

## **Guidance on Prescribing in Primary Care**

Produced by Derbyshire Medicines Management on behalf of Southern Derbyshire CCG, Erewash CCG, North Derbyshire CCG & Hardwick CCG

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## Document control

Update	Date
Update to section 12 – prescriptions for Multi-Compartment Compliance Aids (MCAs)	May 2014
Section 5 – added information on NHS England circular on primary care responsibilities in prescribing and monitoring hormone therapy for transgender and non-binary adults	May 2016
Section 6.2 – added agreed statement on continuing black drugs if started prior to JAPC's decision	May 2016
Section 8 – recommended prescribing intervals updated as agreed by prescribing sub-groups	May 2016
Section 10 – managed repeat systems. Point 10.2 NEW (from the PSNC Community Pharmacy Guide for GPs)	May 2016
Section 14 – link to NHS pick-up of drug company sponsored treatment removed.	May 2016
Section 16 – NHS patients being seen by private providers – NEW.	May 2016
Section 26 – medicines donations overseas – NEW.	May 2016
Appendix 2 – items that should be prescribed by brand – replaced with UKMI table.	May 2016
Appendix 6 – PrescQIPP travel vaccine bulletin replaces Derbyshire County PCT Commissioning guide to primary care vaccination and immunisation payment structures and Guidance on vaccines for travel in primary care. Locally agreed position statement on whether combined hepatitis A and B vaccination can be prescribed on the NHS for travel purposes or prescribed as separate component vaccines with the hepatitis A on FP10 prescription and the hepatitis B prescribed privately included.	May 2016
Section 12.10 – amended wording in paragraph.	August 2016
Section 26 – Disposal of unwanted medicines	February 2017

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## **1 INTRODUCTION**

- 1.1 Aside from consultations, the most common intervention of the National Health Service is the issuing of a prescription.

## **2 PURPOSE**

- 2.1 The purpose of this guidance is to outline expectations for NHS prescribing, detailing standards that all prescribers are expected to aspire to. It also seeks to provide clarification for prescribing situations not covered by the NHS or where NHS responsibility for prescribing is not clear. This guidance is intended to provide information on current best practice to ensure a consistent approach by primary care prescribers.

## **3 SCOPE OF THE GUIDANCE**

- 3.1 This guidance is appropriate for all prescribers; General Practitioners, secondary care prescribers, locum and junior doctors, trainees and community practitioners, supplementary and independent non-medical prescribers within Derbyshire. In addition this guidance is appropriate for all dispensers of medicines and appliances including community pharmacies and appliance contractors.
- 3.2 Prescribers should also refer to other relevant documents relating to prescribing in their respective organisations.

## **4 DEFINITIONS**

- 4.1 ACBS: In certain conditions some foods (and preparations) have characteristics of drugs and the Advisory Committee on Borderline Substances advises as to the circumstances in which such substances may be regarded as drugs.
- 4.2 SLS: Certain drugs may only be prescribed on the NHS to specified patient groups for a specified condition. When such conditions are met the prescriber must endorse the prescription SLS (Selective List Scheme).
- 4.3 JAPC: Joint Area Prescribing Committee. JAPC is a countywide group covering the Clinical Commissioning Groups (CCGs) within Derbyshire. It provides recommendations on drugs and medicines management issues.
- 4.4 Formulary: A list of medicines. The term is often used to describe a limited list of medicines that have been approved for use in a locality.
- 4.5 Guideline: An official recommendation indicating how something should be done or what sort of action should be taken in a particular circumstance.
- 4.6 Policy: A policy is a plan of action which is then applied as concrete programmes and actions. Policy documents will be prescriptive by nature and will detail expectations for the actions of individuals in a particular subject area, setting the parameters within which individuals will operate.

## **5 PRESCRIBING AGAINST NATIONAL AND LOCAL GUIDANCE**

- 5.1 The expectation is that prescribing should be in line with guidance issued by the Derbyshire Joint Area Prescribing Committee (JAPC), national guidelines and policies. Any departure from this requires sound clinical reasons.

- 5.2 Legal responsibility for prescribing lies with the prescriber who signs the prescription. He or she should understand the patient's condition, the treatment prescribed and be able to recognise any adverse effects of the medicine should they occur. Prescribing responsibility will be based on clinical responsibility with JAPC ensuring that local arrangements are in place to ensure such responsibility can be accepted where appropriate.
- 5.3 National and local guidance will often clarify what GPs should prescribe for identified individuals e.g. who should receive an influenza vaccination. Whilst issuing an FP10 outside these recommendations is not prohibited, practices should be aware that this could be considered an example of inappropriate or excessive prescribing as stated in the GMS, PMS or APMS contract.
- 5.4 Where there is a choice of drugs within a therapeutic class, the one with the lowest NHS reimbursement cost should generally be used first line. First and second line choices of many commonly prescribed medicines are included in the JAPC primary care formulary. If a non-formulary medication is required, the reason for prescribing out-side the formulary should be documented.
- 5.5 Prescriptions should be written generically unless there is a cost or clinical reason not to do so. Prescribers may be asked to justify any departure from this. An information leaflet for patients is available in Appendix 1 and a list of drugs recommended to be prescribed by brand (Appendix 2). A leaflet explaining medication changes to patients is available on the medicines management website: [Medication change leaflet](#)
- 5.6 Hospital clinicians should not ask GPs to prescribe medication that is not listed on their trust's formulary or has not been approved by JAPC. Prescribing outside of local formulary, national or local guidance may be considered an example of inappropriate prescribing that would be challenged through provider contracts. Primary care prescribers should feedback such instances to the CCGs using the [Inappropriate request form](#).
- 5.7 NHS England has provided specific information to general practitioners on their responsibilities in prescribing and monitoring hormone therapy for transgender and non-binary adults (updated April 2016). This is available on the Derbyshire medicines management website. General Practitioners should co-operate with the specialist Gender Identity Clinics and prescribe hormone therapy (feminising or virilising endocrine therapy) recommended for their patients by the Gender Identity Clinic as well as undertaking associated monitoring. Although most products recommended do not have an approved indication for the treatment of gender dysphoria, there is extensive clinical experience of the use of these products in the treatment of gender dysphoria. Guidance published by the General Medical Council in March 2016 advises General Practitioners that they may prescribe 'unlicensed medicines' where this is necessary to meet the specific needs of the patient and where there is no suitably licensed medicine that will meet the patient's need.

