

Methods for Determining Product Selection for NHS England Specialised Services High Cost Tariff Excluded Devices

Building the Device Specification

Methods for determining product selection for High Cost Tariff Excluded Devices in Specialised Services

Building the Device Specifications

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Equality and Health Inequalities statement

Promoting equality and addressing health inequalities are at the heart of NHS England's values. Throughout the development of the policies and processes cited in this document, we have:

- Given due regard to the need to eliminate discrimination, harassment and victimisation, to advance equality of opportunity, and to foster good relations between people who share a relevant protected characteristic (as cited under the Equality Act 2010) and those who do not share it; and
- Given regard to the need to reduce inequalities between patients in access to, and outcomes from, healthcare services and to ensure services are provided in an integrated way where this might reduce health inequalities.

Please note: There is a glossary of acronyms at the end of this document.

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Introduction

NHS England Specialised Services is adopting a single national catalogue and single national sourcing and procurement contract for the majority of high-cost tariff-excluded devices (HCTEDs) commissioned through specialised services. There are also a small number of high cost devices that will be commissioned in this way for non-specialised care. This change is taking place in the context of wider strategic change in NHS procurement for all hospital-used goods and services as set out in the Department of Health's Procurement Transformation Programme which articulates a similar national procurement approach in the new NHS Supply Chain Operating Model. As part of this new approach a single procurement partner undertakes category management of the supplier and product market to secure best value for the NHS from amongst the range of available products.

NHS England Specialised Services has established clinical commissioning policies and specifications that determine the scope of treatments for which it is the responsible commissioner. These include interventions mandated through NICE technology appraisal guidance, and treatments developed through the specialised commissioning clinical policy development and prioritisation process. Those processes determine the treatment intervention to be commissioned and the populations for which that treatment is indicated.

Devices for consideration will be those that can be purchased, having already been granted regulatory approvals and scientific opinion relating to safety and efficacy through relevant bodies such as the MHRA and EMA (medicines).

A number of commissioned specialised services require the use of medical devices, many of which are funded outside national tariffs. For each service one, or more suppliers, produce a range of devices and this range typically evolves over time with evolutionary change introducing new features which may or may not be relevant to the delivery of the core requirements of the specification.

This methods statement sets out the basis for **clinically assessing value** within the category management process for high cost tariff excluded devices and describes how the clinical and procurement functions will operate together to determine the clinically informed range of products available to clinicians delivering specialised services.

This approach has a strong clinical focus and will be driven by a series of Device Working Groups (DWGs) which will be established as part of the Specialised Services national purchase and supply system for High-Cost Tariff-Excluded Devices.

In the first instance DWGs will focus on developing device specifications for the existing catalogue of available devices with the aim of optimising device choice to match commissioned requirements and reducing variation in device choice in similar clinical scenarios and improving value. This may include rationalising the range of devices available.

The DWGs will consider device development within the proposed contract / agreement period. In future it is anticipated that industry will register new devices through [HealthTech Connect](#) and DWGs will have a role in horizon scanning of new devices to accelerate adoption of innovative devices where these can be demonstrated to add value.

As part of the new NHS Supply Chain Operating Model in procurement across the NHS, NHS England Specialised Services will see a shift of the HCTED delivery procurement partner changing to the new NHS Supply Chain Operating Model partners. The majority of medical devices will be grouped into different Category Tower Service Providers (CTSPs). Supply Chain Corporation Limited (SCCL) will be governing all the future CTSPs, with the 17 HCTED categories relevant to specialised services split over two separate Category Towers – Health Solutions Team (HST) and Collaborative Procurement Partnership (CPP). At present 15 categories out of 17 are within the programme; with HST having over 90% of current spend. One of the duties of the new NHS Supply Chain Operating Model is to ensure Clinical and Product Assurance (CaPA) of items being procured. To avoid duplication of work, the DWGs will ensure the CaPA requirements are handled within the DWGs. Any issues will be reported to the HCTED Project Group via the DWG Chair and/or DWG Manager.

