NHS
PCA (P) (2015) 17

Healthcare Quality and Strategy Directorate
Pharmacy and Medicines Division

Dear Colleague

PHARMACEUTICAL SERVICES
AMENDMENTS TO DRUG TARIFF IN RESPECT OF SPECIAL PREPARATIONS AND IMPORTED UNLICENSED MEDICINES

Summary

1. This Circular advises of changes in the Drug Tariff effective for dispensings 1 September 2015 in respect of reimbursement of costs borne by community pharmacy contractors when dispensing NHS prescriptions for specialist preparations and imported unlicensed medicines not listed in Part 7S.

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.

21 August 2015

Addresses

For action

Chief Executives, NHS Boards

For information

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4. Reimbursement arrangements for unlicensed medicines are currently detailed at paragraph 14 of Part 1 to the Drug Tariff. Separate arrangements apply depending on whether a reimbursement price is listed in Part 7S or not, when the contractor must seek pre-authorisation from the Health Board of costs before dispensing.

Detail

With effect from 1 September 2015 dispensings

5. This Circular advises of revised arrangements for approval of reimbursement costs in respect of special preparations for which a reimbursement price is not listed in Part 7S of the Tariff. These changes are intended to streamline the approval process whilst continuing to ensure that value for money is achieved for NHS Scotland. In parallel the list of items included in Part 7S has been reviewed and additional items added for which reimbursement prices are available from supplier price lists. This list will continue to be subject to regular review and items may be removed from the list if pricing information is no longer available, and/or new prices may be added and will be removed once a licensed product becomes available. Contractors are therefore advised to check the Tariff each time before dispensing a special preparation.

6. The existing Drug Tariff section in respect of specials and unlicensed medicines is discontinued and replaced by the following revised provisions, in respect of dispensings from 1 September 2015 onwards:

SPECIAL PREPARATIONS AND IMPORTED UNLICENSED MEDICINES

<u>Reimbursement for Preparations listed in Part 7S</u>

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 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.

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 as may be required in accordance with the ***Generic Framework for Specials Authorisation Process across Scotland*** from time to time in force before dispensing including any additional expenses incurred. NHS Circular PCA (P) (2015) 17 includes at Annex A the detail of the ***Generic Framework for Specials Authorisation Process across Scotland***, to apply for dispensings from 1 September 2015 until repealed or amended.

Reimbursement for Preparations not listed in Part 7S but available as a commercially made up item

In order to:

- ensure consistency of procedure and decision making by Health Boards and PSD,
- minimise the need for repeated approvals in cases of repeat dispensings of the same preparation, and
- improve guidance for contractors,

the ***Generic Framework for Specials Authorisation Process across Scotland*** from time to time in force should be followed for approval decisions in respect of preparations not listed in Part 7S.

A Q & A guide for community pharmacy contractors is included at Annex B to NHS Circular PCA (P) (2015) 17.

If a contractor has any doubt about whether approval is needed he/she should seek further advice from the Health Board concerned.

The Health Board should then respond timeously 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.

The contractor will be paid the price endorsed on the prescription form, in accordance with the requirements of the ***Generic Framework for Specials Authorisation Process across Scotland***.

Reimbursement of items prepared by the contractor under the manufacturing part of S.10 of the Medicines Act 1968

Where the special has been prepared 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.

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.

In respect of non Part 7S listed items, the prescription shall be endorsed as laid down in the ***Generic Framework for Specials Authorisation Process across Scotland***.

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.

Only in exceptional circumstances, where it is not possible to follow the procedure laid down in the framework document, will the claim for reimbursement be processed without pre-authorisation by the HealthBoard.

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 Part 7, the contractor or the contractor’s 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.

For imported unlicensed products not listed in this Part, the contractor or the contractor’s 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 COA/COC 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.

The contractor shall retain either the original endorsed COA/COC or an electronic copy thereof for a period of 5 years or for such other period as may from time to time be required by MHRA and/or requirements for GPhC inspections.

Consultation

7. Community Pharmacy Scotland has been consulted on the Drug Tariff amendments advised of above, and on the contents of this Circular.

Action

8. **Health Boards are advised to send a copy of this Circular to all community pharmacy contractors, GP practices and Community Health Partnerships in their areas.**

Community pharmacy contractors should observe the revised procedures herein when dispensing special or unlicensed medications.

Whilst these arrangements relate explicitly to dispensing by community pharmacy contractors, dispensing practices are also advised to note and follow these arrangements when they dispense special or unlicensed medicines.