## 6 ADDITION TO APPROVED MEDICINES STATUS

- 6.1 JAPC must approve all new drug entities for use within primary care in Derbyshire prior to use. This allows the entry of new medicines to the local health economy within an equitable and managed process within the available budget. Primary care prescribers should not continue or initiate prescribing unless funding for use in primary care has been agreed.
- 6.2 JAPC will classify drugs according to the Derbyshire traffic light classification, in order to clarify prescribing responsibility:

**Red:** Prescribing responsibility lies with a hospital consultant or specialist

**Amber:** Initiated within a hospital/specialist setting but suitable for shared care with a GP under a shared care agreement

**Green:** Suitable for primary care prescribing

**Brown:** Not recommended for use, except in exceptional circumstances, due to lack of data on safety, effectiveness and/or cost effectiveness

**Black:** Not routinely\* recommended or commissioned.

\* unless agreed through the individual funding request route or patient on treatment prior to JAPC decision. People on treatment with a BLACK drug or device prior to JAPC's decision should be able to continue treatment until their next medication review where their NHS clinician might consider it appropriate to switch or stop treatment.

Details of approved drugs and current traffic light list can be found at [Traffic Light Classification](#).

Approval routes are as follows:

- 6.2.1 **For products initiated within an acute trust, mental health trust or community hospital and intended to be continued in primary care.** An application should be made by the relevant clinicians to their Trust's Drug and Therapeutic Committee (DTC) with a further application to JAPC with an estimate of anticipated costs in primary care and shared care arrangements where appropriate. As a default the JAPC application form for new drugs should be used. This is available from the JAPC secretary along with shared care templates.
- 6.2.2 **For products used predominantly in primary care.** The CCG Prescribing groups will discuss with the medicine management team and an application will be submitted directly to JAPC. Input to this process from all prescribers within primary care is welcomed (via CCG locality prescribing leads or the Medicines Management Team). The application form used for JAPC submissions should be used and is available from the secretary.
- 6.2.3 In exceptional circumstances, prescribing of a medicine that has not been approved for funding may be considered for individual patients. In these circumstances the prescriber wishing to initiate treatment should make an application to the CCG for funding according to the Individual funding request (IFR) policy. Details are available from [Individual Funding policy](#).

## **7 PRESCRIBING UNDER SHARED CARE GUIDELINES**

- 7.1 Treatments which are suitable for shared care between primary care physicians and specialists are designated shared care status. Prescribers are advised to ensure there is a written agreement from the requesting consultant confirming how and by whom the patient will be monitored both for evaluating effectiveness of treatment, side effects and routine tests required.
- 7.2 Shared care guidelines are normally specific to a drug and an indication. In some cases the guidelines are also specific to the form of the drug.
- 7.3 Shared care will only be requested by specialists where the drug has been approved through their clinical governance process (normally via the Trust's DTC) and is included in their formulary as approved for shared care. Normally a JAPC approved shared care guideline will be available, although in exceptional circumstances, for rarely used medication, a primary care prescriber may accept on-going prescribing for a particular patient under an individual patient specific agreement.
- 7.4 All communication to the GP and patient will refer to the drug by the generic name unless prescribing by brand name due to bioavailability or other issues has been approved by the acute trust's DTC and JAPC.
- 7.5 It is the responsibility of the specialist to initiate the production of shared care guidelines where he/she feels they are appropriate or where JAPC indicates they are necessary.
- 7.6 Details of agreed Derbyshire shared care documents can be found at [Shared Care guidelines](#)
- 7.7 Primary care physicians should be consulted on the content of shared care guidelines and final approval for their use rests with JAPC.
- 7.8 A copy of the shared care guideline (where available) or an electronic link to the document should be included in the letter requesting shared care sent to the GP.

- 7.9 GPs should not refuse to prescribe under shared care for financial reasons alone. GPs may refuse to prescribe where they feel they have insufficient expertise to manage the drug; where they feel the patient's condition warrants specialist management and/or they feel the request falls outside the scope of the approved shared care agreement. Prescribing in this case should remain with the specialist.
- 7.10 Where prescribing continues to take place in secondary care arrangements should be in place to allow patients convenient access to their medicines.
- 7.11 Practices should ensure they have robust systems in place to ensure that medicines supplied by prescribers outside the GP practice are appropriately recorded on the GP clinical system to allow warnings and other alerts to be flagged up. Guidance on recording medication prescribed by other healthcare providers is available on the medicines management website: [Recording medication](#)
- 7.12 A patient information leaflet on prescribing following an NHS referral is available in Appendix 3.

