Area Drug and Therapeutics Committee Prescribing Supplement

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The Scottish Medicines Consortium (SMC) and the managed entry of new drugs in NHS Scotland

The challenge to all in the NHS to improve medicines management was laid down by the report from Audit Scotland – The Bitterest Pill, 1997 –

“A more effective system of medicines management is vital to ensure best value for money from the increasing drugs budget”

Following this the idea of the Scottish Medicines Consortium arose.

The SMC has the responsibility for making recommendations to all NHS Boards and their Area Drug and Therapeutics Committees (ADTCs) about the status of all newly licensed medicines, all new formulations of existing medicines and any major new indications for established products. The advice is issued as soon as possible after marketing of the medicine.

NHS Boards have been advised that usually no new medicine should be used in their area until the SMC makes a recommendation. In addition the Lanarkshire ADTC will review the SMC decisions and provide a local decision on formulary status, within four weeks of publication of the SMC guidance on the website – www.scottishmedicines.org.uk. Final recommendations of the SMC are arrived at after careful consideration of the available evidence. Further guidance from Lanarkshire ADTC will provide a decision on whether to:

- Add the drug to the Lanarkshire Joint Formulary if it is has been accepted by the SMC and is a new class of drug where no other formulary option currently exists
- Add or exclude from the formulary if the drug has been accepted by the SMC but the drug is in the same or similar therapeutic class as existing drugs on the formulary and the SMC has advised that the new drug has no particular advantage or disadvantage over similar drugs already available
- Exclude from the formulary (and therefore advise against use in Lanarkshire) if the
SMC recommends that the drug should not be available in the NHS in Scotland

- Refer the new drug for consideration by the Joint Formulary sub-committee before issuing final advice from the ADTC.
- Refer the new drug for consideration by the NHS Board if funding issues require to be clarified before the drug can be prescribed. (This may apply to a number of specialised drug treatments mostly used in secondary care). As stated above these drugs should not be prescribed before funding has been agreed.
- Practitioners will be informed of Lanarkshire decisions via the ADTC prescribing supplement.

The Joint Formulary Committee – is intended to be a sub-committee of the ADTC with the following remit –

- To establish and implement the NHS Lanarkshire Joint Formulary
- To review and update the Lanarkshire Joint Formulary
- Consider all established drugs not reviewed by the SMC
- To consider requests from practitioners for additions or changes to the Joint Formulary (established drugs only)

Please note that further details of the formulary development process will be provided in next months’ supplement.

Special cases – urgent clinical need

“NHS Scotland is expected to take account of advice and evidence from bodies such as the Health Technology Board and the Scottish Medicines Consortium and ensure that recommended drugs or treatments are made available to meet clinical need”
Mr Malcolm Chisholm, Health Minister (3 January 2003)

Health professionals are expected to take account of SMC recommendations when exercising their clinical judgement – “this recommendation does not, however, override the individual responsibility of health professionals to make appropriate decisions in the circumstances of the individual patient, in consultation with the patient and/or carer”.

In other words NHS Lanarkshire must have a process in place to allow prescribing of a drug still under consideration by the SMC or indeed advised by the SMC not to be used, if there is an urgent clinical need for that medicine.

NHS Lanarkshire ADTC recommends that new drugs should not be prescribed until advice has been provided by the Scottish Medicines Consortium (SMC) and the decision to add the new medicine to the Lanarkshire Joint Formulary has been agreed by the ADTC.

