1 Clinical effectiveness studies

A search strategy will be developed by one of the EAG's information specialists in EMBASE, peer reviewed by a second information specialist, and then translated, adapted and run independently for each individual database. A set of terms relating to non-primary hernia mesh will be combined with relevant search filters designed to identify 1) relevant systematic reviews, and 2) relevant comparative studies.

The following databases will be searched:

- MEDLINE ALL (Ovid, including In-Process and In-Data-Review and Other Non-Indexed Citations, Epub Ahead of Print, and Daily);

- Embase (Ovid);
- Cochrane Library (Cochrane Central Register of Controlled Trials, via [Wiley](#));
- CINAHL (via EBSCOhost);
- International HTA Database ([INAHTA](#)).

Ongoing trials will be searched for (ClinicalTrials.gov, WHO ICTRP); studies conducted in a UK setting will be prioritised if there are more than 20 ongoing studies identified relevant to the decision problem. In addition, MHRA field safety notices and the MAUDE database will be searched for adverse events of meshes indicated for non-primary ventral hernias.

To focus on literature reflecting currently available technologies and clinical practice, the EAG will apply a date limit (up to a maximum of the last 20 years for primary research, shorter for systematic reviews and meta-analyses). If evidence is limited, the EAG will consider relevant evidence that had been excluded for not meeting all aspects of the decision problem. The EAG may seek input from the NICE team, EAG and stakeholders involved in HTE10080 to consider approaches to the evidence base. For example, the appropriateness of applying boundaries to the inclusion of evidence that includes a mixed population of primary and non-primary hernia surgeries.

### **3.1.2 Economic evaluations and models**

A search for economic evaluations and systematic reviews of economic evaluations will be conducted in NHS EED (covering publications up to the end of 2014 after which it ceased to be updated), using the set of intervention terms only. For publications from 01 January 2015 onwards, the EAG will search for systematic reviews of economic evaluations (and primary full economic evaluations if no secondary evidence is identified), in MEDLINE and EMBASE. If a relevant systematic review of economic evaluations is identified the search for primary full economic evaluations will be updated from the date of search for that relevant systematic review. If no relevant systematic review is identified the search for

primary full economic evaluations will cover from 1 January 2015 onwards (to cover the years since NHS EED was last updated with economic evaluations). Sample search strategies for systematic reviews and primary economic evaluations including economic evaluation models, for MEDLINE on Ovid are presented in [Appendix B3](#).

Economic evaluations identified within the proposed literature searching will be considered for relevance to the decision problem. Targeted searches will be undertaken as needed for specific economic parameters if these are not available from the clinical effectiveness or economic evaluation evidence identified. The search would combine the set of intervention terms with a filter relevant for the missing parameter. This may include searches of [IDEAS/RePEc](#), CEA Registry (via [Tufts Medical Center](#)), and the International HTA Database ([INAHTA](#)).

### **3.2 Study selection**

Two levels of study selection will be conducted:

- Step 1: Initial pilot review of a 10% sample of titles and abstracts of records identified in literature searches will be screened against a subset of the inclusion criteria (population, intervention) by two reviewers to ensure consistency in eligibility criteria. Full review of all the title and abstracts will be undertaken by at least two reviewers. Any disagreements will be considered by a third reviewer for arbitration.
- Step 2: Full publications will be retrieved for records included at Step 1 and all will be screened by two reviewers to confirm the technology used and to determine the outcomes with results reported. Any disagreements will be considered by a third reviewer for arbitration.

The flow of studies through both levels of screening will be recorded and displayed in a PRISMA diagram. The EAG may apply a threshold to evidence in a mixed population (that is studies including a mix of primary and non-primary ventral hernia) to determine which whether will remain in this assessment or be more relevant to the ongoing assessment of primary hernia ([HTE10080](#)). Studies excluded following full paper review will have the reason for exclusion documented and tabulated within the EAG report.

Depending on the quality and quantity of the available evidence and in line with the NICE HealthTech programme manual, the EAG may adopt a hierarchical approach. Priority may be given based on setting (such as UK studies or real-world data), study design (such as a randomised-controlled trial, systematic review, or comparative cohort), sample size (Carroll et al. 2025) or other features relevant to the scope of the decision problem. Where a hierarchy is applied, the EAG will liaise with clinical experts to ensure the validity and appropriateness of the approach. Reasons for deprioritisation will be captured in the appendix of the report. The EAG acknowledge that the features considered most potentially impactful on outcomes of importance in this assessment may be identified for HTE10080, therefore may use this information when selecting evidence for prioritisation.