## **8 RECOMMENDED PRESCRIBING INTERVALS**

- 8.1 The CCG does not enforce a primary care policy for repeat medication supply lengths, although 28 day prescription lengths are seen as being a best practice option for many patients balancing convenience for patients with minimising waste. However, the ultimate decision on appropriate prescription length rests with the prescriber when a shorter or longer length may be considered appropriate in some circumstances.
- 8.2 There should be careful consideration where patients request longer prescription quantities, particularly for those that pay prescription charges. The decision to provide a longer quantity has to be balanced against patient need (including financial considerations), safety and the potential for waste. Pre-payment certificates may help some patients financially and repeat dispensing may offer convenience for patients on regular, stable medication (see section 8.8).
- 8.3 There are also situations when a shorter prescription quantity is appropriate for example for patients who are at risk of overdosing, medication needs are changing rapidly or there are issues with medication stability. **Weekly prescriptions should only be used exceptionally if there is a clinical or pharmaceutical need.**
- 8.4 The Department of Health strongly recommend that prescriptions for controlled drugs (schedule 2, 3, and 4) should be limited to a supply of up to 30 days treatment; in exceptional situations, to cover a justifiable clinical need and after consideration of any risk, a prescription can legally be issued for a longer period, but the reason for the decision should be recorded in the patient's notes. Prescription quantity of controlled drugs is monitored by the CCG through electronic prescribing data (ePACT).
- 8.5 Regardless of the prescription supply length that is deemed suitable for an individual patient, prescribers should consider the following practical issues:
- Ensure prescription supply lengths are the same for an individual patient (usually 7, 28 or 56 days). This will help minimise inadvertent over-ordering of items. In particular avoid mixing 28 and 56 day prescription lengths.
  - Items required only occasionally should not generally be placed on repeat prescription unless there is an ongoing need in which case the quantity prescribed should be sufficient to cover the prescription supply length, but should not be excessive.
  - Ensure the issue duration is entered correctly on the repeat template and is in line with the quantity to be issued. This will ensure systems to alert to over and under ordering will work properly on the clinical system.

- 8.6 It is recommended that GP practices have robust repeat prescribing standard operating procedures (SOPs) in place in order to support the continued safe, effective and efficient use of medicines. Circumstances will vary from practice to practice and individual patients but SOPs should include consideration of ordering, record keeping, repeat prescription intervals, recall, reauthorisation of prescriptions, medication review, referral and triage.
- 8.7 GP practices have a contractual obligation to have safe prescribing systems in place and not prescribe excessively. Prescriptions which cover long periods of time without adequate review may contribute to medicines waste and may be considered excessive.
- 8.8 Prepayment certificates (PPC) are the most economical way of paying for prescriptions where more than one regular prescription item is required each month. Patients can purchase a prepayment certificate on line from the NHS Business Services Authority ([www.nhsbsa.nhs.uk](http://www.nhsbsa.nhs.uk)), by post using the FP95 application form, available from pharmacies and doctors, over the phone by calling the PPC order line on 0300 330 1341 or direct from a pharmacy registered to sell PPCs. These can be purchased to cover a 3 month or a 12 month period.
- 8.9 Repeat dispensing allows a predetermined number of batch prescriptions to be dispensed where the patient's condition, medication and dosage are stable. Medication can be collected from the pharmacy without the need for a further repeat prescriptions being ordered from the surgery. This provides convenience for the patients and to enable the workload to be managed for practices and pharmacies. Care should be taken to ensure patients are selected appropriately for repeat dispensing and patients and practice staff understand the repeat dispensing process and actions to be taken if medication changes during a repeat dispensing cycle.
- 8.10 When dispensing batch prescriptions, it is the responsibility of the dispensing pharmacist to check that the patient is taking or using, and is likely to continue to take or use, the medicines or appliances appropriately, and that the patient is not suffering any side effects from the treatment which may suggest the need for a review of treatment.

## **9 ISSUING OF PRESCRIPTIONS**

- 9.1 Practices must develop and implement Standing Operating Procedures for the handling and issuing of prescriptions.
- 9.2 Medicines reconciliation following hospital admission or specialist appointment requires clinical judgement and should only be undertaken by competent health care staff. The level of therapeutic knowledge required would normally be achieved by prescribers, pharmacists or suitably experienced pharmacy technicians or nurses.
- 9.3 Non-clinical staff should only undertake administrative aspects of reconciliation and good checking processes by those with clinical knowledge should always be in place.
- 9.4 Non-clinical staff should not generate acute or new repeat prescriptions and only assist in genuine repeat prescriptions.
- 9.5 Before signing a repeat prescription, prescribers should be satisfied that systems are in place to ensure that
- The patient is issued with the correct prescription.
  - Each prescription is regularly reviewed so that it is not issued for a medicine that is no longer required.
  - The correct dose is prescribed for medicines where the dose varies during the course of the treatment.
  - The patient's condition is monitored appropriately and prescriptions are not issued for patients who require further examination or assessment. This is particularly important in the case of medicines with potentially serious side-effects.



## **10 MANAGED REPEAT PRESCRIPTION SYSTEMS BY PHARMACIES AND OTHER SUPPLIERS OF MEDICINES**

N.B. These services are distinct from “repeat dispensing” which is the process by which patients can obtain supplies of their repeat medicines over a defined period of time (usually 6 months or one year), without the need to contact their GP practice for a new prescription each time a further supply is required.

Repeat dispensing is an Essential Service under the pharmacy contract and all pharmacies must be able to offer this service with appropriate standard operating procedures in place.

