New arrangements for reimbursing specials - Q&A

What are the new arrangements for reimbursing specials?

New reimbursement arrangement for specials will come into effect from 1 November 2011. As part of the new arrangements, a number of specials will be listed in the Drug Tariff. The initial list, which will form a new part of the Drug Tariff (Part VIIIB) will be relatively small but will capture the majority of high cost, high volume specials prescribed. The list and the reimbursement prices of the products listed will be reviewed regularly and the list will be expanded, as appropriate.

For those specials not listed in Part VIIIB, payment will depend on how the product is sourced. A new fee for products made under the Section 10 exemption and new arrangements for out of pocket expenses will apply.

Why are Welsh Government introducing new arrangements for reimbursing specials?

The aim of the new arrangements is to create a more transparent system for reimbursing specials, linking the cost of reimbursement to the cost of the product, while providing value for money for the NHS. Having a Drug Tariff price will create an incentive for pharmacy contractors to procure in a manner that is cost-effective for the NHS. Further, the new arrangements will simplify the arrangements for claiming and payment for sourcing specials.

Is the aim of the new arrangements to stop pharmacies from making lots of excess profit on the purchase of specials?

The aims of the new arrangements are outlined above. The funding arrangements for community pharmacy contractual framework (CPCF) recognise that community pharmacy contractors retain a margin on the products they supply against NHS prescriptions.

Each year, in conjunction with the PSNC, the Department holds a margin survey to investigate how much medicine margin the average pharmacy contractor has retained in the previous year. Taking account of the results of margin survey, the prices of the generic products in Category M are adjusted to ensure that the target amount of retained margin is available. Margin retained from procuring specials is considered as part of these CPCF funding arrangements.

When will the Part VIIIB price be paid for a special?

Under the new arrangements, pharmacy contractors will be paid the Part VIIIB price for any product listed in this Part, regardless of how they sourced the product.

Where there is not a significant price difference between the different formulations, the Part VIIIB listing will incorporate as many formulations as possible under the umbrella of a single drug name, e.g., where amlodipine 5mg/5ml solution is listed; this will incorporate the standard formulation along with sugar free, colour free, lactose free. A formulation will be considered a ‘standard’ where the prescriber has not specified a formulation above stating solution or suspension.

However, where there is a significant price difference between the formulations, the formulations may either be listed separately (solution versus suspension) or treated as a non-Part VIII product.

There may be instances where a drug has both licensed and unlicensed formulations available and as a result one formulation will be listed in Part VIIIB and others in Part VIII or IX. For example, sodium chloride eye drops is listed in Part IXA as an appliance but the preservative free formulation is listed in Part VIIIB. In this instance, the pharmacy contractor will be paid the Part IX price unless the preservative free formulation is specifically prescribed.

How will products not listed in Part VIIIB be reimbursed?

Due to the number of specials potentially available, it is not possible to list all the specials available to prescribe. Therefore, new arrangements have been introduced to reimburse those products not listed.

Payment will depend on how the product was manufactured.

1. Where the product is manufactured by a manufacturer licensed by the MHRA and operating under their specials licence, the pharmacy contractor will be paid the price that they pay (invoice price minus any discount/rebates given) for the product.

2. Where it is manufactured under the section 10 exemption (by the pharmacy contractor or a 3rd party), the pharmacy contractor will be paid the cost of the ingredients in the product.

Apart from the cost of the product, what other payments will be made?

Regardless of whether a product is listed in Part VIIIB or not, contractors will be eligible to an additional payment, which will depend on how the product was sourced.

- Where the product has been prepared by a manufacturer operating under a Specials Licence issued by the MHRA – a payment of £20 to contribute to out of pocket expenses e.g. carriage. This payment must be claimed by endorsing SP on the prescription. The usual way of claiming out of pocket expenses **must not** be used.
- Where the product is prepared under the Section 10 exemption (by the contractor or a 3rd party), a £20 extemporaneous dispensing fee will be paid to recognise the cost of preparing the product or the cost of sourcing the product from a supplier who has produced the product under the Section 10 exemption. This payment must endorse ED on the prescription.

The professional fee will be paid for every special supplied and other fees e.g. CD or expensive item fees will be paid as appropriate.