The decision to define a device as excluded from tariff remains with NHS Improvement and NHS England Pricing function and is not within the remit of Specialised Services.

A summary of the process focusing on the DWG role is included in Appendix A.

The Methods outline the strategic procurement approach that will be used to identify the preferred available device options and produce the device specification.

The methods outline the points where there is interface with NHS Supply Chain procurement process. The procurement approach for each device category will be confirmed prior to the market intervention.

DWGs will provide advice and support to the NHS Specialised Services led procurement process.

After evaluation of the first three DWGs the methods will be updated to account for any changes to process that may be required.

A. Formation of the Device Working Group (DWG)

The process is initiated through either:

- a) NHS England's Specialised Services HCTED Programme Board, in collaboration with NHS Supply Chain, determining the need for a DWG to advise on a device or devices within a Category Tower or sub-category.

or

- b) by the submission of an application by a Clinical Lead, who will lead the Device Working Group through the process, and who will be endorsed by the CRG.

Step A1.

Proposed Device Working Group's (DWG) Clinical Lead. A clinician or healthcare professional, currently working within the NHS, will lead each Device Working Group. Applications will be received on an ongoing basis. The intention is to align DWGs with Category Towers, but the number of DWGs required for each device sub-category can be determined on a case by case basis.

A1.1 All DWGs will have a Clinical Lead¹ who may be the Chair or Clinical Member of a Clinical Reference Group (CRG), or from outside the CRG membership. The Clinical Lead should have detailed clinical understanding of the target intervention and must not have a conflict of interest associated with the technology (see Step A4.2). The Clinical Lead may be a doctor or a healthcare professional from an allied discipline depending upon the device/s under consideration. The Clinical Lead must be currently working within the NHS.

A1.2 A DWG Clinical Lead Application Form is submitted via an on-line form, which includes details about the proposed device. The link to the form will be received by contacting ENGLAND.SpecComm-HCTED@nhs.net. The DWG Manager confirms receipt of the DWG Clinical Lead Application Form and will identify whether a DWG for this topic is required.

Step A2.

The Clinical Reference Group (CRG) Endorses the Clinical Lead. The relevant CRG endorses that the nominated Clinical Lead has the support of peers to lead the process.

A2.1 The DWG Manager contacts the CRG Chair by email to provide a copy of the Clinical Lead Application Form.

A2.2 The CRG Chair confirms on behalf of the CRG members, including affiliated members, that the CRG support the Clinical Lead, liaising with CRG members where appropriate.

¹ Further detail on the role of Clinical Lead can be found in [Appendix C: Roles and responsibilities](#)

A2.3 Where a Clinical Lead is nominated by NHS England Specialised Services the CRG membership are informed and are asked to provide assistance in building clinical involvement in the DWG.

Step A3.

Procurement Leads are identified. Public health and Procurement Leads² are identified from NHS England and the Category Towers procurement partner (currently NHS Supply Chain), who will form part of the DWG and provide support to the Clinical Lead.

A3.1 The DWG Manager will liaise with the Category Towers procurement partner (currently NHS Supply Chain) to nominate a Procurement Lead and with the Public Health Network Chair to nominate a Public Health Lead.

A3.2 The DWG Manager will ensure that the Lead Commissioner is included in the DWG. Where the Lead Commissioner is not based within a NHS England Specialised Commissioning regional hub, a Supplier Manager will be identified to join the DWG to ensure regional involvement on the group.

Step A4.

The Clinical Lead and DWG Manager form the DWG. (Appendix B)

A4.1 The Clinical Lead and DWG Manager will invite members to join the DWG in line with the agreed Terms of Reference (Appendix D). The membership should include at least two healthcare professionals with a detailed knowledge of the product area, one healthcare professional from the same specialty without a detailed knowledge of the product area, representatives or technical experts who are part of the implementation or use the devices (for example, a clinical nurse specialist for adjusting device parameters), a public health lead and a patient voice representative/s, who may have direct lived experience of or is a patient representative of the condition and/or device. Additional members can be co-opted to the DWG as required (for example, bio-engineering expertise).