Where available, the EAG can consider sources of evidence provided in confidence by the companies. The EAG note that NICE have requested that a publishable abstract with data reported should be available for any full texts submitted in confidence for transparency. The EAG will consider eligibility of the full text and abstract summaries in line with the inclusion criteria outlined in Table 2. Records that meet inclusion criteria will be added deduplicated in EndNote.

### **3.3 Data extraction strategy**

Data from included studies reporting clinical outcomes will be extracted into a bespoke table to enable descriptive statistics, including study design, setting, eligibility criteria, population characteristics, intervention characteristics, and list of outcomes where results are reported. Data will be extracted from included studies reporting on economic evaluations outcomes into a bespoke table to enable descriptive statistics, including model design, setting, time horizon, intervention and comparator characteristics, and key findings.

If audit or registry data (for example from the [British Hernia Society Registry](#) or the [Medical Devices Outcomes Registry](#)) is provided to the EAG as a data processor (with NICE acting as the data controller), it should be in a suitable format that can be easily processed by the EAG. Data will be cleaned and formatted in line with a data field specification, if one is available. Otherwise, clinical expert opinion may be sought to understand how to best assess the data.

Data from Hospital Episode Statistics (HES) are currently available to the EAG as pseudonymised data extracts supplied under the DARS agreement (DARS-NIC-170211-Z1B4J). If the EAG considers that this data can be of value in addressing the decision problem, it will be extracted and formatted using the NHS Data Dictionary available on the [NHS Digital website](#). Results of HES analysis will be reported following small number suppression as per the HES analysis guide.

All analysis of routinely collected data will be completed using the statistical programming language R.

### **3.4 Quality assessment strategy**

The EAG will use appropriate critical appraisal checklists relative to the study design for each of the included full publications of clinical evidence (publicly available and confidential data) with the exception of conference abstracts. Where evidence is considered by the EAG outside of its intended study design, for example when considering a single arm of a randomised-controlled trial, the EAG will not apply a formal critical appraisal checklist as this would not offer a true reflection of the study bias in the context of this evaluation. In these instances, and to provide an overall assessment of the evidence base quality, the EAG will provide a high-level narrative summary of the key strengths, limitations, potential sources of bias, and comment on the generalisability of the results to clinical practice in the NHS. Economic evaluations will only be formally quality assessed if they compare surgical non-primary ventral hernia meshes in a UK setting. The Data Suitability Assessment Tool (DataSAT) will be used to assess the suitability and quality of any routinely collected data used to inform the economic evaluation ([NICE ECD9, 2023](#)).

### **3.5 Methods of synthesis and analysis**

The EAG will assess the feasibility of conducting appropriate meta-analysis to compare the different non-primary meshes in line with the decision problem, **Error! Reference source not found.** The EAG note that the meshes in scope are explicitly multi-component technologies. If feasible and appropriate, the EAG will use component network meta-analysis, which is a statistical extension of network meta-analysis that considers individual components of technologies to estimate the contribution of each to the overall treatment effect. The EAG will work with clinical

experts, companies, and the teams involved with HTE10080 to prioritise innovative features which directly or indirectly link to clinical outcomes to facilitate a robust analysis. If data does not allow for quantitative assessment methods, such as meta-analysis, the EAG will perform a narrative synthesis guided by the Synthesis without meta-analysis reporting guidelines (Campbell et al. 2020).

## **4. Real-world evidence**

The EAG note that there may be existing routinely collected evidence sources to provide evidence to address the decision problem, such as UK registry data held by the [British Hernia Society](#). Additional routinely collected data may be held by the [Medical Device Outcomes Registry \(MDOR\)](#). Where available, the EAG may consider these sources of evidence and their value to address the decision problem.

Data from Hospital Episode Statistics (HES) are currently available to the EAG as pseudonymised data extracts supplied under the DARS agreement (DARS-NIC-170211-Z1B4J). If the EAG considers that this data can be of value in addressing the decision problem, it will be extracted and formatted using the NHS Data Dictionary available on the [NHS Digital website](#). This may include anonymised probabilistic linkage of registry and HES data together to determine longitudinal outcomes, where appropriate. Results of HES analysis will be reported following small number suppression as per the HES analysis guide.

All analysis of routinely collected data will be completed using the statistical programming language R.

