NHSScotland

Pre-Health Technology Assessment Free of Charge (pre-HTA FOC) Pricing Schemes

Guidance

Contents

1 Background

1.1 There are established arrangements in place to provide access to medicines, without charge, as part of the Medicines and Healthcare Regulatory Agency (MHRA) Early Access to Medicines Scheme (EAMS). Separate from this, some pharmaceutical companies have chosen to offer medicines free-of-charge whilst awaiting health technology assessment (HTA) by, the Scottish Medicines Consortium (SMC). These pricing schemes are known as Pre-Health Technology Assessment Free of Charge Pricing Schemes (pre-HTA FOC).

1.2 Unlike medicines that are part of the EAMS arrangements, medicines made available via FOC schemes have not been identified by the MHRA as addressing a clear unmet medical need for patients with seriously debilitating or life threatening conditions. For most FOC pre-HTA schemes offered, there is an established therapeutic option available.

1.3 There is currently no standardisation in the types of FOC schemes being offered by pharmaceutical companies. The terms can vary as can the complexity and workload involved in assessing, managing and administering schemes. It would be neither appropriate nor feasible for this pricing approach to be adopted for every new medicine.

1.4 In November 2018, following consultation of Area Drug and Therapeutics Committees (ADTCs), agreement was reached by Health Boards that to reduce duplication of effort and to help manage risks, a national approach should be taken for pre-HTA FOC pricing schemes. This paper outlines the circumstances, agreed by ADTCs, in which National Procurement will enter into a pre-HTA Free of Charge pricing agreement on behalf of Scottish Health Boards and the process for the proposal, review, implementation and on-going management of pre-HTA FOC Schemes.

1.5 This approach relates solely to medicines pricing arrangements. There is no change to the standard Health Board medicines governance processes whether the medicine is free of charge, or not. To avoid introducing inequity in the access to medicine arrangements and to ensure clinical appropriateness and patient safety is considered, standard medicines governance processes must be followed at Health Board level to determine individual patient access to medicines that have not been assessed by SMC (e.g. individual patient treatment requests [IPTR] and peer approved clinical system [PACS]). Where the medicine is unlicensed or used off-label, standard governance routes for unlicensed medicines) must also be followed.

2 Proposal of pre-HTA FOC pricing schemes in NHSScotland

2.1 Pharmaceutical companies should submit proposed schemes to the PASAG Secretariat (NSS.NP-PASAG@nhs.net) using the two documents in Appendix 2

- Pre-HTA Free of Charge Pricing Scheme Application
- Pre Health Technology Assessment Free of Charge Pricing Scheme Agreement

3 Review of pre-HTA FOC pricing schemes in NHSScotland

3.1 The PASAG Secretariat will undertake an initial review of the application to confirm that it has been fully completed and seek clarification where necessary before passing it to the national decision-making group, a sub-group of the National Acute Pharmacy Service (NAPS) Leads group.

3.2 The decision making group will consider whether the proposal meets the eligibility criteria (as outlined below) for NHSScotland Pre-HTA FOC Pricing Schemes.

3.3 A record of the decision will be made using the "decision proforma" (Appendix 2).

3.4 Where necessary, members of the decision making group, will consult appropriate clinical experts and additional stakeholders (such as procurement and finance specialists) within their Board to support the assessment of the proposed scheme.

4 Eligibility criteria for NHSScotland Pre-HTA FOC Schemes

4.1 For the indication within the scope of the proposed FOC scheme:

- The medicine is unlicensed or newly licensed in the UK and pending SMC assessment;
- If not yet submitted to SMC for HTA, the company has a plan to submit and there is reasonable justification for any delay in submission;
- The medicine will be used for patients with life-threatening or seriously debilitating illnesses, where no alternative therapeutic option is available and where a specialist clinician is required to initiate and manage treatment;

4.2 The pharmaceutical company is willing to supply the medicine (for the specified indication) free of charge or at negligible cost in all Health Board areas under the standard NHSScotland terms for pre-HTA FOC schemes. The standard terms are appended to this document, and include:

4.2.1 *Enrolment Period:* New patients can be enrolled in the scheme from the start date of the pricing agreement to the date that either SMC issues advice on the

medicine to Health Boards or that the medicine is available under the ultra-orphan pathway, following the company submission to SMC. The enrolment period should be no less than 3 months.

