

September
2009

impact

H1N1 Swine Flu

At the beginning of July the Secretary of State for Health announced the change in the management of pandemic flu from containment to treatment. Before the introduction of the National Pandemic Flu Service (NPFs) in England some PCTs introduced interim arrangements in which designated community pharmacies supplied antivirals, provided by the PCT, against a locally arranged voucher or token.

With the launch of the NPFs in England individuals who require an antiviral medicine, oseltamivir (Tamiflu®) or zanamivir (Relenza®) are able to access treatment through the following routes:

- The national online and call centre assessment and authorisation service. This service is available through the web and a dedicated call centre facility ('flu line'). People diagnosed with swine flu will be given an authorisation code that a 'flu friend' can use to pick up antivirals from a local Antiviral Collection Point (ACP).
- Healthcare professionals, including those in walk in centres, will be able to assess and authorise antivirals for people who contact them directly such as those who have regular contact with their GP, children under 1 year of age and those who could not use the phone or web service. Two types of antiviral authorisation voucher have been produced, one for antiviral medicines for adults and children aged 1 year and over (AVA) and one for liquid oseltamivir for children under 1 year old (AVB). The authorised antiviral medicine is picked up from a local ACP.

PCTs are responsible for distribution of Antiviral Authorisation Vouchers.

Please remember Antiviral Authorisation Vouchers need to be retained for the PCT and should not be sent by contractors acting as ACPs to NHS Prescription Services.

The Department of Health has made arrangements for the supply of sufficient H1N1 swine flu vaccine for the population of the UK. The first batches are expected in the autumn and a vaccine distribution strategy is being developed (HPV vaccine is supplied free of charge to PCTs). Because of the phased delivery of the vaccine, prioritisation will take place of those who need to receive it first. A range of information materials to support the H1N1 swine flu vaccination programme, training materials and an advertising campaign are being planned and developed.

In order to support accurate data recording and data collection the NHS dictionary of medicines and devices (NHS dm+d) has created both virtual medicinal products (VMPs – the abstract or generic medicinal product) and actual medicinal products (AMPs) for the Baxter and GlaxoSmithKline vaccines. Although currently marked as 'not available' their creation has allowed the generation of the appropriate SNOMED codes. NHS dm+d will facilitate data collection by GP practices.

Switching Signature

NHS Prescription Services must calculate dispensing contractors' payments in accordance with NHS regulations. The system we use to process prescriptions is much more effective at identifying when items have been submitted in the wrong charge status group ('exempt' or 'chargeable'). We transfer items, in accordance with NHS regulations (reproduced in the England and Wales Drug Tariff part XVI, clause 5). We must treat as chargeable items on any forms that are not signed as they should be to declare that the patient is exempt from charge. For items prescribed for contraceptive use, the system will automatically treat these as exempt. The most common reasons we see why forms haven't been signed are:

- The patient is age exempt but the age / date of birth is hand written.
- The patient is between 16 and 18 years old and is in full time education.

- The patient has ticked the box to show they have a medical exemption card but has not signed the form.

We also see some prescriptions issued to patients, who aren't age exempt, living in homes or sheltered accommodation who do not take the prescription to the pharmacy and they (or their representative) have not signed the form.

The only time a patient doesn't have to sign the back of the form is when they are age exempt and their age or date of birth has been automatically printed on the front of the form; or they are a recently released prisoner and 'HMP' has been included in the prescriber's address box on the front.

Our website has information that you might find helpful such as the electronic drug tariff; a short film, which includes how our staff apply the rules when deciding whether to change the charge status of an item or not; and a short quiz for anyone who wants to refresh their or their staff's knowledge on applying the rules.

www.nhsbsa.nhs.uk/prescriptions

Neater means better

The tidier the batch you send to us for processing the less delays this causes in processing. Paper clips, staples, sticky labels, bent or torn forms will jam our scanners and can cause delays in processing.

This is an example of best practice for sending in your batch.

There are tips on how to sort your batch for submission on your FP34 submission document (FP34D for dispensing doctors, FP34PD for personally administered accounts).



Have a look at how NHS Prescription Services processes your claims for reimbursement

If you or your dispensing staff haven't booked your place yet for one of our open days there are still some spaces left.

