Medical Devices: Process for LMMG Prioritisation and Review

This document outlines the review process followed by the Lancashire Medicines Management Group (LMMG) when making recommendations on medical device use.

LMMG Medical Device Process for Prioritisation and Review

1. A request for device review is submitted

Only devices which meet the following criteria will be considered

- CE marked
- Listed in the drug tariff
- Have the potential to impact on primary care prescribing practices
- Formally approved for use by the requesting organisation

2. Additional information is requested by the CSU from the manufacturer as follows:

- A description of the device intended user or usage and confirmation that the device complies with relevant standards. i.e. that the device has a CE mark for the manufacturer's intended use or clarification of the current UK regulatory status for the use under review (if different)
- Evidence relating to the device effectiveness for the intended purpose, including any comparator studies (This may include both published and unpublished data)
- Details of any known safety issues or device related adverse incidents, including details of incidents logged on internal/other relevant databases, MHRA publications/manufacture advisory notes or other relevant publications
- Details of any limitations or restrictions on use e.g. exclusion of specific patient groups or time limits for use
- Confirmation that the device been designed to minimise accidental misuse. I.e. compliance with BS EN 62366:2008 'Medical devices. Application of usability engineering to medical devices and provide details of any known pitfalls relating to use of the device
- Details of any training requirements, a copy of the instructions for use and any other relevant supporting information
- The expected whole life costs of the device including renew and consumables
- Details of specific maintenance, decontamination or disposal procedures

3. A review of published evidence and available safety data is completed by the CSU

4. An expert advisory panel is presented with the relevant information and provide thier opinion as outlined in the 'medical devices, expert advisor evaluation questionaire.'

5. A summary document and draft 'position statement' is produced by the CSU for consulation with LMMG member organisations

6. LMMG member organisations consult with local clinicians, patients and public as appropriate and send comments to the CSU

7. The CSU collates comments and refines the draft 'position statement', the final draft "position statement" is considered by LMMG and a recommendation is made

8. The LMMG recommendation is sent to CCGs for local adoption or adaptation

Appendix 1

MEDICAL DEVICES
EXPERT ADVISER EVALUATION QUESTIONNAIRE

Title: Product name for the treatment/ diagnosis/management of patient population/subgroup and/or stage/disease/ condition

Background: Type/class of device, purpose of product; differences/ claimed improvements on existing treatments; Claimed patient and healthcare system benefits; Mode of action; Website address.

Table 1. Details of Expert Advisors Contributing to this Questionnaire

Name of Expert Adviser	Organisation and Job title	Indicate if this device has been through a decision making process and approved for use by your organisation	Indicate your level of experience with the device* a. I have had direct involvement with its use b. I have referred patients for its use c. I have no experience of using this device but it is relevant to my area of practice	Any declarations of interest

Note: the advice and views presented in this questionnaire will form part of the information used by the Lancashire Medicines Management Committee (LMMG) when making a recommend on the use of this device.

The questionnaire may be completed on a collective or individual basis, however where the views of an individual(s) differ, it should be clearly reflected in the response.

*****Where you/your organisation have experience with using this device please provide details of:

- Number of patients treated and outcomes
- Reported safety issues
- Known device functionality or performance issues

Table 2. Information made available to and considered by the expert advisors as follows	
	Y/N (Details)
The application/request for device review	
Additional information as provided from the manufacturer	
Evidence of effectiveness	
The patient information leaflet/instructions for use	
The device/dummy version of the device	
Local audit/outcomes data	
Other	

1. **What do you consider is the most appropriate use for the device and the typical 'clinical scenario' within which this device is likely to be used?**

2. **What are the most appropriate comparators for this device?** (Provide details of any competing products)

3. **What are the likely additional benefits for patients and the healthcare system of using this device, compared with current practice and comparators?** (Please comment on what specific outcome measures would enable assessment of whether additional benefits for patients are being realised)

4. **What do you consider the potential risks associated with using this device to be?** (Describe both known and potential safety issues and risks associated with this device and outline how these may be minimised. Clarify if there are any known or potential restrictions relating to the safe use of this device e.g. should certain patient groups be excluded from use, or the duration of device use be limited)

5. **Is special training required to use this device safely and effectively?** (Consider ease of use, clarity of instructions and supporting patient information and identify any known or potential pitfalls. If training is required please describe how you anticipate this would be delivered)

6. **What do you consider to be the potential issues relating to functioning, reliability and maintenance of this device which may be important to consider if it is introduced?**

7. **Are there any particular facilities or infrastructure, which need to be in place for the safe and effective use of this device?**

8. **Do any subgroups of patients need special consideration in relation to the device? For example, because they have higher levels of ill health, poorer outcomes or may have problems accessing or using treatments.** (Please explain why).

9. **Are you aware of any evidence relevant to this request which has not been considered in the review provided?**

10. **Please provide comments on the evidence provided** (For example, where the comparators appropriate, was the patient group suitable and did the trial reflect how the device would be used in practice?)