- 10.1 Community pharmacies and other companies requesting prescriptions on behalf of patients should have discussed the need for further repeat items with the patient or carer not earlier than 5 working days prior to submitting the repeat request.
- 10.2 Requests for repeats must be triggered by the patient and decisions to reorder are not taken by pharmacy or other staff without input from the patient.
- 10.3 If a prescriber has concerns that items are being requested inappropriately the CCG may request a copy of the Standard Operating Procedure under which the pharmacy or company is operating repeat prescription requests and ask the pharmacy or company to provide evidence of how their risk management program addresses the issue of over ordering.
- 10.4 The pharmacy or supplying company may be asked to provide to the practice, a pharmacy signature to a statement that the patient has been contacted not earlier than 5 working days to confirm the requested items are required.
- 10.5 Patients should be free to choose from which pharmacy they wish to have their prescribed medicines dispensed.

## **11 RETROSPECTIVE PRESCRIPTIONS**

- 11.1 No products should be supplied to a patient without a signed prescription. Retrospective prescriptions will not be issued by the prescriber except in an emergency situation at the request of the patient/patient's carer or clinical specialist. Dispensing appliance or pharmacy contractors must not request retrospective prescriptions for items already supplied. There is no obligation for prescribers to provide a retrospective prescription and therefore prescribers should strongly consider refusing requests for retrospective prescriptions unless as a result of an emergency situation (see NHS (GMS) regulations 2004, Schedule 5, para 39 (6) and corresponding PMS regulations).

## **12 PRESCRIPTIONS FOR MULTI-COMPARTMENT COMPLIANCE AIDS (MCAs)**

### **Royal Pharmaceutical Society recommendations:**

1. The use of original packs of medicines with appropriate support is the preferred option of supplying medicines to patients in the absence of a specific need requiring an MCA as an adherence intervention
2. In support of independence and re-ablement, patients who can safely self-administer their medicines should be encouraged to do so and where they are unable to do so, there must be appropriate training for carers so that they are able to administer medicines from original packaging
3. Every patient identified as having medicines adherence issues should have a robust individual assessment to identify the best intervention based on their needs and the evidence currently available. This assessment should incorporate a clinical medication review, any reasons for nonadherence, medicines suitability, a consideration of all possible options to support the patient and follow up.

4. Where a patient assessment indicates an MCA is the intervention of choice, it is important that this is supported with the provision of information, appropriate counselling and follow up for the patient and that the health or social care professional is aware of the legal, professional and practice considerations.

The decision to supply MCAs should only be made after taking all factors into consideration.

- 12.1 The provision of 7 day prescriptions remains at the discretion of the prescriber. This should be used to facilitate the most appropriate care for a patient e.g. where there is a clinical or pharmaceutical need for medicines to be supplied every 7 days and not as a method of funding MCAs.
- 12.2 If a patient is assessed by the community pharmacist as needing MCAs under the Equality Act with no other clinical or pharmaceutical issues, MCAs should be provided by the pharmacist (free of charge to the patient) usually via 28 day scripts. Four weeks supply of MCAs should be dispensed at each interval. This applies to patients living in the community, those receiving social care support, and self-medicating patients living in residential homes.
- 12.3 Under the terms of the Equality Act where a person has a physical or mental impairment which has a substantial long term adverse effect on his ability to carry out normal day-to-day activities then it may be decided that medicines be provided in a dosing system, to help the patient to overcome the aspect of their disability that prevents them using their dispensed medicines. Having a disability does not equate with an entitlement to dosing systems – the nature of the disability must be such as to prevent the patient from being able to use their medicines, if not supplied in a dosing system. It should be noted that other interventions e.g. changes to labels and packaging may be as beneficial in some situations.
- 12.4 Provision of MCAs under the Equality Act falls within the Pharmacy contract and no further reimbursement is allowed. Prescriptions should usually be provided for 28 days.
- 12.5 Community Pharmacists who decide not to provide MCAs, as they either feel the patient does not meet the Equality Act criteria or that provision of an MCA is not a reasonable adjustment, should keep records clearly showing the rationale for the decision.
- 12.6 If a patient is assessed by the community pharmacist as needing MCAs under the Equality Act, but there is a clinical or pharmaceutical issue involved requiring weekly dispensing (e.g. the medicines are only suitable for weekly dispensing; the patient is at risk of overdose or medicines regime changing frequently), MCAs should be provided by the pharmacist (free of charge to the patient) via 7 day scripts. One week of MCA will be dispensed at each interval. This applies to patients living in the community, those receiving social care support, and self-medicating patients living in residential homes. N.B Repeat dispensing may be considered appropriate in these circumstances.
- 12.7 If a GP believes that a patient would benefit from an MCA but on assessment by the community pharmacist the patient does not meet the Equality Act requirements, then the GP can choose to provide 7 days scripts with the pharmacist dispensing the MCA on a weekly basis, so long as the pharmacist is happy to provide the service in this manner. Alternatively, arrangements could be made for the patient to pay the pharmacist for providing an MCA service, or other local arrangements made.
- 12.8 If Care Homes want patients' medicines to be supplied in MCAs as part of their internal policies, then this will be outside the scope of the NHS and will be negotiated between the nursing home and the community pharmacist.
- 12.9 Derbyshire County Council providers and Derby City Council providers will provide medication assistance to patients already receiving home care support as a last resort. The health sector has an obligation to try all possible avenues of supporting patients to self-medicate first, which may include the supply of MCAs if appropriate.

