FORMULARY AND MANAGED ENTRY SUBGROUP

Procedure for Evaluation of Medical Devices

GMMMG Greater Manchester Medicines Management Group NHS

Part of the remit of the Formulary and Managed Entry Subgroup (FMESG) will be to review those medical devices that can be prescribed within primary care. This procedure outlines how the subgroup will evaluate these requests.

What is a Medical Device?

The term "medical device" covers a wide range of products used every day in primary and community care settings. Devices include items such as needles, syringes, infusion pumps, endoscopes, examination gloves, dressings, walking sticks, and blood glucose meters. In other words, any instrument, apparatus, appliance, material or health care product, excluding drugs, used for, or by, a patient or service user for:

- Diagnosis, prevention, monitoring, treatment or alleviation of disease.
- Diagnosis, monitoring, treatment, or alleviation of, or compensation for, an injury or impairment.
- Investigation, replacement, or modification of the anatomy or of a physiological process.
- Control of conception.

The medical devices that will be considered by FMESG are any newer devices (<18months old) that can be prescribed on a FP10 prescription.

A complete list of prescribable devices is available in Part IX of the Drug Tariff - available online here: http://www.ppa.org.uk/ppa/edt_intro.htm (updated monthly)

Please note that FMESG will expect NHS Trusts to continue to evaluate medical devices for quality, effectiveness and safety through local processes before submission to FMESG for review with a comprehensive evaluation report.

The Decision Making Process

- Only devices that have been through a decision making process within the Trust and approval granted will be considered for evaluation by FMESG. i.e. approval by the Trust Medical Devices Committee.

- A proper evaluation of devices is required to ensure that prescribing is justified. FMESG will expect a full evaluation, from the provider recommending the device.

- If a robust evaluation has not been made then the Trust will not be able to request primary care prescribing.

- Devices must be approved by FMESG before requests for primary care prescribing of any devices can be sent to GP's.

- Any available clinical evidence on use of the medical device will be identified and looked at independently by FMESG as with new medicines.

- The evaluation provided by the Trust will need to consider all the points outlined below.

Points to be covered by Evaluation Report:

1. Identification of Need

All medical devices and equipment should be selected and acquired in accordance with the Medical Devices Agency and the National Audit Office recommendations.

When considering the purchasing of medical devices the following should be taken into account in the justification of need for the device: Clinical need, Risk management and Infection Control, Equipment replacement, Changes in design, technology, or clinical practice, Patient specific needs and NICE Best Value Technology Appraisals.

2. Evaluation and Selection of New Equipment

Before moving onto selecting a device, it is important to make a realistic estimate of the total costs of acquiring a piece of equipment for its whole life.

'Total' costs include such things as maintenance, training and running costs, and to make sure that the likely benefits outweigh these costs. In addition details of how the device will be cleaned and decontaminated need to be taken into consideration.

The patient should be given full details on how they can clean or get the device cleaned properly.

3. Reduction of Variety

Consideration should always be given to the range of similar equipment already in situ in the organisation. Additionally, issues regarding staff familiarity and training and subsequent clinical risk should be taken into account.

It is good procurement practice to identify and rationalise the range of products in use within the organisation. Excess diversity can be expensive and standardisation on items of common use can make savings both in maintenance (spares) and consumables costs.

Standardisation on medical devices should be considered in order to achieve best value for money, to minimise the amount of training/re-training as staff move between areas of work and, ultimately, to reduce clinical risk.

4. Equipment Audits

The GMMMG FMESG needs access to adequate information in order to make an informed decision, particularly regarding new products which may be being considered.

Therefore the provider will be expected to undertake an audit of use in accordance with Trust policies and the report of this audit should be made available to the subgroup so that they can evaluate all available data.

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