4.2.2 *Access to free-stock for patients enrolled on the Scheme:* Once a patient is enrolled in the scheme, they are eligible to receive free of charge stock until:

- Ninety days after issue of SMC advice to Health Boards (advice is confidential for the first 30 days) where the new medicine is accepted for use or for restricted use in NHS Scotland; or
- Ninety days after the medicine is available for prescribing in NHSScotland under the ultra-orphan pathway; or
- As long as patient(s) established on the medicine continue to require it on clinical grounds if the medicine is not recommended by SMC or where the patient is within a sub-group that falls outside of an SMC prescribing restriction.

4.3 The medicine is fully free of charge or a negligible price per pack (that is £1 per pack, or less) and the offer is not a partial price discount.

- Note, where a company is planning to offer a simple Patient Access Scheme (PAS) as part of the HTA submission to SMC, and is willing to make that discount available regardless of the SMC decision, the Patient Access Scheme Assessment Group (PASAG) Secretariat will support communication of the discounted price to Boards via the established communication route for PAS pricing;

4.4 There is no requirement for patient-identifiable data to be shared as part of the FOC scheme;

4.5 The order form/process to be used by Boards to order stock under the proposed scheme is not more burdensome to administer than the Template Order Form appended to this document;

4.6 There must be sufficient information available on pricing of the product and associated costs (for example for companion diagnostics, monitoring, and supporting treatments) for Boards to forecast potential future costs;

4.7 The pharmaceutical company agree not to market the scheme directly to clinical staff, patients, or patient groups/charities. Communication will be via the internal NHS communication channel used for PAS.

5 Implementation and communication of pre-HTA FOC pricing schemes

5.1 A standard pricing agreement has been developed ("Pre-HTA FOC Pricing Scheme Agreement" in Appendix 2).

5.2 Where the decision-making group has opined that the pre-HTA FOC is acceptable for implementation in NHSScotland, National Procurement will pass the agreement through the standard National Procurement governance processes for entering into pricing agreements before entering into the scheme on behalf of all Health Boards.

- any requests by companies for variations to the standard agreement will introduce delays.

5.3 The PASAG Secretariat will communicate the decision to Health Boards via the established communication route for PAS (via Directors of Pharmacy, Directors of Finance and ADTC Chairs). A centrally held register of proposed FOC schemes that have been endorsed or not endorsed will be made available to Health Boards.

5.4 Where a scheme proposal is not considered acceptable for implementation in NHSScotland, reason(s) will be given to the company (anonymised copy of the decision proforma completed by the decision making group) and shared with Boards.

5.5 A free of charge scheme will not mean that the medicine is automatically available for use. Standard medicines governance processes should be followed at Health Board level.

- Decisions relating to individual patient access to medicines that have not been assessed by SMC are via processes such as IPTR and PACS.
- Where the medicine is unlicensed or used off-label, standard governance routes for unlicensed medicines should be followed.

5.6 All Health Boards should have a local policy that documents the local framework for use of medicines supplied FOC which may include systems to track stock and supplies for patients enrolled and not enrolled in the FOC scheme.

5.7 Normal financial governance associated with purchasing the medicine should be followed. The medicine should be purchased or acquired by a pharmacist or member of pharmacy staff acting under delegated authority. A purchase order number should be provided to the supplier before stock is released.

