Health and Social Care Board

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

Via email only
Trust Chief Executives

Tel : 028 90321313
Fax : 028 90 553625
Web Site : www.hscboard.hscni.net

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Dear Colleague,

PROCESS FOR THE MANAGED ENTRY OF NEW MEDICINES

The HSC Board, in conjunction with the Public Health Agency, has been developing new arrangements for the managed entry of medicines, with the aim of ensuring timely and equitable access to those medicines for which there is an evidence base on efficacy and cost-effectiveness. This letter sets out the detail of those new arrangements the Board will introduce with effect from 1 April 2014.

Current position

With regard to the availability of more specialist drugs/therapies in secondary care, arrangements are in place through routine commissioning to ensure appropriate and timely access to evidence-based medicines. Currently, the Board normally commissions the use of a drug/therapy when a NICE TA has been issued and as part of the agreed process with the Department.

Furthermore, when a drug/therapy is not routinely commissioned (but is licensed for use in the UK), arrangements are in place for requests on an individual patient basis to be considered by the Board through the IFR process as detailed in my letter to Trusts of March 2012. When the use of a treatment is required in a clinical emergency, arrangements are in place that facilitate a clinician prescribing the drug, with Board approval sought retrospectively.

Requests for drugs/therapies for rare diseases are dealt with as part of routine commissioning arrangements or the IFR process, depending on the circumstances of the particular drug.

In relation to the use of non-specialist medicines, prescribers look to evidence based clinical guidance such as the NI formulary, NICE clinical guidelines and various other sources of information. With the implementation of the NI formulary, there is now a recognised standard for prescribing in the majority of instances for medicines already on the market.

Improving Current Arrangements

Notwithstanding the existing systems and processes which have been effective in the vast majority of circumstances, the Board recognises the need to refine the existing arrangements and, in particular, to provide greater clarity on the approach to be taken in relation to medicines for which the evidence base is evolving.

In addition to the current arrangements whereby the Board commissions a new medicine when a NICE TA has been issued, it is our intention to commission drugs/therapies that hold a UK licence and for which one of the following apply:

- A NICE TA has been issued recommending use of the drug/therapy but the DHSSPS endorsement process has not been completed. In such circumstances, providers need to be in a position to comply with the specifications contained in the TA, including any discount applied to cost of the drug/therapy; or

- NICE is in the process of reviewing the drug/therapy for the intended indication, an FAD has issued and it recommends use of the therapy for a particular indication. In such circumstances, providers need to be in a position to comply with the specifications contained in the FAD, including any discount applied to cost of the drug/therapy; or

- NICE is not intending to review a drug/therapy but SMC has approved its use. In such circumstances, providers need to be in a position to comply with the specifications contained in the SMC decision, including any discount applied to cost of the drug/therapy; or

- NICE is intending to review but the decision is not imminent and the drug/therapy is SMC approved. In such circumstances the Board will have the discretion to reflect

the SMC position, pending a recommendation from NICE. In such circumstances, providers need to be in a position to comply with the specifications contained in the SMC decision, including any discount applied to cost of the drug/therapy.

Outwith the circumstances outlined above or when NICE/SMC have **not** recommended a drug for use, that medicine will not be routinely commissioned in NI in either primary or secondary care. When such circumstances apply the Board will advise providers accordingly. However, where a hospital consultant considers there are clinically exceptional circumstances that apply to their patient despite a decision not to recommend use of a drug, they will be able to request access to the drug under the process in place for consideration of Individual Funding Requests (IFRs).

Unlicensed and Off-label Medicines

In regard to the process for consideration of requests for funding of medicines that do not hold a UK licence for any clinical indication, the Board has carefully examined the relevant issues that apply to such circumstances and will continue with existing arrangements such that the clinical decision making process should remain at Trust level. The prescribing clinicians will remain responsible for the clinical decision making in regard to the choice of drug/therapy required. Trusts will remain accountable for scrutinising requests for unlicensed use of medicines through their existing clinical governance infrastructure, without reference to the HSCB. As is currently the case, Trusts would routinely be expected to cover the costs of approvals, again without reference to the HSCB.

The Board recognises that there will be occasions when the decision to support the use of an unlicensed drug on clinical grounds may exceptionally generate costs that are of such materiality that they exceed that which a single Trust could reasonably be expected to absorb. In this context the Board would not expect Trusts to apply to the HSCB for funding unless the financial threshold for an individual patient was likely to exceed £50k in a single financial year. In any application to the Board requesting funding, the clinical background to the decision to support the drug would not be considered by the HSCB.

The position above is the approach in regard to medicines which have no UK licence. It is also useful to clarify the position for drugs used for indications other than a licenced indication, (i.e. 'off-label'

use), where definitive advice from NICE is not available. In this circumstance, for the majority of medicines that clinicians wish to prescribe 'off-label', the prescribing clinician will continue to be responsible for the governance issues, and Trusts will continue to provide the treatment without any need to seek approval from the HSCB unless the financial threshold for an individual patient was likely to exceed £50k in a single financial year. Where definitive advice is available from NICE on the cost effectiveness of 'off-label' use of a medicine the Board will ask Trusts to comply with this advice as they would comply with NICE advice on licenced use of a drug. In circumstances where such definitive advice is not available, the Board would expect that the drug is made available in accordance with the Trust's agreed policy on the use of the particular medicine.

Monitoring Arrangements

Our commissioning intentions as outlined above will be supported by robust administrative arrangements to ensure timely communication, appropriate monitoring and reporting, and appropriate financial planning and scrutiny in both primary and secondary care.

Specifically, we will introduce the following:

- The Board will ensure that all information regarding the managed entry of medicines will be available on a dedicated HSCB webpage from the 31 March 2014. We ask that Trusts check this website regularly and ensure that all relevant personnel are updated as appropriate regarding the managed entry of drugs.

- The Board will expect that, for all <u>specialist</u> drugs commissioned through the new arrangements, Trusts should put in place robust arrangements such that they can provide evidence of compliance with the Board's commissioning position, and related expenditure, when requested. It is expected that Trusts will be asked to provide detail of prescribing levels on a quarterly basis and to provide the supporting information on compliance with relevant guidance on an annual basis. The Board will also keep these arrangements under review and will refine them in light of experience.

We anticipate that this will improve the current systems for managed entry of new medicines and further discussion with Trusts on operational aspects can be taken forward through the Medicines Management Commissioning Team liaison meetings.

In parallel, it should be noted that work has been initiated in respect of E-prescribing which will support the monitoring and audit of prescribing in secondary care.

Yours sincerely

John Compton CBE
Chief Executive