Health and Social Care Board

Health & Social Care Board
12-22 Linenhall Street
BELFAST BT2 8BS

Tel : 03005550115
Web Site :
www.hscboard.hscni.net

Trust Chief Executives

11 February 2019

Dear Colleagues

MANAGED ENTRY OF NEW MEDICINES FEBRUARY 2019

I am writing to advise you of changes to the Managed Entry of New Medicines as set out in Appendix 1.

The specific change to which I wish to draw your attention is in regard to the commissioning position.

The Process for the Managed Entry of New Medicines was established by the HSC Board in March 2014. In the intervening time, a number of developments at both a national and local level mean that the managed entry process needs to be updated to reflect such developments. Most recently this has included access to medicines funded in England via the Cancer Drugs Fund.

In Northern Ireland, there are substantive routine commissioning processes in place to ensure appropriate and timely access to evidence-based medicines. The Board commissions the use of a medicine when a NICE Technology Appraisal (TA) has been issued and as part of the agreed process with the Department. Furthermore, when a licensed medicine is not routinely commissioned, arrangements are in place for the HSC Board to consider requests for funding on an individual patient basis through the Individual Funding Request (IFR) process.

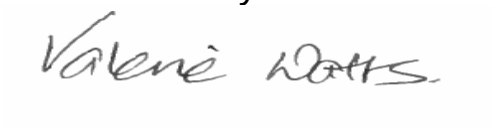
The Process for the Managed Entry of New Medicines is intended to address the majority of circumstances by which new medicines are introduced in Northern Ireland. In situations where the introduction of a medicine sits outside what is considered usual, the Board will assess the

pertaining circumstances and advise of the particular commissioning position.

If a circumstance arises that cannot be accommodated by the managed entry process the Board and Agency will consider this matter and advise the HSC accordingly.

Appendix 1 summarises the circumstances whereby new medicines are introduced in Northern Ireland. I ask that you share this with relevant staff within your organisation.

Yours sincerely



Valerie Watts
Chief Executive

Enc

Appendix 1: The Managed Entry of New Medicines. HSC Board Commissioning Arrangements. February 2019		
Scenario		**2019 position**
1	NICE has issued a Technology Appraisal (TA) which recommends the use of the therapy for a particular indication and this has been endorsed by the DoH as applicable in NI.	The Board normally commissions the use of the drug/therapy as part of the agreed process for the implementation of Technology Appraisals in line with DoH Circular HSC (SQSD) 2/13. The Board commissions medicines for which a TA has been issued that recommends the use of the therapy within the CDF.
2	A drug/therapy is not routinely commissioned, but is licensed for use in the UK for particular indication(s).	Arrangements are in place for requests, on an individual patient basis, to be considered through the IFR process and subject to demonstration of clinical exceptionality as outlined within the IFR policy.
3	NICE has issued a TA which recommends the use of a drug/therapy but the Departmental endorsement process has not been completed.	The Board initiates interim commissioning arrangements, via the Cost Per Case (CPC) mechanism, in circumstances where providers are in a position to comply with the specifications contained in the TA, including any discount, Patient Access Scheme, Managed Access Agreement or Commercial Arrangement applicable to the drug/therapy. The Board currently reviews CPC-funded medicines on a six-monthly basis with a view to moving them into routine commissioning where possible. Note: All therapies recommended by NICE for inclusion within the Cancer Drug Fund in England will be funded on cost per case basis in Northern Ireland for as long as NICE indicates that funding via the Cancer Drugs Fund is appropriate.
4	NICE is in the process of appraising a drug/therapy for a particular indication and a Final Appraisal Document (FAD) has been issued which recommends use of the drug/therapy for that indication.	The Board initiates interim commissioning arrangements (via the CPC mechanism) in circumstances where providers are in a position to comply with the specifications contained in the FAD, including any discount, Patient Access Scheme, Managed Access Agreement or Commercial Arrangement applicable to the drug/therapy. Where a discount, Patient Access Scheme, Managed Access Arrangement or Commercial Arrangement have yet to be finalised as part of the FAD process, the therapy can only be accessed via an Individual Funding Request.
5	NICE is not intending to appraise a drug/therapy but the drug/therapy has been recommended for use by another UK health technology appraisal body.	The Board has the discretion to adopt the recommendations made by another UK health technology appraisal body. The Board will initiate interim commissioning arrangements (via the CPC mechanism) in circumstances where providers are in a position to comply with the specifications contained in the health technology appraisal, including any discount, Patient Access Scheme, Managed Access Agreement or Commercial Arrangement applicable to the drug/therapy.

6	NICE is appraising the drug/ therapy and a recommendation is awaited.	The Board has the discretion to adopt the recommendations of another UK health technology appraisal body. The Board will initiate interim commissioning arrangements (via the CPC mechanism) in circumstances where providers are in a position to comply with the specifications contained in the technology appraisal, including any discount, Patient Access Scheme, Managed Access Agreement or Commercial Arrangement applicable to the drug/therapy.
7	NICE has issued an appraisal via the Highly Specialised Technologies (HST) programme.	The Board is in a position to commission drugs/therapies that have been recommended for use via the NICE Highly Specialised Technologies programme and have been endorsed by the Department of Health for use in Northern Ireland. For HST medicines that have not been endorsed for use in Northern Ireland, funding for individual patients (for the medicine's licensed indication) can be accessed via the IFR arrangements subject to a demonstration of clinical exceptionality as outlined within the IFR Policy.
TA = Technology Appraisal; CPC = cost-per-case; HST = Highly Specialised Technology; CDF = Cancer Drugs Fund		