Yours sincerely

Rose Marie Parr
Chief Pharmaceutical Officer and
Deputy Director, Pharmacy & Medicines Division

Generic Framework for Specials Authorisation Process across Scotland (An authorisation is required for every individual patient)

ANNEX A

Patient presents with a prescription at the community pharmacy. The GP practice system **(EMIS / INPS)** if used may have informed the prescriber that the product is unlicensed. This does not exempt the community pharmacist from undertaking the appropriate clinical checks. The pharmacy proceeds to secure supply unless the pharmacist when undertaking the clinical check deems it necessary to first contact the prescriber.

No Health Board Authorisation Required

The product is NOT listed in Scottish Drug Tariff Part 7s

a. Authorisation obtained for patient prescription within last 12 months with less than 20% price variation from original authorisation
b. Preparation is available from an NHS manufacturing unit within Scotland/ England/ Wales
c. Endorse the fixed non part 7S handling charge as a handling charge (hc)
d. If other OOP expenses apply (including wholesaler handling charges) endorse as postage and packing costs (pp)

The product is listed in Scottish Drug Tariff Part 7s

Health Board Authorisation Required

a. The product is not listed on Scottish Drug Tariff Part 7s.
b. One quote to be sourced including postage & packing, handling charges, shelf life etc.
c. Reauthorisation for the same patient and product if price varies >20% from the original authorisation prescription
d. Reauthorisation required after 12 months for clinical validation
e. Endorse prescription electronically and on paper with invoice price, less any rebate plus any additional cost authorised e.g. OOP expenses (including wholesaler handling charge) should be endorsed as postage and packing costs (pp)
f. Endorse the fixed non Part 7S handling charge of £30 as a handling charge (hc)

Recovery by Health Boards of unauthorised expenditure e.g. where the full amount has not been authorised or the contractor has purchased at a higher price than was pre-authorised

1. If a contractor sources a product at a greater price than agreed the Health Board may reclaim the difference between the agreed price and the final invoice price.
2. If the contractor has not obtained authorisation the Health Board may reclaim the difference between the price that would have been approved and the invoiced price.
3. If the Health Board intends to reclaim monies they will inform the contractor giving them 28 days to appeal any decision.
4. All appeals will be considered on an individual basis by Health Board with a written response within 28 days

ANNEX B

"Specials" Frequently Asked Questions for Community Pharmacy

Pre-authorisation:

Q: When do I need to seek authorisation?
A: You need to seek authorisation for all "Specials" manufactured medicines (which are different from wholesalers' "Special requests" or "Special orders"), unlicensed or imported medications that are:

a. not listed in Part 7S or Part 7U of the Scottish Drug Tariff
b. unavailable from an NHS manufacturing unit within Scotland/ England/ Wales
c. you have followed the process in the ***Generic Framework for Specials Authorisation Process across Scotland***.

Q: What is the difference between Part 7S and Part 7U in the Scottish Drug Tariff?
A: For the purposes of authorisation if a medication is in the Scottish Drug Tariff 7S or 7U, no authorisation is necessary. Part 7S lists unlicensed "Specials" obtainable from Specials Manufacturers, Part 7U lists commercially available products that do not have a product licence.

Q: Should I contact the prescriber to let them know what they have prescribed is a "Special" before I phone for authorisation?
A: Yes, if deemed appropriate whilst carrying out the appropriate prescription clinical check. It should not be assumed that the prescriber is aware that the product is an unlicensed "Special". Both prescriber and pharmacist have shared responsibility when prescribing and dispensing medication. If prescribers are made aware that the item which they have prescribed is unlicensed, this creates an opportunity to prescribe a licensed alternative if appropriate.

Q: How can I find out if a medicine requires to be authorised or not?
A: A good starting place is the BNF. If the product is available as a licensed formulation, this will be listed. Some unlicensed medications are also mentioned in the BNF but are clearly marked as such. If you have checked the BNF and don't think the item is licensed, then check the Scottish Drug Tariff Part 7S and 7U and if still in doubt – phone your Health Board for further advice!

Q: What is a Part 7S item?
A: Part 7S was added to the Scottish Drug Tariff in February 2013 from a list of the most commonly used unlicensed "Specials" in Scotland. A reimbursement price is now listed in the Scottish Drug Tariff for all of these items, regardless of where it is obtained. Handling charges or other out of pockets <u>cannot</u> be claimed on Part 7S items as this is incorporated into the Scottish Drug Tariff reimbursement price.