The following recommendations have been published by the SMC and reviewed by the Lanarkshire ADTC during August 2003. Please note the decisions on formulary and/or prescribing status in Lanarkshire, agreed by the ADTC (the formulary will be finalised over the next few months and although not available at this time any new drugs notified for formulary inclusion now, will be included in the final printed version): -
<table>
<thead>
<tr>
<th>Date of SMC recommendation</th>
<th>Drug/product</th>
<th>Indication</th>
<th>SMC recommendation</th>
<th>Lanarkshire recommendation and ADTC comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>11/08/03 No 55/03</td>
<td>Valdecoxib (Bextra®)</td>
<td>Symptomatic relief of osteoarthritis and rheumatoid arthritis</td>
<td>Recommended for general use within NHS Scotland. <strong>No advantage or disadvantage over other COX-2 selective NSAIDs.</strong></td>
<td>Not added to the Lanarkshire formulary as alternatives exist – celecoxib, rofecoxib, etodolac and meloxicam.</td>
</tr>
<tr>
<td>11/08/03 No 56/03</td>
<td>Enfuvirtide (Fuzeon®)</td>
<td>In combination with other antiretroviral drugs for HIV.</td>
<td>Recommended for restricted use within NHS Scotland. Use only by clinicians experienced in the management of HIV infected patients</td>
<td>Approved for use in Lanarkshire according to clinical guidelines but referred to NHS Board to consider funding issues. <strong>To be prescribed only on a case by case basis until funding has been clarified.</strong></td>
</tr>
<tr>
<td>11/08/03 No 57/03</td>
<td>Memantine (Ebixa®)</td>
<td>Moderate to severe Alzheimer’s Dementia</td>
<td><strong>Not recommended</strong> for use in the NHS in Scotland</td>
<td>Not approved for use and not added to the Lanarkshire formulary. Patients already receiving the drug should continue. Memantine should not be prescribed for new patients.</td>
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<tr>
<td>08/09/03 No 59/03</td>
<td>Olopatadine 0.1% eye drops (Opatanol®)</td>
<td>Treatment of ocular signs and symptoms of seasonal allergic conjunctivitis</td>
<td>Not recommended for use within NHS Scotland</td>
<td>Not approved for use in Lanarkshire. Excluded from the formulary.</td>
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<tr>
<td>08/09/03 No 61/03</td>
<td>Ezetimibe (Ezetrol®)</td>
<td>Hyper cholesterolama as an add on to diet either with a statin (where statin alone is not effective) or as monotherapy if a statin is not tolerated</td>
<td>Recommended for restricted use in NHS Scotland in combination with a statin where patients fail to reach target cholesterol levels with optimised statin doses alone. Also as monotherapy if a statin is poorly tolerated</td>
<td>Approved for use in Lanarkshire but referred to the cardiovascular subgroup of the ADTC to define its use</td>
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<tr>
<td>08/09/03 No 64/03</td>
<td>Perindopril +indapamide (Coversyl Plus®)</td>
<td>Treatment of essential hypertension in patients whose blood pressure is not adequately controlled by perindopril alone.</td>
<td>Recommended for general use in NHS Scotland. Perindopril plus indapamide produces a modest reduction in blood pressure in patients with essential hypertension uncontrolled by perindopril alone</td>
<td>Recommendation noted but not added to the formulary as it is equally effective to prescribe an ACEI and diuretic separately. Low dose bendrofluazide remains the first choice thiazide.</td>
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<tr>
<td>08/09/03 No 62/03</td>
<td>Valganciclovir (Valcyte®)</td>
<td>Prevention of cytomegalovirus infection in CMV negative patients who have received a solid organ transplant from a CMV positive donor</td>
<td>Recommended for restricted use in NHS Scotland. Once daily dosing is a benefit over the three times daily existing treatment</td>
<td>Recommendation endorsed for use within specialist services in Lanarkshire. Additional funding not required.</td>
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<tr>
<td>08/09/03 36/03</td>
<td>Desogestrel (Cerazette®)</td>
<td>Contraception</td>
<td>Recommended for restricted use in NHS Scotland. This is a progestogen only pill (POP). Use should be restricted to those who cannot tolerate or have a contra – indication to oestrogen containing contraceptives</td>
<td>The recommendation is endorsed by the ADTC however this drug should not be prescribed while further advice is sought from the Family Planning specialists in Lanarkshire</td>
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<tr>
<td>08/09/03 48/03</td>
<td>Norelgestromin- ethinyl estradiol patch (Evra®)</td>
<td>Female contraception.</td>
<td>Recommended for restricted use in NHS Scotland. More expensive than oral contraceptives but may be of benefit in women who have poor compliance to COCs</td>
<td>Recommendation endorsed in Lanarkshire. However supply should only be made by the Family Planning service and only for women who have poor compliance with COCs</td>
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