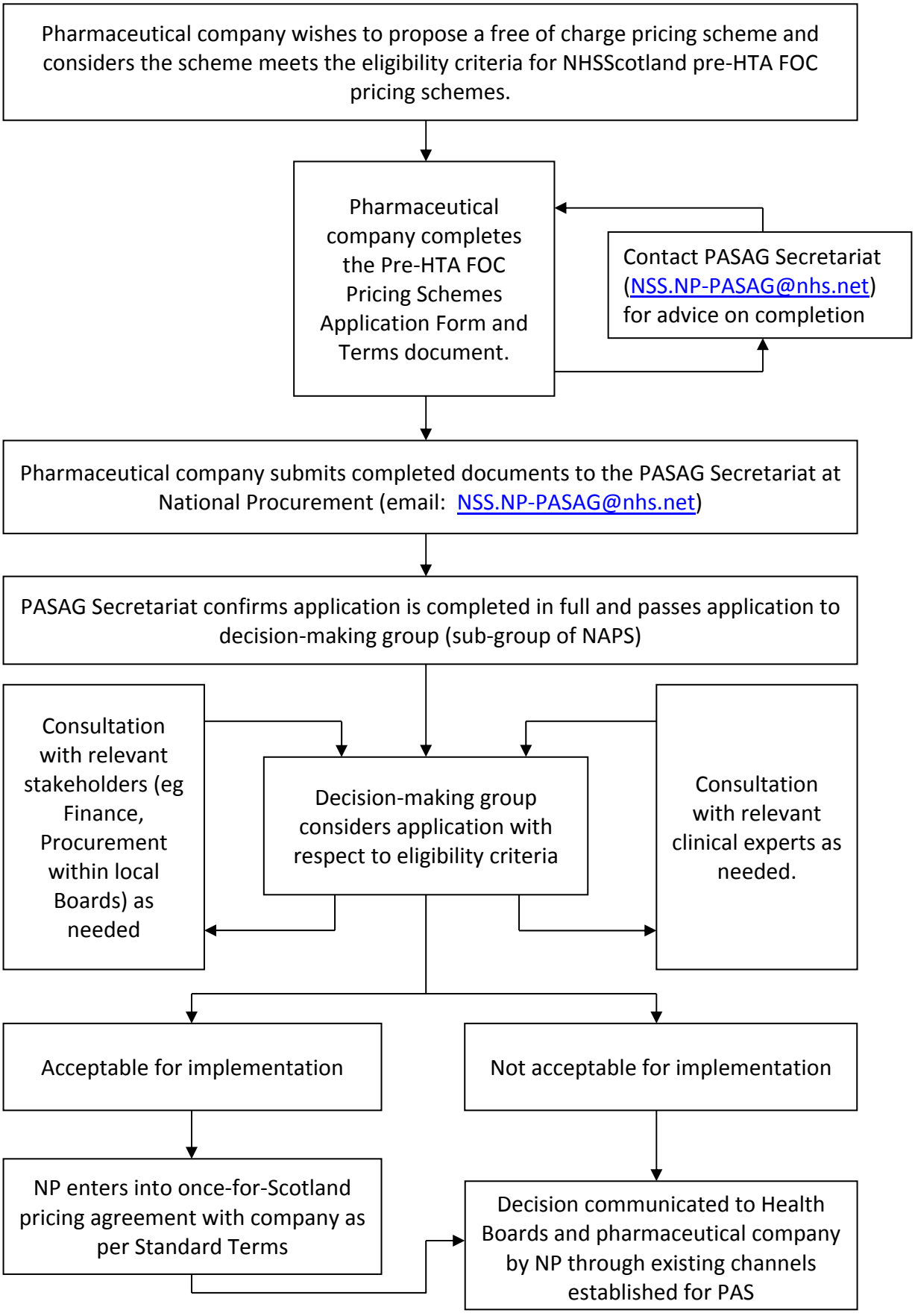
5.8 The PASAG Secretariat will monitor implementation of nationally agreed FOC schemes to ensure the requirements on companies within the pricing agreement are being adhered to and will collate relevant information on the benefits gained and problems arising to support review of the national approach.

5.9 The PASAG Secretariat will alert Boards when the scheme ends.

5.10 The approach will be reviewed to take into account experience following its implementation.

Appendix 1

Overview - submission and assessment of pre-HTA FOC pricing schemes



Appendix 2

Embedded documents

Document name	Embedded file
Pre Health Technology Assessment Free of Charge Pricing Scheme Agreement	 Pre HTA FOC Agreement v1.0 Final
Pre-HTA FOC Pricing Schemes Application Form	 Pre-HTA FOC Application (v1) - gen
Template - order form for FOC stock	 Pre-HTA FOC Template Order Form
Decision proforma for review of proposed pre-HTA FOC pricing schemes	 Decision proforma for review of propose
Template - supporting information for Board implementation	 FOCXXX - generic name (Brand Name) F