## **5. Economic analysis methods**

Where data is available, the EAG will perform an economic evaluation of the additional or innovative features of non-primary mesh from the perspective of the UK NHS and PSS, consistent with the methods recommended in the NICE reference case ([NICE HTE manual](#)).

## 5.1 Model development

The EAG will construct an executable economic in R programming language. The EAG will start by considering the appropriateness of the economic model developed for the primary ventral hernia topic ([HTE10080](#)) and generalisability to this non-primary topic. The economic model will include functionality to assess the impact of innovative features on key outcomes (as listed in the NICE Scope, see Table 1) where data permits. The model structure will be developed as such that it could be used for a technology-based assessment (that is technology A compared with technology B) where evidence is lacking for features.

The economic model will be parameterised with evidence identified by the EAG, information provided by Companies, and from Clinical Expert advice. Should there be gap in parameter information, assumptions will be made, and Clinical Experts will be consulted to ensure the appropriateness of the assumption and outcomes considered in the economic model. The EAG will use the highest quality evidence where available, prioritised according to the hierarchy of evidence described previously. The unit costs of resources utilised will be taken from [NHS reference costs](#), [Personal Social Services Research Unit \(PSSRU\)](#), NHS Supply Chain, information provided by Companies and evidence identified from published economic evaluations (or from targeted literature searches if no suitable evidence identified). Both costs and outcomes will be discounted at 3.5% annual discount rate, and the perspective of analysis will be that of the UK NHS and personal social services. Health benefits will be quantified as quality adjusted life years (QALYs) through the combination of utilities of health states considered in the economic model (including utility decrements for any adverse events or complications, if appropriate) and time spent in each state. Utilities used in the economic model will be identified from published economic evaluations (or from targeted literature searches if no suitable utility weights are identified from published economic evaluations) and information provided by the Companies.

The EAG will include outcomes within the economic model whether there is an expected different in rate or impact on cost of HRQoL across different features. The EAG will clearly report all assumptions employed to build the model structure, along

with all data inputs and their respective source. It is envisaged that the economic model will be evaluated over the lifetime horizon, however the exact time horizon of the economic model will be informed by Clinical Experts and the evidence identified.

Comparisons in the economic evaluation are expected to be conducted at the feature level rather than across multiple brands of surgical meshes with the same features. The comparator intervention may vary by patient group and subgroup and will endeavour to represent standard practice within the NHS without that feature present, which will be further validated with Clinical Experts for this purpose. Following the hierarchy of evidence, features expected to provide efficiency gains or increase costs will be assessed through a cost-comparison analysis. The economic evaluation results will be presented as an incremental cost-effectiveness analysis in terms of incremental costs, incremental QALYs, and incremental cost-effectiveness ratio in line with NICE's reference case and the final scope. The EAG will also consider the estimation of net monetary benefit (NMB), incremental NMB or economically justifiable price (eJP) where appropriate. The eJP for additional features will be calculated based upon a willingness-to-pay threshold of £25,000. This eJP will then be compared to the additional cost currently being charged for meshes with those additional features, where possible, to identify which meshes provide value for money. The cost effectiveness of surgical mesh for treatment of non-primary ventral hernias with innovative features will therefore be estimated in terms of an incremental cost per innovative feature in comparison to the predetermined price range for a surgical mesh that meets basic technology requirements.

Where appropriate, and if data allow, sensitivity analysis will be undertaken to explore uncertainty, which may include deterministic and probabilistic sensitivity analysis. Where probabilistic sensitivity analysis is undertaken, results will be presented using the cost-effectiveness plane and cost-effectiveness acceptability curves. Scenario analyses will be undertaken where considered appropriate and advised by Clinical Experts. For example, the EAG may conduct threshold analysis to determine the maximum technology price at which a net incremental NMB gain is seen against a comparator.

## 5.2 Model validation

The internal validity of the economic model will be checked independently by health economists within the EAG and will be undertaken by varying model input parameters and assessing whether the model results are sensitive and logical. Each model parameter will be checked against its source to ensure that it has been incorporated within the economic model appropriately. The model structure, assumptions, clinical parameters, and results from the economic model will be shared with Clinical Experts to assess clinical validity.