A4.2 All members of the DWG are required to complete a detailed self-declaration of conflicts of interest, in line with the NHS England Declarations of Interest policy³ (<https://www.england.nhs.uk/ourwork/coi/>). The completed declarations should be returned to the DWG Manager.

² Further detail on roles and responsibilities can be found in [Appendix C: Roles and responsibilities](#)

³ <https://www.england.nhs.uk/ourwork/coi/>

A4.3 The DWG will work virtually where possible and will hold at least:

- one initial meeting (for example, to agree the device notification form (Step A5))
- one further working group meeting (for example, to consider the information and evidence received and to form the draft device specification (Step A6))
- one final working group meeting⁴ (for example, to consider the outputs from the procurement process (Step A6))

The outputs from each meeting are likely to vary for each DWG depending on ways of working.

Step A5

A Prior Information Notice (PIN) is published. NHS Supply Chain will publish a Prior Information Notice, with the aim of enabling the DWG to understand the market and support delivery of a decision by NHS England Specialised Services on the procurement route to market.

A5.1 Suppliers will be invited to express an interest in participating in the programme via **PIN**, which will aim to identify all interested parties.

A5.2 In response to the PIN Suppliers will provide product level detail of products currently in the market and those due to be launched via completion of the **Device Notification Form** (DNF) as part of a request for information (RFI). The DWG will develop questions to be included in the DNF relevant to the specific device category.

A5.3 The nominated Procurement Lead will contact the ABHI to obtain support and canvass support from their membership in the PIN.

A5.4 The DWG Manager will contact each supplier who has completed a DNF and invite them to present their current device/s to the DWG. This will usually be as a Webinar session. The suppliers will also be invited to present anticipated changes to the device technology and clinical area over the horizon period (including information about relevant current commercial or public-sector research in clinical settings along with expected publication date). The horizon period will be determined by the DWG according to the devices being considered and to provide context about potential changes to the device during the period that will be covered by the new contract or framework.

A5.5 To ensure consistency, the Specialised Services HCTED Programme will provide oversight of DWG outputs. Additional members may be co-opted to the DWG for this discussion as determined by the DWG.

A5.6 Membership of the DWG includes strict non-disclosure requirements which ensure that future technological changes can be discussed on a fully commercial in confidence basis. Where a commercial in confidence agreement is not agreed, no horizon scanning discussions will take place with that supplier and information from that supplier will not inform the report. Suppliers will still be invited to present their current devices as per Step A5.4.

A5.7 The DWG develop the horizon scanning report based upon the Device Notification forms and the information provided by suppliers.

A5.8 Commercial in confidence discussions relating to elements of technological change will be reported in Part II of the report which will not be included as part of any engagement exercises (see Step B1).

Step A6.

The DWG form the draft Device Specification. The DWG draft the Device Specification which will be developed to identify the key clinical outcomes which the device/s should achieve as well as its specific indications and applications. (A formal evidence review can be commissioned to support the process). A specification for a device may have been developed for a previous procurement and this information will be shared with the DWG when reconsidering the new specification.

A6.1 The device specification will include an evidence summary, based upon NICE Technology Appraisal, other relevant guidance, NHS England clinical commissioning policy and/or other relevant evidence review. The DWG will capture what items have been considered and the consensus view on the importance and relevance to the device being considered. The specification must reflect the available evidence for the device sub-category being considered. Where this information is not available, the DWG will determine whether an additional evidence review⁵ is required in order to inform the device specification. Where an evidence review is required, this will be commissioned by the Clinical Effectiveness Team (see Step A7) in line with the agreed methodology.

A6.2 The DWG forms a device specification, using a standard template which, based upon the evidence identified and consensus of the working group, determines and outlines:

⁵ It is envisaged in most scenarios a full evidence review will not be required.

