NHS Circular:
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Finance, eHealth and Pharmaceuticals
Pharmacy & Medicines Division

The Scottish Government

PHARMACEUTICAL SERVICES REIMBURSEMENT OF SPECIAL PREPARATIONS AND IMPORTED UNLICENSED MEDICINES

31 January 2013

Summary

1. This Circular advises of changes to the Drug Tariff effective for dispensings 1 February 2013 onwards in respect of reimbursement of costs borne by community pharmacy contractors when dispensing NHS prescriptions for specialist preparations and imported unlicensed medicines.

Background

2. Professionally NHS Boards and clinicians have responsibilities regarding the use of unlicensed medicines under Article 5.1 of Directive 2001/83/EC.

3. Unless there is a specific clinical reason, clinicians are advised by the Chief Pharmaceutical Officer that they should not continue to use an unlicensed preparation where there is a licensed product which has been accepted for use within NHS Scotland by the Scottish Medicines Consortium (SMC) and is available. This reflects the Medicines and Healthcare Products Regulatory Agency (MHRA) advice on this issue.

4. Reimbursement arrangements for unlicensed medicines are currently detailed at paragraph 14 of Part 1 to the Drug Tariff. The relevant section reads:

SPECIAL FORMULATIONS
Where a pharmacist contractor for some reason cannot dispense the prescription extemporaneously or elects to have it made up as a "special", the pharmacist contractor must provide to Practitioner Services Division (PSD) the reasons why a "special" was necessary. In any doubtful cases PSD, before pricing, may refer matters to the Health Board to ascertain if the additional costs involved through use of a "special" were necessarily incurred and were reasonable. Only in circumstanceswhere the Health Board is satisfied that the use of a "special" was necessary, will the invoiced "special" price be reimbursed. In other cases, payment of ingredient costs and dispensing fees will be made on the basis that the prescription had been dispensed extemporaneously.

Addresses

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5. Updated arrangements are now being introduced into the Tariff to publish formal reimbursement prices for the most commonly prescribed preparations of unlicensed medicines.The introduction of a formal tariff is intended to:

-focus prescribers on ensuring that prescription of an unlicensed preparation is appropriate in the light of the requirements detailed above

- encourage community pharmacy contractors to seek out the most cost effective source of a preparation consistent with the care needs of the patient concerned,

-provide greater transparency of costs involved for all parties including prescribers and NHS Boards

-clarify the role of NHS Boards in ensuring value for money in the dispensing of these preparations by community pharmacies to meet patient need

-streamline claim arrangements for the items concerned with benefits both for dispensers and for Practitioner Services Division in processing claims.

Detail

6. The existing paragraph in Part 1 of the Drug Tariff at section 14 headed SPECIAL FORMULATIONS is accordingly deleted with effect for dispensings from 1 February 2013 and replaced with the following:

SPECIAL PREPARATIONS AND IMPORTED UNLICENSED MEDICINES

Where a pharmacist contractor for some reason cannot dispense the prescription extemporaneously or elects to dispense it as either a special preparation or to dispense an imported unlicensed medicine, the pharmacist contractor must **unless it is a special preparation listed in Part 7S** seek reimbursement authorisation from the contractor's Health Board before dispensing including any additional expenses incurred.

This request for advance reimbursement authorisation should state why in the pharmacy contractor's view the approach proposed is necessary and the cost of the preparation proposed along with all other relevant details.

The Health Board should then timeously respond to the contractor concerned either prospectively approving reimbursement of the dispensing proposed or advising what alternative course of action it would consider to be more appropriate clinically and/or represent better value in meeting the needs of the patient as identified by the prescriber.

Reimbursement for Preparations listed in Part 7S

Where the preparation concerned is included in the list from time to time in force in Part 7S to this Tariff the reimbursed price will be the price listed there. These Tariff prices are set to include a handling allowance. Other than in exceptional cases as detailed below no further remuneration or reimbursement will be made in respect of such a dispensing and no out of pocket expenses may be claimed in respect of any such dispensing.

In exceptional cases only where next day dispensing is considered to be necessary the contractor must seek prior Health Board authorisation (from the officer nominated by the Health Board concerned for this purpose and for receipt of the COA/COC as required below and notified to all community pharmacy contractors in its area) for any

net additional costs arising above the base Tariff price. The Health Board should then timeously respond to the contractor concerned either prospectively approving reimbursement of the prospective additional costs arising or advising what alternative course of action it would consider to be more appropriate clinically and/or represent better value in meeting the needs of the patient as identified by the prescriber. In the latter case the Health Board should share the advice with the prescriber concerned. Where such prior approval is obtained the prescription should be endorsed with the net additional costs concerned when submitted for reimbursement supported by the supplier's invoice.