You can book your place through our helpdesk on **0845 610 1171** or by emailing prescriptionpricinghelpdesk@ppa.nhs.uk

You will find more information about the open days on our website.

<http://www.nhsbsa.nhs.uk/prescriptions/opendays>

Date	Location
17 September 2009	Wakefield
5 November 2009	Middlebrook
8 December 2009	Wakefield

The dates above still had spaces at the time of going to press.

Electronic Prescription Service - release 2

In July this year, the first pharmacy went live with Release 2 of the Electronic Prescription Service. Release 2 brings with it a number of new features which will allow prescribers and dispensers to issue and dispense electronic prescriptions rather than simply use the prescription messages of Release 1.

Release 2 allows dispensing contractors to send prescriptions electronically to the NHS Prescription Services (NHS RxS). To enable this each prescription will be supported by a reimbursement endorsement message which the contractor must submit electronically. Contractors will also tick the appropriate box on their FP34C if any electronic prescriptions have been submitted for reimbursement.

Contractors will send electronically to NHS RxS the same essential information as they do now for reimbursing and remuneration, including endorsements for items such as broken bulk or NCSO concession. Electronic endorsements are similar to those made on paper – and have to be available within a EPS system as part of Release 2 compliance. A full list of prescriber and dispenser endorsement requirements is available on our website.

NHS RxS will still calculate contractors' reimbursement and remuneration according to the rules in the NHS England and Wales Drug Tariff.

Release 2 allowance

As outlined in the Drug Tariff, pharmacies deploying Release 2 will be eligible for a one-off allowance of £1,000 per contractor. Like Release 1, there will be a time limit for pharmacies to claim their R2 allowance. Contractors must

electronically submit a synthetic reimbursement endorsement message to NHS RxS by a date yet to be determined of which three months notice will be given, in order for the Release 2 allowance to be paid. The allowance is a one-off payment in relation to pharmaceutical services provided at the same premises irrespective of any subsequent merger or sale or relocation to new premises. The allowance payment will be included on the pharmacy payment schedule.

The process for submitting the synthetic reimbursement endorsement message is as follows: A contractor will be provided with a synthetic message (which will be a digitally signed test prescription to download and dispense). These will be issued as part of the deployment process by NHS CFH. The contractor will 'dispense' the script, send a notification and an electronic reimbursement message to the spine. The EPS will then forward the pharmacy's synthetic message to NHS RxS. This will also act as the trigger to tell NHS Choices that the contractor is now ready to be nominated by a patient to receive their electronic prescription.

NHS Connecting for Health's website has further details about EPS Release 2 implementation and deployment, including business process guidance for initial implementers.

The key new features of Release 2 are:

- The ability for prescribers to apply electronic signatures to prescription messages
- The option for patients to select, or 'nominate' a dispenser for their electronic prescription to be sent to
- Electronic cancellation of prescriptions
- Electronic repeat dispensing
- Submission of electronic reimbursement endorsements to the reimbursement agency

Useful links

NHS Connecting for Health: www.cfh.nhs.uk

NHS RxS's EPS endorsement guidance:

www.nhsbsa.nhs.uk/PrescriptionServices/1972.aspx

Drug Tariff:

www.nhsbsa.nhs.uk/prescriptions/drugtariff



The Prescribing Review report on Type 2 Diabetes,

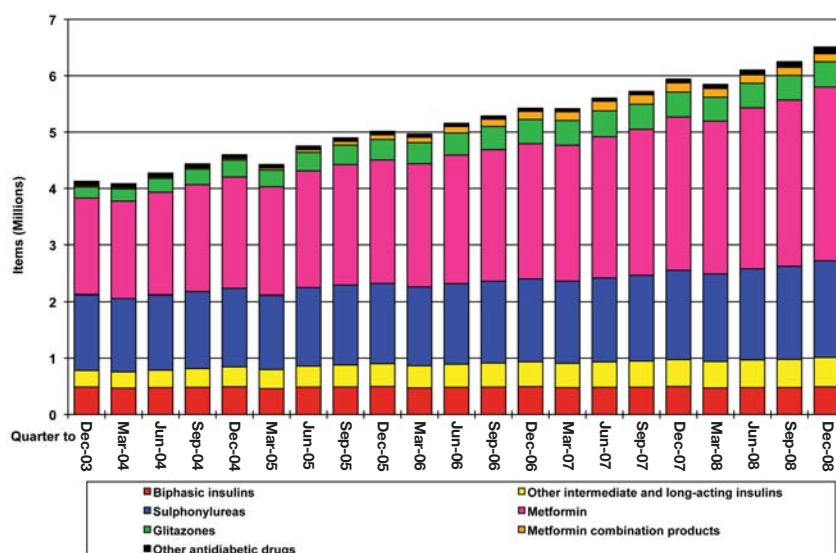
available to general practitioners in May 2009, is reproduced here for readers with an interest in patterns and trends of prescribing.

Type 2 diabetes is the most common form of diabetes, accounting for 90–95% of cases.¹ Charts 1 and 2 reflect the effect of increasing prevalence on prescribing and costs of products used in the management of type 2 diabetes. People with type 2 diabetes are at increased risk of developing microvascular (e.g. kidney and nerve damage) and macrovascular (e.g. cardiovascular and cerebrovascular disease) complications. These multiple vascular risk factors mean that diabetes care is typically complex and time-consuming. The necessary lifestyle changes, complexities of management and side effects of therapy make self monitoring and education for people with diabetes central parts of management.² In May 2008 NICE updated its clinical guidance on the management of type 2 diabetes. The key points and changes made from earlier guidance are discussed in this article.

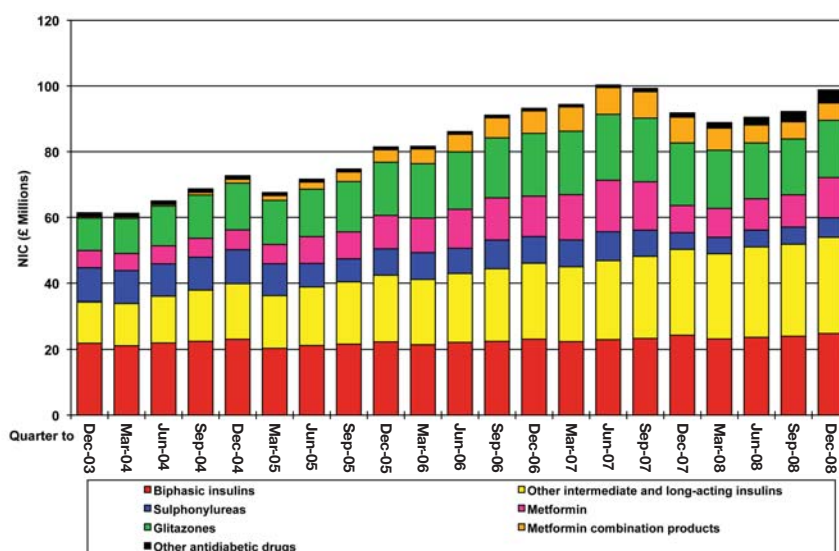
Patient education and lifestyle management

Structured education should be offered to every person and/or their carer at or around the time of diagnosis, with annual reinforcement and review. A patient-education programme that meets the criteria laid down by the Department of Health and Diabetes UK Patient Education Working Group should be chosen.³ Individualised

Trends in Prescribing of Drugs for Type 2 Diabetes in General Practice in England (Chart 1)



Trends in Spending on Drugs for Type 2 Diabetes in General Practice in England (Chart 2)