Therefore, there may be instances where patients with social care support are also receiving MCAs, as this enables the patient to safely self-medicate without social care needing to provide this additional support.

- 12.10 GPs and other healthcare professionals are reminded that they too have a duty to make reasonable adjustments to the management of patients' medicines under the Equality Act; in the first instance this should include rationalisation of the medication and administration times, but this may include the prescribing of weekly prescriptions if there are clinical or pharmaceutical reasons why a longer length of supply would be problematic. Where weekly prescriptions are issued, the pharmacist is expected to supply one week's supply of medicines at weekly intervals. If a pharmacist identifies clinical or pharmaceutical reasons why weekly prescriptions might be required, this can be facilitated using the Request form for Weekly Prescriptions and the pharmacist should send this completed form to the GP detailing the reasons why weekly prescriptions have been requested.
- 12.11 The GP can only make a reasonable adjustment as a GP. They cannot make an adjustment to a Pharmacist's Equality Act assessment.
- 12.12 If a patient or their carer (including provider carers) need or want an MCA but the patient does not meet the Equality Act requirements, then this will be outside the scope of the NHS and will be negotiated between the patient, their GP and the community pharmacist.
- 12.13 Supplying 7 day prescriptions where there is not a clinical or pharmaceutical need is not appropriate.

### **13 PRESCRIBING FOLLOWING A PRIVATE CONSULTATION**

A large number of patients opt to have some or all of their investigations and treatment privately. Some use private health insurance whilst others are willing to pay to be seen more quickly or for receiving their care in private facilities. Patients are free to switch between NHS and private care. Treatment is defined by "episodes of care" which may either be continuous or consist of a series of treatment and care episodes.

#### **13.1 When a patient is referred by the patient's GP for a private consultation:**

- 13.1.1 The responsibility for prescribing rests with the doctor who has clinical responsibility for a particular aspect of the patient's care. Where an NHS doctor refers a patient (privately or otherwise) to a consultant for advice, but retains clinical responsibility, any recommended medication should be issued on an NHS prescription, provided it is considered normal clinical practice and within CCG guidelines and formularies.
- 13.1.2 Patients who opt to be referred privately (i.e. outside the NHS) are expected to pay the full cost of any treatment they receive in relation to the care provided privately. Any drugs prescribed or treatment provided by a clinician in the course of a private consultation should be at the patient's expense. Patients should be informed of this expectation prior to referral.
- 13.1.3 Patients are at liberty to switch between private and NHS care at any time but should only be provided with an NHS prescription if the medication would usually be provided on the NHS. Following a private consultation, the private clinician may recommend a particular medication and patients may request their GP to prescribe. GPs receiving such requests should provide an NHS prescription if there is a clinical need and the patient would normally receive treatment under the NHS, using the same principles of NHS referrals. However there is no obligation to prescribe the recommended treatment if it is contrary to normal clinical practice or CCG guidelines or formularies. By prescribing a clinician assumes clinical responsibility for the treatment.
- 13.1.4 A consultant who, following a private consultation, has recommended treatment for the patient's clinical circumstances, should continue to prescribe until the GP has agreed to prescribe treatment.

- 13.1.5 If the medication recommended is part of a special NHS arrangement or listed as a “specialist only” (RED on the traffic light classification) then the patient should be referred to the appropriate NHS service. Treatment of sub-fertility is a case in point and therefore GPs should not be asked to prescribe.
- 13.1.6 If the GP does not feel able to accept clinical responsibility for the medication, responsibility for prescribing remains with the private consultant. The consultant may suggest an alternative therapy for the GP to consider or the GP may consider whether to refer to an NHS consultant who can consider whether to prescribe the treatment as part of NHS funded treatment but only if this is in line with normal referral protocols for the NHS.
- 13.1.7 Medication recommended by private consultants may be more expensive than those prescribed for the same clinical situation as part of NHS treatment. In such circumstances, local prescribing advice should be followed by the NHS GP.
- 13.1.8 When a private referral is made, patients may be given the leaflet shown in Appendix 4, explaining the situation regarding NHS prescriptions following private consultations. Enclosing a copy with any referral letter may also be useful.
- 13.2 When a patient self-refers for a private consultation:**
- 13.2.1 People who refer themselves independently of the GP (i.e. outside of the NHS) whether in the UK or abroad are expected to pay the full cost of any treatment they receive in relation to the care provided privately. The leaflet shown in Appendix 4 may be useful to explain this to patients.

## **14 PRESCRIBING OF TREATMENTS INITIATED AS PART OF A CLINICAL TRIAL AFTER THE TRIAL HAS FINISHED**

- 14.1 NHS Derbyshire CCGs will not normally agree to pick up the ongoing funding of treatments for patients who have completed clinical trials unless either:
- 14.1.1 The CCG has agreed through normal commissioning processes prior to the trial commencing that the CCG will provide funding for the trial participants’ ongoing treatment once they have left the trial. This agreement will be documented through normal commissioning processes and according to the Trust’s governance procedures. In that event, the NHS organisation hosting the clinical trial is required to document the agreed exit strategy in the trial protocol and state the CCG will provide funding for the trial participants’ ongoing treatment once they have left the trial and provide detail as is appropriate to each individual study; or
- 14.1.2 A CCG has agreed to fund the treatment as a service development for all patients in the clinical category of those patients leaving the clinical trial; or
- 14.1.3 The CCG’s IFR Panel has considered and approved a request to provide individual funding for a patient. However, if such a request is made the fact that the patient has been involved in a clinical trial shall not amount to an exceptional clinical circumstance or be used by the IFR Panel to justify a finding of exceptionality. It is the consenting clinician’s responsibility to ensure that patients are fully informed of and agree to their management plan at the end of the trial. This includes making patients aware of this commissioning policy and, where relevant, any successful or unsuccessful request for post-trial funding. Their consent should be documented.