Part 7S will take effect for all dispensings 1 February 2013 onwards. It may be updated monthly but will also be subject to a regular quarterly review with the first review to take effect before publication of the May 2013 Tariff.

Reimbursement of all other Special preparations and Imported unlicensed medicines

Prescriptions for special preparations not listed in Part 7S will be paid depending on how the special was sourced. Where the special has been sourced

- From a manufacturer holding a MHRA specials licence, the contractor will be paid the price endorsed on the prescription form. This price should be invoice price ***less*** any discount or rebate which may be linked to the procurement of this product.

- Under the manufacturing part of the Section 10 exemption from the Medicines Act 1968, the contractor will be paid the cost of the ingredients used to manufacture the special.

Prescriptions for imported unlicensed medicines not listed in this Part will be paid the price endorsed on the prescription form. This price should be invoice price ***less*** any discount or rebate which may be linked to the procurement of this product.

Endorsement requirements for reimbursement of Special Preparations and Imported unlicensed medicines

It is not necessary to endorse prescription forms for unlicensed medicines listed in Part 7S other than where prior approval for additional costs for next day dispensing has been sought and received from the Health Board or with the endorsement requirements otherwise outlined elsewhere in the Drug Tariff.

For products not listed in Part 7S, contractors shall endorse the form according to how the unlicensed medicine was sourced.

1. Where the unlicensed medicine is manufactured under a specials licence or sourced under an importers licence issued by the MHRA, the contractor shall endorse the

   - invoice price including any additional cost incurred ***less*** discount/rebates (the actual price paid for the product)

   - manufacturer's/importer's licence number

   - batch number of the unlicensed medicine.

2. Where the special has been prepared under the manufacturing part of the Section 10 exemption from the Medicines Act 1968, by the contractor or by a third party, the contractor shall endorse the names, quantities and cost of the ingredients used in preparing the special.

Further requirements when supplying unlicensed medicines

Contractors shall

a. Keep the following records for 5 years:

- The source of the special or imported unlicensed product
- The person to whom and the date on which the special or imported unlicensed product was sold or supplied
- The prescriber's details
- The quantity of each sale or supply
- The batch number of the special

b Make available these records for inspection by the Licensing Authority.

For specials not listed in this Part, the contractor or his representative must stamp, date, initial and endorse the Certificate of Analysis (COA)/Certificate of Conformity (COC) with the invoice price less discount and prescriber's details. At the end of each month, the contractor shall send a copy of the appropriately endorsed COA/COC to the nominated officer of the Health Board of the prescriber, allowing the Health Board to match expenditure to the special supplied.

For imported unlicensed products not listed in this Part, the contractor or his representative shall make every reasonable effort to obtain a Certificate of Analysis (COA)/Certificate of Conformity (COC) for each imported product sourced.

- Where a COA/COC is available, the contractor must stamp, date, initial and endorse the COA/COC with the invoice price less discount and prescribers details.
- Where a COC/COA is not available, the contractor must stamp, date, initial and endorse the invoice with the invoice price less discount (where not clearly detailed by the supplier) and the prescriber's details.

At the end of each month, the contractor shall send a copy of the appropriately endorsed COA/COC/invoice to the Health Board of the prescriber, allowing the Health Board to match expenditure to the special supplied.

The endorsement should also state that the Health Board has pre-authorised the reimbursement of the item concerned and quote the name of the authorising officer and date of authorisation.

Only in exceptional circumstances, where it not possible to obtain pre-authorisation, will the claim for reimbursement be processed without pre-authorisation by the Health Board.

Drug Tariff Amendment

7. Community Pharmacy Scotland has been consulted on the contents of this Circular and the Drug Tariff has been amended giving effect to the amendments advised by this Circular.

Action

8. NHS Boards are asked to bring this Circular to the attention of community pharmacy contractors, local pharmacy committees, GPs and Community Health Partnerships and when doing so to identify for them the name and contact details of the officer nominated in accordance with the requirements outlined in paragraph 6 above to:
- pre- authorise exceptional additional costs for Part 7S dispensings, and dispensings of all other Special Preparations and Imported unlicensed medicines, and to
-receive appropriately endorsed COA/COCs .

Yours sincerely

W.SCOTT
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