Q: Where do I find out what is a Part 7S or Part 7U item?
A: This is in the Scottish Drug Tariff. Check the ISD website (see below) and click on Part 7 Excel spreadsheet relevant for that month.

http://www.isdscotland.org/Health-Topics/Prescribing-and-Medicines/Scottish-Drug-Tariff/Drugs-and-Preparations-with-Tariff-Prices.asp

Note the Scottish Drug Tariff is updated on a monthly basis and it is advisable to check the current month details for any changes.

Q: What if there is another strength listed in the BNF but not the one that is prescribed?
A: This indicates that the item prescribed is not routinely available, and likely to be a "Special". But, if other licensed strengths or formulations are available, these should be part of the information provided to the prescriber when you contact him or her to notify that the item is unlicensed as these may be appropriate for the patient.

Q: Where do I find information on what licensed alternatives are available?
A: The BNF is a useful reference source in the first instance. Your Health Board may also be able to help provide advice or guidance on suitable licensed alternatives.

Q: Where do I find information on what supplier to contact for a quote?
A: The eventual choice of supplier is a matter for you to decide. The ***Generic Framework for Specials Authorisation Process across Scotland*** is there, however, to help ensure that NHS Scotland achieves value for money in reimbursing the costs you may incur. Experience suggests that provision from NHS production units generally represents value for money. In the first instance therefore, you are recommended to contact the NHS production units to ask if they supply the product. If not, they may be able to advise you who to contact for a particular product. Patients discharged with a "Special" from the specialist children hospitals may provide the community pharmacy with a letter detailing where to obtain further supplies. Otherwise, most pharmacies will have a list of preferred "Specials" suppliers or the Health Board may be able to provide some additional information.

Authorisation:

Q: What items do not need authorisation and are automatically approved?
A: A "special" preparation which is listed in Part 7S or Part 7U or is available from an NHS manufacturing unit within Scotland/ England/ Wales.

Q: Do I need to phone the Health Board every time I receive a prescription?
A: You should refer to the ***Generic Framework for Specials Authorisation Process across Scotland*** to understand the circumstances in which you need to seek prior authorisation. In accordance with the terms of the ***Generic Framework for Specials Authorisation Process across Scotland*** you only need to call at the first time of dispensing for that drug for that particular patient for a 12 month period. Follow up calls are only required within the year if the prescribed preparation alters or if the price changes by 20% from the original authorised amount. Occasionally the Health Board at time of original authorisation may state shorter authorisation periods due to a clinical reason. *NB: it is the community pharmacy staff's responsibility to keep an eye on the price and contact the Health Board for re-authorisation if the price changes.*

Q: Do I need to get re-authorisation if the price increases or decreases?
A: You will need to contact the Health Board if there is a significant price change i.e. greater than 20% from the original authorisation cost agreed.

Q: I can get the item from another supplier cheaper than the Health Board's recommended supplier. Do I need to use the Health Board's recommendation or use the cheaper supplier?
A: As long as you are satisfied about the quality of the product from the other supplier, then you can obtain your items from them, but can only reclaim the price you pay plus £30. The Board is likely to hold supplier and price on file as a "just in case". The Health Board may provide specific supplier for clinical reasons but will advise community pharmacists of this at the time of authorisation.

Q: My usual specials supplier cannot provide this item. Where can I find a list of other suppliers?
A: A list of the Special Order Manufacturers can be found at:-

http://www.medicinescomplete.com/mc/bnf/current/106216.htm#_106216

Your Health Board may also have a list of "Specials" suppliers or manufacturers that you could use. However, this list will not be exhaustive
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Q: When I call for authorisation, do I need to provide a quote?
A: Ideally, yes. This supports the Health Board to seek the most cost-effective price and build up information of where "Special" items can be obtained and at what cost.

Q: Will the Health Board approve any quote that is provided?
A: Health Boards have the right to challenge any high costs for a "Special" and may suggest to contractors an alternate supplier where the cost is more in line with previous similar requests which had been authorised. Some wholesalers may price match this cost.

Q: My wholesaler is insisting it is a "Special" even though it is in the BNF. Do I need to seek authorisation?
A: If the product is licensed but the wholesaler says it is a "Special order", then you do not need to seek authorisation.