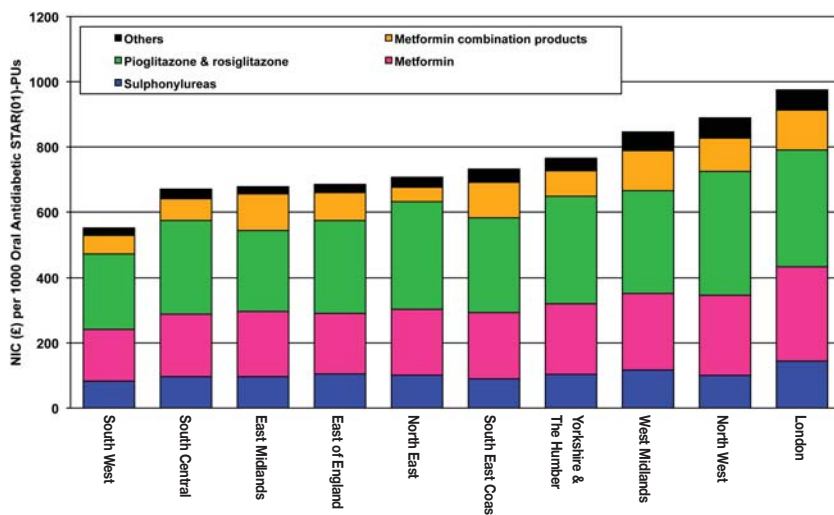
ongoing specialist nutritional advice should be provided and integrated into a personalised diabetes management plan combined with other aspects of lifestyle modification, such as increasing physical activity and losing weight. When setting a target glycated haemoglobin (HbA1c) level the person should be involved in decisions about their individual target level, which may be above 6.5% as recommended by the NICE clinical guideline.²

From 1 June 2009 the reporting of HbA1c results in the UK will give the result in the current HbA1c-DCCT units (%) and in new HbA1c-IFCC units (mmol/mol). This dual reporting will continue until 31 May 2011 when only the new units will be used.

Blood pressure

NICE recommends offering lifestyle advice if blood pressure (BP) is confirmed as being consistently above

Variation Between Strategic Health Authorities in Spending on Oral Antidiabetic Drugs (Quarter to December 2008) (Chart 3)



140/80mmHg or above 130/80 mmHg if there is kidney, eye or cerebrovascular damage. If lifestyle advice does not reduce BP to below these values then medication should be added. The first-choice antihypertensive drug is a once-daily ACE-inhibitor. For people of African-Caribbean descent or in people whose BP is not controlled to target on monotherapy a diuretic and/or calcium channel blocker should be added, with other drugs added as needed. A calcium channel blocker is recommended for women who may become pregnant. BP should be monitored every 4 to 6 months once a person has attained and consistently remained at their BP target.²

Anti-thrombotic therapy and lipid management

The NICE guidance also advises the use of aspirin 75mg daily in patients 50 years and older, whose BP is less than 145/90mmHg and under 50 years if significant other cardiovascular (CV) risk factors are present. However in October 2008 the results of the POPADAD⁴ trial were published. This study raises questions over the level of CV risk at which the benefits of aspirin use outweigh the gastrointestinal risks. Aspirin should still be given for secondary prevention of CV disease in people with type 2 diabetes. However, for primary prevention in type 2 diabetes, consideration on an individualised basis following an assessment of the benefits and risks may be more appropriate. Clopidogrel is recommended only in those with clear

aspirin intolerance except in the context of acute cardiovascular events and procedures.² NICE recommends simvastatin 40mg for most people aged 40 or older (unless their 10 year CV disease risk has been estimated at less than 20%), and younger people if their CV risk factors seem particularly poor. If a total cholesterol of less than 4 mmol/L or LDL-cholesterol of less than 2 mmol/L is not attained the dose can be increased to 80mg in line with the guideline recommendations.

Blood glucose management

In June 2008 two large randomised controlled trials of intensive glucose monitoring were published. ACCORD⁵ found no evidence of a lower risk of non-fatal myocardial infarction, non-fatal stroke or death from cardiovascular causes in the intensive treatment group in which HbA1c was lowered to a median of 6.4%, compared to the standard treatment group maintained at a median of 7.5%. The intensive blood sugar lowering treatment arm of the study was stopped 18 months early because of the higher mortality within this group. ADVANCE⁶ found that intensive control (HbA1c 6.5%) reduced the incidence of combined major macrovascular and microvascular events compared to standard control (HbA1c 7.3%). This was primarily because of a reduction in the incidence of nephropathy with no significant effect on retinopathy. There were no significant effects between intensive and standard control of blood glucose on major macrovascular events,

death from cardiovascular causes or death from any cause. A further trial looking at the effects of intensive glucose control (HbA1c 6.9%) compared to standard glucose control (HbA1c 8.4%) on cardiovascular events in patients with long-standing type 2 diabetes was published in December 2008 (VADT⁷). It found that intensive control had no significant effect on the rates of major cardiovascular events, death or microvascular complications. These studies have stimulated considerable debate about the benefits of intensive glycaemic control in older adults with type 2 diabetes and whether there is an increased risk of adverse outcomes.