- the requirements for each device to meet the clinical conditions required
- clinical scenarios where enhanced specifications may be appropriate
- the key clinical outcomes which the device/s should achieve, as well as its indications and applications
- includes patient related outcomes
- outlines the criteria for scoring the exercise, in line with guidance from Category Tower/NHS Supply Chain.
- The DWG will develop key performance indicators (KPIs) consistent with SCCL's aims.

Step A7.

Evidence review commissioned and completed. This step is only completed for those device specifications for which the DWG has agreed that a supporting evidence review should be produced.

A7.1 In situations where there is no existing evidence review available via a NICE Technology Appraisal, NHS England clinical commissioning policy and/or other relevant evidence review (for example Getting It Right First Time (GIRFT)), the DWG will consider the need for a formal evidence review for that device sub-category.

The DWG will notify the NHS England Specialised Commissioning Clinical Effectiveness Team (CET) that an evidence review is required. The CET will provide a recommendation as to whether a separate evidence review is required. The CET identifies a lead public health consultant to form the Population Intervention Comparison Outcomes (PICO) framework which will be submitted to the organisation commissioned to complete the evidence review. This is built from the information in the Device Notification Forms and is tested with the DWG.

A7.2 The CET coordinates the commissioning of the evidence review which will be conducted in line with the agreed CET evidence review methodology.

A7.3 The CET establishes communication between the evidence review team and the Device Clinical Lead to clarify elements of the evidence review.

A7.4 The CET receives the evidence review and assures the quality of the document. The final version of the evidence review is submitted to the DWG Manager. The DWG will need to determine whether any changes to the specification are required.

Step A8.

Specialised Services Clinical Panel Assurance. It provides assurance, via the Specialised Services Clinical Panel, that the draft Device Specification appropriately reflects the available evidence.

- A8.1** The draft Device Specification is completed ready for submission to Commercial Medicines and Devices Investment Group CMDIG and the Specialised Services Clinical Panel, together with the completed Evidence Review.
- A8.2** The draft Device Specification is circulated to the CRG for comment. The DWG will consider comments from the CRG prior to submission to the Clinical Panel.
- A8.3** The draft Device Specification is circulated to the CM&DIG for comment. The DWG will consider comments from the CM&DIG prior to submission to the Clinical Panel
- A8.4** Submissions are made via the CET, at least two weeks ahead of the next Specialised Services Clinical Panel meeting.
- A8.5** The DWG Manager submits the completed Device Specification and Evidence Review to the CET for inclusion in Specialised Services Clinical Panel meeting papers.
- A8.6** The Specialised Services Clinical Panel will consider the documents submitted to determine whether it is content that the Evidence Review, and Evidence Review Summary have been completed satisfactorily and that the draft Device Specification adequately reflects the available evidence. The DWG Chair may be available via telephone to answer any specific queries.
- A8.7** The CET drafts the Specialised Services Clinical Panel's report on the draft Device Specification, capturing the discussion and conclusions of the meeting. The CET then submits the draft report for sign off by the Specialised Services Clinical Panel Chair.
- A8.8** The CET sends out the agreed Clinical Panel report to the Device Working Group Clinical Lead, copying in the DWG Manager, the Head of Clinical Effectiveness and the National Programme of Care Senior Manager.
- A8.9** If any changes are required as part of Clinical Panel assurance, the device specification is amended by the DWG and signed off by the DWG Chair.

B. ENGAGEMENT

Engagement includes patient engagement and stakeholder testing.

Step B1.

Patient Engagement: This should be undertaken for those device categories within this programme where it is possible and beneficial to capture representative experiential data and insight into patient benefit from an end-user viewpoint. The patient engagement phase provides an opportunity for patients, and patient groups where appropriate, to comment on the documents which have been developed by the relevant DWG(s). Users will be asked to comment on factors that they consider impact on patient's experience of using devices. DWG patient members will help devise questions to include in the process and promote engagement with patient groups and other patients. Any comments received during the engagement phase will be considered by the DWG and captured in the engagement report form.