How have the Part VIIIB prices been calculated?

A system similar to that used for the calculation of the price of category M generics has been employed, using sales and volume data from suppliers. Under a memorandum of understanding (MOU), a selection of licensed specials manufacturers have provided sales information to DH, which has been used to set a reimbursement price that includes margin.

When setting the value of the payment for out of pocket expenses (e.g. carriage, wholesalers charges), the DH used information supplied by specials manufacturers concerning the cost of carriage for a wide range of specials e.g. liquid specials, controlled drugs and fridge lines. Emergency supply and location were also considered.

When considering the value of the payment for products prepared under the Section 10 exemption, the time and equipment needed to extemporaneously prepare a product was assessed.

The prescriber has prescribed a 'liquid' – what will I be paid?

Where a drug is listed in Part VIIIB as both a solution and suspension e.g. Amitriptyline 10mg/5ml, pharmacy contractors will need to clarify which formulation the prescriber wanted the patient to receive. To ensure prompt and accurate payment, the pharmacy contractor should endorse the prescription with the formulation provided.

Where only one formulation has been listed in Part VIIIB, e.g., Bendroflumethiazide 2.5mg/5ml oral suspension, the pharmacy contractor will need to clarify what the prescriber wanted the patient to receive. Depending on whether they supplied the product listed in Part VIIIB or supply a non Part VIII special, the pharmacy contractor will need to endorse as appropriate to ensure accurate and prompt payment.

What are the endorsement requirements for specials?

Endorsement requirements outlined in Part II Clause 9 of the Drug Tariff applies when endorsing specials. For products listed in Part VIIIB, typically the contractor will only need to indicate whether they are claiming the £20 payment for out of pocket expenses (by endorsing SP) or claiming the extemporaneous dispensing fee (by endorsing ED).

However, for products not listed in Part VIIIB, contractors must endorse the prescription according to how the special was sourced.

1. Where the special is manufactured under a specials licence by a manufacturer holding a Specials Licence issued by the MHRA, the contractor must endorse the:

    - Invoice price less discount/rebates (i.e. the amount actually paid for the product)
    - Manufacturer's licence number
    - Batch number of the product.

2. Where the special has been prepared under 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.

Where any of the above information is missing, the prescription form will be returned to the contractor for clarification and may delay payment.

How often will the Specials Tariff be updated?

In general, there will be two types of review. There will be a:

- Rolling quarterly review. This review will reassess prices only and prices will be updated as appropriate.
- Six monthly review in which prescribing data will be examined to allow products to enter and exit the list. The aim is to produce a list that can be easily updated to incorporate changes in prescribing habits.

Flexibility concerning these reviews will be required, especially in the initial period as Part VIIIB becomes established. Furthermore, where a special becomes available as a licensed product outside of these reviews, the Drug Tariff will be updated to reflect the introduction of the licensed product.

My usual supplier sells the special I require at a price higher than the Drug Tariff; can I claim the extra cost?

No. Pharmacy contractors are expected to shop around and negotiate lower prices in a similar way they do for generics.

I have contacted a number of manufacturers and I cannot source the product below the Drug Tariff price – what should I do?

Unless there are exceptional circumstances pharmacy contractors should be able to purchase the products in Part VIIIB below the Tariff price. Pharmacy contractors will need to ensure they have considered a range of suppliers and where they are still having difficulties, pharmacy contractors should contact PSNC. The PSNC will monitor the situation and will consider whether it is appropriate to apply to the Department of Health for an NCSO concession.

Where an NCSO concession is granted, pharmacy contractors will be able to source the product from wherever it is available and be paid the cost of product they have procured. To ensure they are paid this cost, they must endorse in line with Part II Clause 9C of the Drug Tariff.

What will happen to Part VIII Category E products?

With the introduction of Part VIIIB, category E will be deleted from the Tariff from November. The ingredients of products listed in category E will also be deleted, as appropriate.

How will I know if my supplier is an MHRA licensed manufacturer or operating under the manufacturing part of the Section 10 exemption from the Medicines Act?