## **15 PRIVATE PRESCRIPTIONS**

- 15.1 **Private prescriptions for NHS patients.** GPs should provide their NHS patients with any medication deemed clinically appropriate on an NHS prescription. A private prescription should only be provided in the circumstances listed below:

- 15.1.1 Prescribers may provide private prescriptions for their NHS patients when the item is not prescribable on the NHS. This includes: items on the DH “blacklist”; drugs for the prevention of malaria; drugs where the indication is outside those indicated on the selective list scheme; travel vaccines not included in current public policy and travel packs or drugs prescribed solely in the anticipation of the onset of an ailment while outside the UK (e.g. antibiotics for travellers’ diarrhoea, acetazolamide for altitude sickness).
- 15.1.2 NHS patients may be charged for the issue of a private prescription and will need to pay for the cost of the drugs for malaria prophylaxis and travel related prescriptions, including travel vaccines where remuneration is NOT provided under the NHS. NHS patients should not be charged for the issue of private prescriptions for drugs on the DH “blacklist” or SLS drugs prescribed outside the SLS criteria.
- 15.1.3 NB Where NHS policy recommends that a generic medicine is used and a patient requests a branded equivalent, a private prescription should not be issued to an NHS patient (unless the product falls into the categories stated above). Whilst not prohibited, practices should be aware that this practice is strongly discouraged.
- 15.2 NHS GPs providing private care e.g. private GP appointments or an occupational health service cannot issue an NHS prescription as this would constitute a breach of the GMS, PMS or APMS contract.
- 15.3 Occupational Health vaccinations - The ‘Immunisation against infectious disease’ (2006) gives clinical recommendations for the use of vaccines, however it does not identify those which are recommended to be NHS funded. Where no remuneration is available from the CCG for individual vaccines, NHS prescribing is strongly discouraged. A patient sent by an employer to request occupational health immunisations should be advised that this is not the responsibility of the practice. The employer (not the patient) will have to make private arrangements with a practice, or occupational health provider to administer the vaccine(s) and any other screening or monitoring required. Hepatitis B vaccinations for occupations as listed in the BNF should normally be provided by the employer via their own occupational health provider or private agreement with a local practice. This includes healthcare students where Hepatitis B vaccination should be provided by the educational establishment, including advice on avoiding blood-borne infections, needle-stick injuries etc. For further advice on specific patient groups, see Appendix 6 or contact the occupational health or public health team.
- 15.4 Immunisations given for occupational health purposes should only be given as part of a full occupational health service and practices that feel that they have the necessary knowledge and skills to deliver such a service may contract with employing organisation to do so. They may then immunise their own patients that also happen to be employees of that organisation and accept payment from the employing organisation. Further information is available from the GPC including template letters to medical schools, patients and employers.

## **16 NHS PATIENTS BEING SEEN BY PRIVATE PROVIDERS**

- 16.1 Medicines required by the patient immediately should be provided by the private provider without charge to the patient. A private prescription may be provided for the patient to have dispensed at the private provider’s pharmacy, although the patient should not be charged.
- 16.2 The private provider can request the GP to prescribe medicines not required immediately as long as sufficient information is provided to allow the GP to prescribe safely and the medicine is included in local formularies and guidelines. Patients should be made aware that the medicine is not required urgently.
- 16.3 Providing a private prescription to an NHS patient to be dispensed any where other than the private provider’s pharmacy is NOT recommended.

## **17 PATIENTS TRAVELLING ABROAD**

### **17.1 Travel vaccinations**

17.1.1 Guidance for prescribers on risk assessment for travellers and appropriate advice can be found at the National Travel Health Network and Centre website (NaTHNaC) at [www.nathnac.net](http://www.nathnac.net)

17.1.2 Travel vaccines that were previously set out in the 'Red Book' are included in the global sum and may be provided on the NHS free of charge to patients who require them under some circumstances. These are tetanus, polio, hepatitis A & typhoid.

17.1.3 Travel vaccinations available under the NHS should be obtained in one of two ways:

- purchased by the practice and personally administered. Payment claimed through FP34PD or FP34D (for typhoid and hepatitis A) or by issuing an FP10 and claiming via the prescription pricing division (PPD).
- obtained by the patient on FP10 prescription. A prescription charge is payable to the pharmacy unless the patient is exempt. In this situation no claim for a personal administration fee should be made.

17.1.4 Centrally supplied vaccines should not be used for travel purposes. Note: different batch numbers are used to identify use between those vaccines for use in the childhood programme and those used for travel purposes - Immform stock should not be used for travel vaccinations

17.1.5 Hepatitis A&B combination vaccine - NHS patients cannot be charged for Hepatitis A where indicated for travel and therefore cannot be charged for combination Hepatitis A & B where indicated for travel.

17.1.6 Travel vaccines that are not available on the NHS can be offered to patients as a separate private service (see below). A private script can be issued for the patient to take to a pharmacy and practices may charge at their discretion. Alternatively practices may keep a stock and may invoice the patient. It is advised that practices develop a practice protocol outlining the charges for private travel services which is available to patients. The DH recommends that vaccines against diseases that are not likely to be transmitted to others on return should be paid for by the patient.