Stakeholder testing should be undertaken for device categories within this programme to test the accuracy and completeness of documents produced. The core stakeholder list comprises those who have registered as stakeholders to the relevant CRG through the NHS England website. In addition the DWG and patient voice representatives will help identify other key device specific stakeholders.

- B1.1.** The DWG will complete a stakeholder mapping exercise and develop an engagement plan, outlining the approach that will be taken for this device.
- B1.2.** The DWG Manager must forward the following documents to the Specialised Services National Programme of Care (NPoC) Manager who will arrange for documents to be shared via the NPoC generic email address for the purposes of stakeholder testing:
- DWG membership list
 - Supplier list
 - Wider Commercial Stakeholder List
 - Draft Device Specification
 - Formal Evidence review (where completed)
 - Draft horizon scanning information (Part I only)
 - Draft scoring sheet and weighting
 - Questions for patients
- B1.3.** Stakeholder testing will take place for 30 days for all devices. The Specialised Services NPoC Business Support will notify all stakeholders identified through the mapping exercise, as well as those on the wider commercial stakeholder list, including those on the validated supplier list, that the opportunity to provide feedback is live. At the end of the period, the responses will be collated by the DWG Manager. An assessment of whether Section 13Q applies (the legal duty to involve the public in commissioning) will also be carried out where appropriate.
- B1.4.** The DWG meets to consider all responses and, taking into account the stakeholder responses, amends the Device Specification, the horizon scanning report and the scoring sheet as appropriate. The DWG will create an Engagement Report, summarising the feedback received and outlining the amendments that were made to the suite of documents following stakeholder testing, if relevant.
- B1.5.** Where additional engagement is undertaken, as outlined in the engagement plan, this will be included in the Engagement Report and these responses will also be considered.
- B1.6.** The Engagement Report is discussed at Specialised Services NPoC Board before final sign off of the report and amended documentation.

C. THE PROCUREMENT PROCESS

- C1.1.** The Procurement lead on the DWG will provide analysis and advice to NHS England Specialised Services on the procurement approach. The DWG will provide clinical support to the Procurement lead and to NHS England Specialised Services.
- C1.2.** NHS England Specialised Services will liaise with NHS Supply Chain to ensure clinical assurance meets CaPA requirements.
- C1.3.** The Procurement lead on the DWG will take the device specification through the appropriate procurement intervention.
- C1.4.** The DWG will provide support to the Procurement lead on the procurement process and to NHS England Specialised Services on the evaluation of the responses from the process, as appropriate.
- C1.5.** NHS England Specialised Services will liaise with NHS Supply Chain to ensure clinical assurance meets Clinical and Product Assurance CAPA requirements.
- C1.6.** During the process, NHS England will consider the commissioning plan required to support implementation of the proposal pending approval.
- C1.7.** After the conclusion of the procurement, the proposal will be considered by NHS England's Specialised Services HCTED programme and through its internal sign off processes with final sign off through the NHS England Commercial Medicines and Devices Investment Group (CM&DIG).

C2.0 Prior Information Notice

In order to assess the current markets for each of the categories under the Device working Groups a Prior Information Notice (PIN) will be published requesting information of both current and future devices and their use within the market.

When required this can be extended to provide details of where it will be published, by whom and under what system.

C2.1. Assessment of PIN responses

The information provided in the PIN will be confidential and provided only to the members of the relevant DWG. The DWG will use the information gathered as part of the development of the specification as outlined in the methods document.

The combined information of the specification and knowledge gained from the PIN regarding the scope of the market will inform the method utilised as part of the tendering exercise as detailed below.

C3.0. Procurement Process

The main options for pricing exercises are outlined below. Each of the options and award under them will be informed by the DWG specification. The award of business will be clearly outlined in the each of the procurement exercises.

C3.1. Framework agreement

Currently NHS Supply Chain has frameworks that cover the defined category areas under the Specialised Services HCTED programme. Each of these frameworks can be utilised in their current format using the pricing submitted by individual suppliers to provide pricing for commitment.

Dependent upon the PIN new framework agreements may be introduced to provide a more specific focus on individual device areas.