It is for each pharmacy contractor to determine whether their supplier has a specials licence issued by the MHRA. They may ask their supplier when placing the order; however, the following websites may also be useful

- http://www.mhra.gov.uk/home/groups/is-lic/documents/publication/con2030303.pdf ,
- http://www.acsm.uk.com

How will I know if a licensed manufacturer has prepared the product under their licence or under the Section 10 exemption?

The British Pharmacopoeia outlines the requirements for the labelling of medicinal products including manufacturer's ML number (where appropriate) and manufacturers name and address. As a result, specials manufacturers must print their name, address and licence number on the product label where they have manufactured it under their MHRA specials licence. As those companies or pharmacies manufacturing solely under the section 10 exemption will not have a licence number, they are required to print their name and address only.

In January 2008, the MHRA issued the guidance note 14, "*the supply of unlicensed relevant medicinal products for individual patients",* which also states that where a specials manufacturer is also a registered pharmacy supplying products prepared under the Section 10 exemption, the labels of these products should not make reference to the manufacturer's licence or number.

Contractors may also wish to consider other professional guidance when deciding how to source their specials

- http://www.walsall.nhs.uk/Library/PublicHealth/CommunityPharmacy/ppjune2010-specials.pdf
- http://www.rpharms.com/best-practice/specials.asp

I normally source my specials from a manufacturer holding a specials manufacturing licence – how will I be paid for my specials?

Where the product is listed in Part VIIIB, the pharmacy contractor will be paid this price regardless of how they sourced the product – from a specials manufacturer or prepared under the Section 10 exemption of the Medicines Act 1968 (by the pharmacy contractor or by a third party)

Where a special not listed Part VIIIB has been manufactured under a specials manufacturing licence, the pharmacy contractor **will be paid the supplier's invoice price less discount** (the supplier may be the manufacturer or a 3rd party e.g. a wholesaler). To ensure accurate and prompt payment, **the pharmacy contractor will need to know what they have paid for the product - invoice price less all discounts and rebates.**

However, there are times where a specials manufacturer prepares specials under the Section 10 exemption. In these circumstances, the contractor will be paid the cost of the ingredients used to prepare the product.

To claim the appropriate additional payment, the contractor must endorse SP if the product was manufactured under the manufacturer's Specials Licence and ED if it has been prepared under the Section 10 exemption.

I normally source my specials from a manufacturer operating under the Section 10 exemption – how will I be paid for my specials?

Where the product is listed in Part VIIIB, the pharmacy contractor will be paid the Part VIIIB price regardless of how the product was sourced.

Where a special is not listed in Part VIIIB and has been prepared under the Section 10 exemption (by the pharmacy contractor or a third party), the pharmacy contractor will be paid the cost of the ingredients used in preparing the product. To ensure accurate and prompt payment, the pharmacy contractor will need to endorse the ingredients used in preparing the product along with the quantity and cost of each ingredient used.

To claim the appropriate additional payment, the contractor must endorse ED as the product has been prepared under the Section 10 exemption.

I normally source my specials through a wholesaler – how will I be paid for my specials?

Where the product is listed in Part VIIIB, the pharmacy contractor will be paid the Part VIIIB price regardless of how they sourced the product. For products not listed in Part VIIIB the pharmacy contractor will be paid depending on whether the product is manufactured by a specials manufacturer operating under their specials licence or under the Section 10 exemption (as outlined previously). The pharmacy contractor will therefore need to establish how the product has been prepared.

Along with payment for the product, the contractor will also be paid the appropriate additional payment depending on whether the product was manufactured by a MHRA licensed specials manufacturer under their licence (they must endorse SP) or manufactured under the Section 10 exemption by the contractor or by a 3rd party (they must endorse ED).

I have extemporaneously dispensed a product for my patient – how will I be paid?

As outlined above, where the product is listed in Part VIIIB, the pharmacy contractor will be paid the Part VIIIB price regardless of how they sourced the product.

Where a special is not listed in Part VIIIB and has been prepared under the Section 10 exemption by the pharmacy contractor, the pharmacy contractor will be paid the cost of the ingredients used in preparing the product. To ensure accurate and prompt payment, the pharmacy contractor will need to endorse the ingredients used in preparing the product and the quantity of each ingredient used.

To claim the appropriate additional payment, the contractor must endorse ED as the product has been prepared under the Section 10 exemption.