When oral glucose control therapies are required NICE recommends:

- Metformin as the first-choice oral hypoglycaemic. Sulphonylureas may be considered in the non-overweight or if metformin is contraindicated or not tolerated.
- If blood glucose control remains or becomes inadequate on metformin a sulphonylurea may be added. A rapid acting insulin secretagogue may be considered for people with non-routine daily lifestyle patterns. A thiazolidinedione (glitazone) should only be considered at this stage if hypoglycaemia on a sulphonylurea is a problem.
- The next stage would be to add in a thiazolidinedione or human insulin after discussion with the person.

A thiazolidinedione should not be commenced or continued in people who have evidence of heart failure or who are at higher risk of fracture.² When selecting a thiazolidinedione for initiation and continuation of therapy, account should be taken of up-to-date advice from the relevant regulatory bodies; the European Medicines Agency and the Medicines and Healthcare products Agency (MHRA).

Exenatide is not recommended in the NICE Clinical Guideline 66 for routine use in type 2 diabetes.² Reports of acute pancreatitis have been received by the MHRA in association with the use of exenatide leading to the MHRA issuing a Drug Safety Update in May 2008.⁸

NICE also made no recommendations on the use of gliptins in its guidance. A new guideline on the use of newer agents in type 2 diabetes mellitus is expected in May 2009.

Chart 3 shows a variation in spending on oral antidiabetic drugs by SHA with those areas of higher spending reflecting a higher prevalence of type 2 diabetes.

Self-monitoring of blood glucose

Self-monitoring of blood glucose should only be offered to a newly diagnosed patient as an integral part of their self-management education.² The purpose of self-monitoring should be discussed along with agreement about how the results should be interpreted and acted upon. There is a lack of good evidence that self-monitoring of blood glucose improves clinical outcomes in people with type 2 diabetes on oral therapy and yet the prescribing of blood glucose testing strips has risen by 11% to 1.4 million items per quarter and spending has risen 13% to £35.2 million over the last 5 years.

Complications of diabetes

Foot problems, kidney disease, and the presence of neuropathy should be assessed at diagnosis and at least annually thereafter. All people with diabetes should be referred for retinal screening at diagnosis as part of a formal screening programme.

Prescribing Data (Reporting quarter = Oct-Dec 2008, Index quarter = Oct-Dec 2003)

Metformin prescribing has increased by 81% over the last 5 years, accounting

for 56% (3.1 million items) of all antidiabetic drugs and 27% of the cost (£12.2 million). There has been a 27% increase in prescribing of sulphonylureas to 1.7 million items and cost has fallen by 42% to £5.9 million. Gliclazide accounts for 25% of all antidiabetic drugs and 10% of cost. At 1.4 million items (£4.5 million) it is the most commonly prescribed sulphonylurea. Glimepiride has risen 44% to 185,000 items whereas cost has fallen 44% to £931,000. Prescribing of rosiglitazone is 3% of all antidiabetic drugs (173,000) and 15% of the cost (£6.8 million). Pioglitazone accounts for 5% of antidiabetic drugs (275,000) and 24% of the cost (£10.6 million). Metformin combinations account for 144,000 items per quarter (3%), accounting for 12% of the cost on antidiabetic drugs (£5.3 million). In total the glitazones and glitazones combined with metformin represent 50% of the cost of antidiabetic drugs but only 11% of items. Repaglinide and nateglinide items are 27,300 and 7,800 (£365,000 and £215,000 respectively). Sitagliptin and vildagliptin prescribing is 36,000 and 1,500 items, costing £1.5million and £52,000 respectively. Intermediate- and long-acting insulins account for 71% of all insulin prescribing and 72% of cost (1 million items, £53.9 million). Of these, insulin glargine is the most commonly prescribed long-acting insulin, 304,000 items (30%) at £17.9 million (33%). Biphasic insulins account for 49% (492,000 items) of all prescribing of intermediate- and long-acting insulins, and 46% of the cost (£24.9 million).