Q: How long is an authorisation valid for?
A: See the advice in the ***Generic Framework for Specials Authorisation Process across Scotland***. In accordance with that advice, after 12 months following authorisation community pharmacy staff are advised to review all "repeat" "Specials". Re-authorisation to be undertaken following clinical validation with the Prescriber that the "Special" is still required. In certain circumstances, occasionally Health Boards may issue an authorisation for a "one off" supply, or for a period shorter than 12 months. This will be advised at the time of the initial authorisation and if further supplies are needed then re-authorisation will be required.

Q: I know this isn't a "Special" but should I ask for authorisation because it's an expensive drug?
A: No, if the product is licensed, then you don't have to seek authorisation. However, by calling and checking it does give the Prescribing Team the opportunity to check that a GP can prescribe some of these items or refer back to acute care services if necessary.

Q: The patient has indicated that he/she cannot tolerate a licensed product. Can the contractor seek to have a special formulation made?

A: MHRA does allow for a special formulation if the patient cannot tolerate the licensed formulation. The contractor should confirm with the prescriber that the situation is genuine and obtain permission to seek a special formulation. The contractor should then contact the NHS Board and explain the situation, including that the prescriber has agreed to this change. The Board will advise on how to proceed, including confirmation that other licensed products are not suitable for this patient.

Q: The prescriber has ordered a licensed product that is currently unobtainable, with no projected date of return to full supply. Can the contractor ask for a special formulation?
A: The contractor should discuss this with the NHS Board. It is possible that a contingency arrangement is in place, such as temporary supply from a NHS production unit. The NHS Board may confirm the supply situation with National Services Scotland (NSS). It is possible that more than one quote may be required if the product has to be made to order.

Q: What is the process if a special product has been ordered and a licensed version suddenly appears?
A: The Board will accept that some products are announced with minimal notice. If the order is dated from before the announcement of the licensed version, any authorisation granted will be honoured. The contractor will be expected to make further supplies using licensed stock. If licensed stock appears not to be available, the contractor should contact Community Pharmacy Scotland using the product shortage mechanism. Community Pharmacy Scotland will liaise with NSS to take this forward.

Q: The prescriber has ordered a liquid preparation as "oral suspension". Part 7S lists the "oral solution" only. Will I be able to obtain a non-tariff version?
A: Under most circumstances, the answer is "no". Part 7S contains products that are more likely to occur, based on the physical properties of the active ingredient and significant excipients. It would be worth checking with the patient and if necessary the prescriber to confirm the acceptability of the Part 7S product. Otherwise authorisation from the Health Board will be necessary.

If there is very good evidence of a significant clinical difference between the two formulations, the Health Board, at their discretion, may grant authorisation as a deviation outside Part 7S. There are no known examples of the third BP formulation type "oral emulsion", but should this occur, the same ruling will apply.

Q: The prescriber has ordered a topical product based in White Soft Paraffin. There is a listing in Part 7 for the same ingredients in Yellow Soft Paraffin. Can I order the product in White Soft Paraffin?
A: Products have been rationalised towards Yellow Soft Paraffin which has been recognised in the list of approved special formulations drawn up by the British Association of Dermatologists. The two versions of Soft Paraffin are therapeutically equivalent, with the only a "cosmetic" difference where the yellow paraffin has been treated with oxygen to bleach out the colour. The matter should be discussed with the prescriber with an aim to amend the prescription to yellow soft paraffin.

Post-Authorisation:

Q: How do I endorse the prescription?

A: Items listed in the Scottish Drug Tariff Part 7S items do not require to be endorsed. For all non-listed Part 7S "Specials", if the item is authorised, the prescription is endorsed 'SP' with the actual price paid i.e. NHS net cost price, excluding VAT, of the product. This should be endorsed in pence in the format 'pppp'. The contractor should also endorse the £30 fixed handling fee using the 'HC' endorsement in pence in the format 'pppp'.

Any other out of pocket expenses (including wholesaler handling charges) are justified using the existing endorsement code of 'PP' (postage and packing) and should also be in pence in the format 'pppp'.

These endorsements should be applied both to the paper form and to the electronic claim using the PMR system.

PSD requirements are listed at:

http://www.communitypharmacy.scot.nhs.uk/endorsing_guide/Section2/2.2.11.3.html

Q: Do I need to keep records of the supply in the pharmacy?
A: Yes, you are required by the MHRA to keep a record for 5 years of the source of the product, person, quantity, batch number and date to whom it was supplied; and prescriber's details. Ideally, this should be recorded in the "Specials"/extemp book within the pharmacy.