Will broken bulk be allowed on specials?

That will depend on how the pharmacy contractor has sourced the product. When setting the reimbursement prices of products listed in Part VIIIB, available pack sizes were taken into account and the minimum quantity is based on the smallest available pack size produced. As a result, broken bulk cannot be claimed on products listed in Part VIIIB.

However, where a product has been extemporaneously prepared by the pharmacy contractor, broken bulk will be allowed on the ingredients used to prepare the product. This recognises that the pharmacy contractor may not have the opportunity to use the remainder of the open container used to prepare the special.

Will out of pocket expenses be allowed on specials?

Yes but as outlined above, pharmacy contractors will not claim their out of pocket expenses in the same way that they have traditionally claimed these expenses. As outlined previously, under the new arrangements, pharmacy contractors will be paid a flat payment, initially set at £20 for each prescription for a special that was manufactured by a specials manufacturers operating under an MHRA specials licence. This is to contribute to any expense incurred when sourcing the product from a third party e.g. carriage.

Pharmacy contractors must endorse SP on the prescription form to reflect that they are claiming this payment.

If I am charged more than £20 as an out of pocket expense, can I claim the additional expense?

No. The value of this fee recognises that there will be times where pharmacy contractors will have paid less than the value of the payment in procuring the product but also times where they will have paid more. Overall, it should balance out.

I extemporaneously prepare some of my orders for specials – is there an extemporaneous dispensing fee?

Yes. With the introduction of these arrangements, the extemporaneous dispensing fee has been changed to reflect the work involved in extemporaneously dispensing a product. There will be a flat payment of £20 paid where a product has been prepared under the Section 10 exemption (by the contractor or a 3rd party).

Pharmacy contractors must endorse ED on the prescription form to reflect that they are claiming this payment.

The value of the out of pocket expenses payment and extemporaneous dispensing payment are the same – why do I have to endorse them differently?

Pharmacy contractors are required to supply any information that may be required to calculate prices, payments, fees or allowances payable to pharmacy contractors.

By coincidence the initial value of both payments have been set at the same value. However, this may change at a later date when the payments are reviewed. Pharmacy contractors must endorse accurately to ensure prompt and accurate payment.

Will I still be able to claim Discount not Given (DNG) on my specials?

That will depend on whether the product is listed in Part VIIIB or not. Where a product is listed in Part VIIIB, DNG will not be available, as margin has been added to the reimbursement prices of products listed.

However, where a product is not listed in Part VIIIB, pharmacy contractors will endorse the prescription with the invoice price less discount/rebate (the cost actually paid by the pharmacy contractor). In these cases, contractors will not need to endorse 'DNG' but discount will not be deducted. Special care should be taken when endorsing the price paid to ensure that the net price paid is endorsed and not the full invoice price. There may be a risk of payment being claimed that is not due (i.e. fraud) where not all discount has been reflected in the amount endorsed.

What records do I need to maintain under the new arrangements?

Under the current requirement on record keeping, there are obligations[1] already in place requiring the pharmacy contractor to:

a. Keep the following records for 5 years:

- The source of the product
- The person to whom and the date on which the product was sold or supplied
- The quantity of each sale or supply
- The batch number of the product

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

In addition to the above, pharmacy contractors shall keep a record of the prescriber details, which would be available for inspection by the Local Health Board (LHB) of the prescriber and/or pharmacy contractor, allowing the LHB to match expenditure to the product supplied.

For specials not listed in Part VIIIB, the contractor or his representative will stamp, date, initial and endorse the Certificate of Analysis (COA)/ Certificate of Conformity (COC) with the price paid and prescriber's details. At the end of each month, the contractor shall send a copy of the COA/COC to the LHB of the prescriber along with details of the prescriber, allowing the LHB to match expenditure to the special supplied.

1 MHRA Guidance Note No.14: the supply of unlicensed relevant medicinal products for individual patients

As a LHB, we have introduced our own local specials arrangements - can we continue to use them?

The Welsh Government would recommend that any LHB undertaking arrangements separate to the new arrangements should consult their legal teams to ensure they are operating within the law. The only remuneration arrangements for pharmaceutical services that LHBs have the power to determine locally are remuneration for enhanced services.