Key Messages

Offer structured education, lifestyle modification advice and specialist nutritional advice.

Involve the person in setting a target HbA1c.

Use aspirin 75mg in higher-risk patients and those 50 years and older, whose BP is less than 145/90mmHg.

First-choice antihypertensive is an ACE inhibitor (plus diuretic or calcium channel blocker for people of African-Caribbean descent). A calcium channel blocker is recommended for women who may become pregnant.

Metformin is the first-choice oral hypoglycaemic.

References

1. Srinivasan, B., Taub, N., Khunti, K. and Davies, M. (2008) Diabetes: glycaemic control in type 2. Clinical Evidence. BMJ Publishing Ltd. www.clinicalevidence.com
2. NICE. Type 2 diabetes: the management of type 2 diabetes Clinical Guideline 66. May 2008. www.nice.org.uk/CG066
3. Structured patient education in diabetes: report from the patient education working group. www.dh.gov.uk
4. Belch J, MacCuish A, Campbell I et al. The prevention of progression of arterial disease and diabetes (POPADAD) trial: factorial randomized placebo controlled trial of aspirin and antioxidants in patients with diabetes and asymptomatic peripheral arterial disease. *BMJ* 2008;337:a1840
5. Action to Control Cardiovascular Risk in Diabetes study group. Effects of Intensive Glucose Lowering in Type 2 Diabetes. *N Engl J Med* 2008;358:2545-2559
6. ADVANCE Collaborative group. Intensive Blood Glucose Control and Vascular Outcomes in Patients with Type 2 Diabetes. *N Engl J Med* 2008;358:2560-2572
7. Duckworth W, Abraira C, Moritz T et al Glucose Control and Vascular Complications in Veterans with Type 2 Diabetes. *N Engl J Med* 2008;360:129-139
8. MHRA. Drug Safety Update. Exenatide (Byetta): risk of acute pancreatitis. Volume 1, Issue 10 May 2008.

No cheaper stock obtainable

Pharmacies may have difficulties in obtaining stocks of medicines for a variety of reasons such as:

- quality issues with a specific manufacturer of the product.
- raw ingredients in short supply.
- exporting of the product outside the UK.
- quotas imposed by manufacturers/wholesalers as part of direct to pharmacy schemes.

The Drug Tariff Part II clauses 8 and 9 include provision for when a pharmacy contractor cannot obtain a product in Part VIII at the price listed so that contractors can be reimbursed a higher price when appropriate. If a pharmacy has problems obtaining a Part VIII product or problems obtaining the product at the set Drug Tariff price, they should contact the PSNC Information Team (01296 432 823). PSNC will then contact the main wholesalers to establish the extent of the problem and if necessary make an application for the product to be given NCSO status (No Cheaper Stock Obtainable). PSNC contacts NHS Rx Services who investigate further as to whether a product is in short supply and why. Information is then presented to the Department of Health.

If a decision is made that due to exceptional circumstances there is no product available to contractors at the Part VIII price, claims for a product with a higher price will be accepted. Information is available on the NHSBSA web site at <http://www.nhsbsa.nhs.uk/PrescriptionServices/935.aspx> as to products where the Department of Health and the Welsh Assembly Government have agreed to allow NCSO for that month. The list of products is updated each month and if a product is still in short supply, the PSNC will reapply for NCSO status.

Contractors should make all reasonable effort to obtain a product at the Drug Tariff price but if they do not succeed they can claim for a product at a higher price providing it has been approved for an NCSO claim. The prescription should be endorsed with:

- the brand name or manufacturer or wholesaler of the product.
- the pack size used (if there is more than one pack).
- "NCSO" or "no cheaper stock obtainable."
- the date.
- the dispenser's or contractor's initials.

Part IX Consultation

To improve the current quality of care to patients and provide a consistent level of care the DH reviewed the arrangements under Part IX of the Drug Tariff in the recent publication 'Proposed new arrangements under Part IX of the Drug Tariff for the provision of stoma and urology appliances - and related services - in primary care (June 2008): consultation response'. The purpose of this review is to ensure, through implementation of the outcome, that:

Equitable payment to dispensing appliance contractors (DACs) and Pharmacy contractors for equivalent services will be ensured.