Invitations to participate will be made through the standard OJEU regulatory framework.

C3.2. Request for pricing

Under existing frameworks there are options to request pricing through the re-opening of competition as outlined within each of the relevant framework agreements. This method can be utilised to provide commitment to the market utilising the assessment criteria described in each specific framework agreement.

C3.3. Contract

A contract could be utilised to provide specific commitment to device areas. This commitment may be to length of time and/or volume/value. Details of the commitment will be clearly outlined in the tendering/equivalent process documents as will the method of evaluation. The outcome of a contract will be to provide firm commitment to awarded suppliers.

C4.1 Evaluation and Award

The evaluation criteria for each pricing exercise will be detailed within the relevant tender/equivalent documentation. This will show the method of evaluation, scoring method and weighting for each element.

NHS England Specialised Services will consider formal sign-off of the Award through the agreed approval process within NHS England's Commercial Function.

C4.2. Award Implementation

This will be considered through NHS England Specialised Services with DWG advice and it is anticipated the impact will vary based upon the level of changes anticipated as a result of the award.

C5.1 Contract Management

NHS England's Specialised Services HCTED Programme Board will provide oversight.

It is anticipated this will include:

- Details of how contracts will be reviewed to ensure adherence to awards.
- To include scheduled supplier review meetings to assess uptake versus award
- Method for addressing imbalance versus award
- Method for review of market changes, volumes commissioned, locations commissioned, changes to technology
- Method for introduction and adoption of innovation

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Glossary

ABHI	Association of British Healthcare Industries
CaPA	Clinical and Product Assurance
CET	Clinical Effectiveness Team (NHS England)
CM&DIG	Commercial Medicines & Devices Investment Group
CRG	Clinical Reference Group
DNF	Device Notification Form
DWG	Device Working Group
EMA	European Medicines Agency
HCTED	High-Cost Tariff-Excluded Devices
SCCL	Supply Chain Corporation Limited
HST	Health Solutions Team
CPP	Collaborative Procurement Partnership
MHRA	Medicines and Healthcare Regulatory Agency
NICE	National Institute for Health and Care Excellence
NPOC	National Programme of Care
PICO	Population Intervention Comparison Outcomes
PIN	Prior Information Notice
RFI	Request for information
OJEU	Official Journal of the European Union

Appendix A: Part I and Part II

	NHS England Specialised Services	NHS Supply Chain
Building the Specification	Determine Need for DWG	
	Endorse the Chair and confirm procurement lead	
	Recruit DWG members	
	Declaration of Interests submitted and recorded	
	DWG develop Device Notification Form (DNF) to go out with Prior Information Notice (PIN)	
	Stakeholder Mapping and Engagement plan drafted	Procurement lead issues PIN with DNF
		Procurement lead contacts ABHI to canvass support from membership
	Suppliers can present current device portfolio and reference expected changes within the agreed horizon period	Any Commercial In Confidence information to be included in Part II only and will not be shared with stakeholders
	Draft specification to include review of information gathered from sources. A formal evidence review of published evidence may be commissioned through Clinical Effectiveness Team	
	DWG consider horizon scanning and context for the device being considered. Complete horizon scanning information	
	Draft specification shared with CRG and CM&DIG for comment	
	Draft specification submitted to Clinical Panel with the available evidence considered and the formal evidence review where applicable	
	DWG consider Clinical Panel comments and signs off draft	CaPA Assurance
	Engagement: Stakeholder testing for 30 days as standard but additional activities can be considered	

	Review stakeholder responses and draft engagement report – where further activities undertaken a Patient Insight Report will be completed	
	Amend Device Specification as required and confirm evaluation criteria	Consider procurement options and existing Frameworks or need for a new Framework
	Complete Device Specification	Invitation to participate published
		Procurement responses received
	Evaluation of responses by DWG / NHSE Specialised Services	Support to NHSE Specialised Services / DWG.
	Complete Implementaion Plan	
	Award Recommendation drafted NHSE Specialised services HCTED Programme Board agree sign off of recommendations to send to NHSE CM&DIG	
	NHSE Commercial Medicines and Devices Investment Group (CM&DIG) to provide final sign off and award authorisation	Award confirmed to Suppliers