- For destinations where a vaccination available under the NHS is not specifically recommended but the patient requests vaccination.
- The following vaccines are not available on the NHS: Meningitis, Tick Borne Encephalitis, Hepatitis B, Japanese Encephalitis, Rabies, Yellow Fever Vaccine.

17.1.7 General practices are entitled to charge NHS registered patients a private fee for vaccinations supplied as noted in section 15.

17.1.8 Reimbursement for vaccines provided privately cannot be claimed on the FP34PD form

17.1.9 No charge should be made to any NHS patient of the practice for providing travel advice. This represents appropriate health promotion for patients wishing to travel abroad and is therefore classed as an essential service within the GMS contract. It is also unacceptable for GP practices to charge a fee for the administration of NHS travel vaccinations.

### **17.2 Travel medication**

17.2.1 Malarial prophylaxis: The Department of Health has issued guidance (FHSL(95)7) that medication for malaria prophylaxis may not be reimbursed under the NHS.

17.2.2 Some medicines for malaria prevention are available to purchase "over the counter" at community pharmacies and patients should be advised to purchase where possible. Community pharmacists have access to up to date advice about appropriate prophylactic regimes and can advise travellers accordingly.

- 17.2.3 Prescription Only Medicines for malaria prophylaxis should be prescribed on private prescription. When issuing a private prescription or if they provide the medication, practices can charge a fee for one but not both (i.e. prescription and supply).
- 17.2.4 Patients should be advised to purchase sufficient prophylactic medicines to cover the period of their travel, commencing one week (two and a half weeks for mefloquine) before departure so that if adverse events occur there will be time to switch to an alternative and continuing for at least four weeks on return. Malarone is an exception being started 1-2 days before travel and stopped one week after leaving. The importance of mosquito nets, suitable clothing and insect repellents to protect against being bitten should be stressed.
- 17.2.5 Drugs prescribed in anticipation of illness whilst abroad: patients may be offered and charged for a private prescription for prescription only medicines e.g. ciprofloxacin for traveller's diarrhoea. See section 15.

### 17.3 Supply of regular medication

- 17.3.1 Under NHS legislation, the NHS ceases to have responsibility for medical care of patients when they leave the UK. People travelling within Europe are advised to carry a European Health Insurance Card (EHIC) at all times, this gives entitlement to local health care arrangements. Patients should be advised to check specific entitlements prior to travel and obtain adequate holiday insurance cover. The following guidance is provided to ensure good patient care:
- 17.3.2 Medication required for a pre-existing condition should be provided in sufficient quantity to cover the journey and to allow the patient to obtain medical attention abroad. For patients who will be out of the country for less than 3 months, it is reasonable to provide sufficient medicines for an existing condition if clinically appropriate.
- 17.3.3 Patients leaving the UK for more than 3 months should be advised to register with a local doctor for their continuing medical needs. This may need to be paid for by the patient. It is reasonable for GPs to provide sufficient medication to give patients time to do this. It may be worth mentioning to patients that medicines can be purchased without a prescription from pharmacies in some countries. NB: It is wise to check with the manufacturer that the medicines required are available in the country being visited.
- 17.3.4 Any patient absent (or intending to be absent) from the country for more than three months should be removed from the practice list [Clause 216 of the Standard Medical Services Contract].
- 17.3.5 General practitioners are not responsible for NHS prescription of items required for conditions which may arise while travelling e.g. travel sickness or diarrhoea. Patients should be advised to purchase these items from community pharmacies prior to travel, or to obtain a private prescription for POMs if appropriate. For conditions unresponsive to self-medication, the patient should normally seek medical attention abroad.
- 17.3.6 Emergency travel kits are available in two forms. The basic kit contains items such as disposable needles and syringes, IV cannulae, sutures and dressings. The POM kit contains additional items such as plasma substitutes and medicines. A private prescription is required for the latter. The kits or a list of suppliers are available through travel clinics or community pharmacies. Neither kit is available under the NHS.
- 17.3.7 Patients travelling abroad with prescribed controlled drugs (Schedules 2,3,4 (part I & part II) for their own personal use will require a personal export or import license if carrying more than 3 month's supply or travelling for three calendar months or more. This should be applied for at least 10 working days in advance of the date of travel. A completed application form will be required as well as a letter from the patient's GP or drug worker. See [here](#) for details.
- 17.3.7.1 Any person travelling for a period up to and including 3 months, carrying no more than 3 month's supply of medication or prescribed a schedule 5 controlled drug will not require a Home Office Licence regardless of the drug(s) being carried.

17.3.7.2 For patients travelling with less than 3 month's supply, medication should be carried in their hand luggage and along with a covering letter from their GP.

The letter should include their name, address, date of birth, outward and return dates of travel, countries they are visiting, list of drugs including dosage and total amounts of each to be carried.

Some countries have their own import regulations and it is advisable travellers contact the country's embassy to check before travel.

There is no allowance in the GMS contract to reimburse GPs for providing this service and it would be up to the practice's discretion whether a charge to the patient is made.

## **18. PRESCRIBING FOR MINOR AILMENTS**

18.1 The General Medical Council (GMC) advise that prescribers should only prescribe drugs to meet the identified needs of patients and not for their own convenience or simply on patient demand. Declining patient requests from the outset (e.g. requests for simple analgesia or for antibiotics for viral infections) may deter patients from making similar future demands.