Transparency between what is paid for services and what is reimbursed for items will be achieved.

Value for money for the NHS will be secured.

The outcome of the review can be viewed in full at http://www.dh.gov.uk/en/Consultations/Responsestoconsultations/DH_097226

All pharmacists and DACs will be required to provide some essential services, to include:

- A repeat dispensing service.
- A home delivery service and supply of wipes and disposal bags.
- Provide appropriate advice - the pharmacist or DAC will provide appropriate advice about any appliance to patients that will enable them to utilise, store and dispose of the appliance appropriately.
- Dispensing referral - if a pharmacist or DAC cannot dispense the item prescribed they must refer the prescription form, with the patient's consent, on to another contractor.

In addition all pharmacies and DACs will be able to choose to provide either one or both of the advanced services:

- Stoma appliance customisation - this refers to the process of modifying stoma appliances based on patients' measurements.
- Appliance use reviews to improve the patient's understanding and use of the appliance - Pharmacists and DACs will be able to claim for providing a review of the continuing suitability in relation to Part IXA (catheters), Part IXB or Part IXC appliances. Such reviews must be conducted by a specialist nurse or a pharmacist.

Hints&Tips

● Out of pocket expenses – remember to endorse your prescriptions

Contractors claiming for out of pocket expenses are still required to endorse the item on a prescription form which they are claiming in accordance with Part II, Clause 12 of the Drug Tariff. This is for audit purposes. NHS Prescription Services still needs you to fill in the relevant section on your submission document so that we can process your out of pocket expenses claim more efficiently.

Part II, Clause 12 of the Drug Tariff states:

"Where, in exceptional circumstances, out-of-pocket expenses have been incurred in obtaining a drug, appliance or chemical reagent other than those priced in Part VIII Category A and M, Part IXA and Part IXR of the Tariff and not required to be frequently supplied by the contractor, or where out-of-pocket expenses have been incurred in obtaining oxygen from a manufacturer, wholesaler or supplier specially for supply against a prescription, payment of the amount by which such expenses on any occasion exceed 10p may be made where the contractor sends a claim giving full particulars to the Pricing Authority with the appropriate prescription form."

● Working with the rest of the UK

NHS Prescription Services sometimes get queries about how English contractors should deal with prescriptions from the rest of the UK, so we've put together a few hints and tips on common queries.

● Scottish pre-payment certificates

Scottish pre-payment certificates are valid for prescriptions dispensed in England.

● Patient charges

It doesn't matter which UK country a prescription was issued in, it's the dispensing country that counts. So if a Welsh or Scottish prescription is dispensed in England, the patient will be charged at the rate applicable in England, unless of course they've completed the declaration of exemption on the back of the form.

● Controlled drug private prescriptions

Regardless of which UK country the prescription comes from, private prescription forms for controlled drugs dispensed in England must be sent to NHS Prescription Services.

New to NHS Prescription Services - Customer Service and Payment Team

On 1 June 2009, NHS Prescription Services introduced a new, small but dedicated team, the Customer Service and Payment Team.

Part of the job of the team is to give you the opportunity to talk to us face to face about issues that you're concerned about, and for us to help keep you up to date with what we're doing to tackle those issues. We are currently planning some dates to attend some LPC meetings, and we'll publicise these and future dates on our website.

We know from the calls our helpdesk get, that some contractors and their staff would like help with how to sort and submit their monthly accounts. Although the team is a small team, some of them will be coming out and about to help contractors and their staff improve their knowledge in these areas. With over 11,000 contractors across England we'll try and see people as soon as we can.

**To arrange a contractor visit phone: 0191 203 5867
or email: contractorvisit@ppa.nhs.uk**

Contact details for the NHS Prescription Services

Got a question about dispensing contractor reimbursement, endorsement guidance, or prescription searches?

Contact our helpdesk.

Phone **0845 610 1171** or

e-mail prescriptionpricinghelpdesk@ppa.nhs.uk