Appendix B – Category Towers: Categories within Specialised Services HCTED

HCTED Device Working Group (DWG) 2018			
Category Tower	Medical Category	Device Category	Related CRG
6 (HST)	1. Audiology	1. Bone Anchored Hearing Aids <i>Now referred to as Bone Conducting Hearing Implants (BCHIs)</i>	Specialised Ear and Ophthalmology
6	2. Neuromodulation	2. Deep brain, vagal, sacral, spinal cord and occipital nerve stimulators	Specialised Pain, Specialised Colorectal, Specialised Urology, Neurosurgery
		3. Intrathecal drug delivery pumps	Chemotherapy
6	3. Heart Rhythm Management	4. ICD (Implantable Cardioverter Defibrillator)	Cardiac Services
		5. ICD with CRT (Cardiac Resynchronisation Therapy) capability	Cardiac Services
6	4. Electrophysiology	6. 3D mapping and linear ablation catheters - complex cardiac ablation catheters	Cardiac Services
		7. Catheters	Cardiac Services, HPB Services, Cancer
6	5. Structural Heart	8. Occluder, Vascular, Appendage and Septal devices	Cardiac Services
		9. Percutaneous valve repair and replacement devices - mitral/pulmonary valve Heart Valves	
6	6. Complex Stenting	10. Peripheral vascular stents	Vascular Services
		11. Carotid, iliac and renal stents	Vascular Services / Cardiac Services
		12. Endovascular stent graft	Vascular Services
6	7. Neuroradiology	13. a) Aneurysm coils	Neurosciences
		13. b) Flow diverters for intracranial aneurysms	
		14. Intracranial stents	

4 (CPP)	8. Orthopaedics	15. Circular external fixator frames	Trauma NPoC
		16. Bespoke orthopaedic prostheses	Not currently live within programme
		17. Maxillofacial bespoke prostheses	

Appendix C – DWG Roles and responsibilities

Clinical Lead

- Chair the Device Working Group and ensure that they work within the DWG Terms of Reference.
- Drafts all documentation for agreement by the DWG.

DWG Manager / Lead Commissioner

- A core member of the DWG and required for quoracy (if necessary, nominates a deputy who is empowered to make all DWG decisions and sign-off approvals).
- Together with the Chair of the DWG, will invite members to join the DWG, in line with the agreed terms of reference.
- Receives all potential conflicts of interest from DWG members and reviews these in line with NHS England policy (<https://www.england.nhs.uk/ourwork/coi/>).
- Liaises with the DWG to agree the Supplier List is accurate and complete.
- Together with the Chair of the DWG, will ensure that NHS England policies and procedures (including the relevant methods document) are adhered to and will act as secretariat to the group.
- First point of contact for the DWG.
- Oversees development of all documentation.

Procurement Lead

- A core member of the DWG and required for quoracy.
- Ensures that the DWG operates in line with procurement regulation.
- Ensures that the Supplier List is available to each DWG.

Specialised Services Clinical Panel

- Provides assurance that the draft Device Specification appropriately reflects the available evidence (where an evidence review is completed).
- Receive the final appraisal report and provide assurance that the clinical benefit element of the report is well defined.

Public health lead

- Work with the Clinical lead to draft and agree a PICO document for those DWGs requiring an evidence review. Provide advice on assessment of evidence as required.

Specialised Services Finance Leadership Group

- Provide assurance that the financial elements of the approach have been well-defined and maximal cost benefit achieved.

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Appendix D: Device Working Group Terms of Reference

SPECIALISED COMMISSIONING DEVICE WORKING GROUP TERMS OF REFERENCE

Purpose

The function of the Device Working Group (DWG) is to recommend the preferred High-Cost Tariff-Excluded Devices which will be commissioned through NHS England Specialised Services.