## 6. User preference assessment

In parallel to the evidence review and economic analysis the EAG will do a user preference assessment. In line with the decision problem outlined in the Final Scope, the EAG will seek to recruit people who make the choice about which non-primary mesh product to determine the key considerations and factors when choosing between the technologies, as outlined within the Final Scope. The EAG may use the outputs of the primary mesh user preference ([HTE10080](#)) as a starting discussion point for efficiency. The EAG acknowledges that the choice of surgical mesh should be made as part of shared decision-making and understand that NICE will be gathering information on patient perspectives.

The aim of the user preference assessment is to supplement the clinical and economic evidence by:

- identifying the key preference criteria that are important to users of the technology when deciding which technology to choose;
- understanding the relative importance of these criteria via SMART ranking and swing weighting (which may include weighting only the top 10 ranked criteria);
- understanding how users apply these criteria when choosing a technology.

The process will involve two workshops and two email exercises. An output of this piece of work will include a 'performance matrix'. This will include the most important

criteria to users and how they would measure performance in these criteria. Within this approach performance rules may not be developed for any criteria with a weight less than 5%, this is to ensure that only the criteria which are the most important to users are considered.

The results of user preference work will be summarised within the main External Assessment Report. Each technology will be compared to matrix using evidence identified. The user preference work may be used to inform the economic modelling, to explore if alternative scenarios or revisions are needed. User preference criteria not captured in the evidence analysis will be outlined in the assessment report.

Where possible, the EAG will consider streamlining the approach alongside the existing user preference assessment for HTE10080 to focus on any key differences between mesh selection between primary and non-primary cases.

## **7. Handling information from the companies and other stakeholders**

The EAG will consider data or evidence supplied by the companies or stakeholders involved. If the data meet the inclusion criteria for the review they will be considered in more detail. It may not be possible to include information supplied by Companies if received by the EAG later than 14 July 2026 (3 months before draft report submission deadline). The EAG will include routinely collected evidence sources if data are received before 14 July 2026. If data are received later than this, the EAG will first consider the feasibility of analysing this data and may not be able to include it. The EAG may seek clarification or additional information from companies and other stakeholders where necessary. All correspondence between the EAG and companies will happen through NICE.

Any 'commercial in confidence' data provided by a company and specified as such will be highlighted in **blue and underlined** in the assessment report. Any 'academic in confidence' data provided by a company, and specified as such, will be highlighted in **yellow and underlined** in the assessment report. If confidential information is included in the economic model, the EAG will provide a copy of the model with 'dummy variable values' for the confidential values (using non-confidential values). Any

'personally identifiable' data provided will be highlighted in **pink and underlined** in the EAG Report. Any 'confidential price agreements' data provided will be highlighted in **green and underlined** in the EAG Report. All confidential information, as identified above, will be redacted before publication on the NICE website. If confidential information is included in any economic models produced, then a version using dummy data or publicly available data in place of confidential data will be provided.

## 8. Competing interests of authors

None.

## References

[Campbell M, McKenzie JE, Sowden A, Katikireddi SV, Brennan SE, Ellis S, Hartmann-Boyce J, Ryan R, Shepperd S, Thomas J, Welch V, Thomson H. Synthesis without meta-analysis \(SWiM\) in systematic reviews: reporting guideline. BMJ. 2020 Jan 16;368:l6890. doi: 10.1136/bmj.l6890. PMID: 31948937; PMCID: PMC7190266.](#)

[Carroll C, Cooper K, Harnan S, Wailoo A. \(2025\) Technical Support Document 27. Prioritising studies and outcomes for consideration in NICE HealthTech literature reviews.](#)

[NHS England. Surgical mesh. \(2025\).](#)

[NICE HealthTech programme manual](#) (2025) NICE Process and Methods PMG48

## Appendix

### Appendix A: List of 21 companies providing surgical mesh

As listed on [NHS Supply Chain website](#) (as of 22 May 2026)

- Advanced Medical Solutions Ltd
- Aquilant Limited
- Assut UK LTD
- B. Braun Medical Limited
- Becton Dickinson U.K, Limited
- Boston Scientific Ltd

- Carrow Medical Limited
- Elemental Healthcare Ltd
- Eurosurgical
- HC21 (UK) Ltd
- Ideal Medical Solutions
- Johnson & Johnson Medical Ltd
- JUNE Medical
- Lawmed Ltd
- Medtronic Limited
- pfm medical UK Ltd
- Q Medical Technologies Ltd
- Raise Healthcare Pvt Ltd
- Sela Medical UK LTD
- TELA Bio Ltd
- W.L. Gore & Associates (UK) Ltd.