DWGs will be formed for each target intervention (as well as any new or innovative device categories) and membership may therefore be tailored depending on the topic concerned.

Membership

The membership should include:

- Chair - the clinical lead who has been endorsed by the Clinical Reference Group (CRG) as part of initiating of the DWG. This may be a clinician or other healthcare professional as appropriate.
- The DWG Manager who will, together with the Chair, ensure that NHS England policies and procedures are adhered to and will act as secretariat to the group.
- Lead Commissioner (and Supplier Manager, if Lead Commissioner is not hub based)
- An NHS Supply Chain nominated procurement lead
- A Public Health Lead (nominated by the Public Health Network)
- At least 2 additional clinical members, with a detailed knowledge of the product area, to ensure adequate clinical knowledge of all parts of the clinical pathway of the proposition.
- One clinical member from the same speciality, with a detailed knowledge of the product area.
- Representatives or technical expertise who implement or use the devices (for example, a clinical nurse specialist for adjusting device parameters)
- Ideally, a Patient and Public Voice representative with direct lived experience / a Patient Voice Representative of the condition and/or device.

Further membership might include:

- Co-opted industry representatives

Roles and Responsibilities

The DWG supports the process to improve value when commissioning High Cost, Tariff Excluded devices which will be commissioned by NHS England for use by Specialised Services as indicated in the methods document including:

- Declaring all potential Conflicts of Interest, in line with the NHS England Conflict of Interest policy (<https://www.england.nhs.uk/ourwork/coi/>).
- Agree the Device Notification Form, identifying bespoke elements of the form as required.
- Liaise with suppliers to encourage the formation of commercial in confidence agreements.

- Completing a clinical review of products currently used against the patient conditions that they are used for and review any other products that are known to be coming available.
- Form the Device Specification, outlining the key clinical outcome required by a device, its indications and applications.
- Work with the Public Health Lead and Commissioning Lead to agree the 'Population, Intervention, Comparator and Outcomes' (PICO) (subject to final sign off by the Clinical Effectiveness Team (CET)), where an evidence review is required to inform the device specification.
- Ensure relevant clinical evidence has been considered in the evidence review.
- Support the Procurement Team by developing the Device Specification
- For the procurement intervention support drafting of a scoring sheet, with weightings, by which to assess submissions.
- Patient Voice Representatives will be expected to support identification of relevant stakeholders and use their contacts to encourage engagement in the work of the DWG.
- Patient Voice Representatives will be expected to consider device features relevant to patient experience and outcomes
- Where public engagement or consultation has taken place, review all responses on the draft specification and associated documents and reviewing and redrafting documents as required.
- Where engagement or public consultation has taken place, recording reasons for resulting actions and amendments from consultation in a consultation report.
- Scoring each supplier submission against the agreed criteria.
- Drafting and agreeing the final device appraisal report.
- Consider any challenges raised by suppliers to the final device appraisal and reviewing and amending the appraisal report based upon challenge.

Rules of Working

- DWGs will work virtually wherever possible (for example, via webinars).
- Members need to act impartially, bringing their collective clinical, commissioning and patient expertise and experience to form an appropriate suite of documents.
- Any potential conflicts of interest should be overtly recorded and managed honestly and appropriately, in line with NHS England policy. All members will be required to complete a conflicts of interest form. All conflicts of interest will be publicly available.
- Members will need to be able to dedicate adequate time to the role of the DWG, to enable completion of all stages of development within the agreed timescales
- Where there is not complete consensus amongst the DWG members, a brief outline of the points of controversy agreed by the DWG should be submitted alongside the final appraisal report when it is submitted to Specialised Services Clinical Panel.
- Respect need for confidentiality in relation to some information seen by the group (for example, market sensitive data).

Quoracy

In all endeavours, the listed attendees are to be supported to attend thereby developing mutual consensus. As a minimum to be quorate, the presence of the DWG Chair, at least one other clinical member from the product area, Procurement Lead and DWG Manager are required.

DWNG Pilot