## **19. PRESCRIBING OF LICENSED MEDICINES WITH LIMITED THERAPEUTIC VALUE OR EVIDENCE BASE**

19.1 Prescribing of products considered by both the British National Joint Formulary Committee and the Derbyshire Joint Area Prescribing Committee to be of limited therapeutic value and/or where there is no recognised evidence base is not supported. Such products are included in the Derbyshire JAPC Black List.

19.2 An information leaflet is available in Appendix 5

## **20. PRESCRIBING LICENSED MEDICINES FOR AN UNLICENSED USE (OFF LABEL)**

20.1 Prescribing of medicines that are licensed, but are being used outside of their product license is not generally recommended. However, it is recognised that some circumstances may necessitate prescribing "off-label".

Points for consideration:

20.1.2 Prescribers have a duty in common law to take reasonable care and to act in a way consistent with the practice of a responsible body of peers of similar professional standing.

20.1.3 Prescribers should be satisfied that an alternative, licensed medicine would not meet the patient's needs.

20.1.4 Legal responsibility for prescribing falls to the practitioner who signs the prescription.

20.1.5 In situations following a recommendation by a consultant, the prescriber is unlikely to be found negligent if they have taken steps to become familiar with the drug; are able to monitor the drug completely; and have access to effective consultant support.

20.1.6 When an unlicensed use of a medicine is prescribed, the prescriber is professionally accountable for his judgement in doing so, and may be called upon to justify his actions. It is recommended that the decision is discussed with the patient and documented in the patient record.



## **21. PRESCRIBING UNLICENSED MEDICINES and SUBSTANCES NOT IN THE ADVISORY COMMITTEE ON BORDERLINE SUBSTANCES (ACBS) LIST**

- 21.1 The Derbyshire CCGs advise against prescribing at NHS expense, products that do not have a UK Product License unless they are included in specific guidance that has been approved by JAPC. This includes:
- 21.1.2 Medicines licensed outside of the UK, products being used outside of UK licensed indications (see above)
- 21.1.3 Other preparations such as health supplements e.g:
- Antioxidants for Age-related Macular Degeneration (e.g. ICAPS<sup>®</sup>, Ocuville<sup>®</sup> etc),
  - Gamolenic acid
  - Cod liver oil
  - Co-enzyme Q10<sup>®</sup>
  - Elena<sup>®</sup>'s skin product
  - Progest Cream<sup>®</sup>
- 21.1.4 Herbal medicines e.g. Ginkgo Biloba, St John's Wort.
- 21.1.5 Other unlicensed products (any preparations not listed in the BNF) such as specials (see below). Please note this list is not exhaustive.
- 21.1.6 Prescribing of borderline foods and dietary products should comply with the recommendations of the Advisory Committee of Borderline Substances (ACBS) who recommend products on the basis that they may be regarded as drugs for the treatment of specified conditions. Doctors should satisfy themselves that the products can be safely prescribed, that patients are adequately monitored and that where necessary, expert hospital supervision is available.
- 21.1.7 A complete list of conditions can be found in the BNF or Drug Tariff Part XV. Prescriptions should be endorsed "ACBS".
- 21.1.8 There are several areas where prescriptions for dietary products do not comply with the ACBS recommendations and responsibility lies with the individual GP who may use their judgement to make exceptions. This may occur following recommendations from a dietician or for a medical condition requiring nutritional support for a defined period of time.eg following maxillo-facial surgery.
- 21.1.9 JAPC will strongly support any doctor who declines prescribing dietary products for patients (or nursing or residential homes) outside the ACBS criteria or using them as an alternative to liquidising/purchasing appropriate food.

## **22. PRESCRIBING OF UNLICENSED SPECIALS**

Commercial companies may manufacture individual products known as 'specials' where there is no commercially available, licensed, preparation to meet a patient's clinical needs. These products do not have a license. Before prescribing a special, consideration should be given to alternative licensed preparations available (first choice option), or whether a licensed preparation can be given in an unlicensed way e.g. crushing tablets, opening capsules (second choice option). The Medicines Management Team can provide advice on specific products.

- 22.1 Liquid specials generally tend to have shorter shelf lives, can be difficult for patients to obtain, and are usually much more expensive than the capsule or tablet version of the same drug, although it is acknowledged that these products may be unavoidable for a small number of patients.

- 22.2 Prior to considering prescribing an unlicensed special the treatment should be reviewed and if still necessary, alternatives should be considered.
- 22.3 Unlicensed drugs are not covered by the Medicines Act, so there is no approved summary of product characteristics (SPC) for prescribers to consult. (N.B. prescribers are only indemnified by a drug company if there is an SPC and if the drug is used within licensed indications)
- 22.4 Practices are advised to review patients receiving prescriptions for these items and consider an alternative licensed preparation if appropriate. Initiation for new patients is not recommended. See [further specials guidance](#)

## **23. PERSONALLY ADMINISTERED ITEMS**

- 23.1 Items that can be claimed as personally administered include
- Vaccines, anaesthetics and injections;
  - Intrauterine contraceptive devices (including drug releasing IUCDs, contraceptive caps and diaphragms);
  - Pessaries which are appliances
  - Sutures (including skin closure strips) – for emergency wounds etc.

N.B Implanon/Nexplanon cannot be claimed as a personally administered item (since an implant, rather than injection). An FP10 prescription should be provided. A prescription charge is not payable since a contraceptive.

Goserelin (even though an implant) can be claimed as personally administered item, as can leuprorelin and triptorelin.

High volume vaccines (e.g. influenza, typhoid, hepatitis A, hepatitis B, pneumococcal, meningococcal) can be claimed for on the form FP34PD. For other items an FP10 prescription needs to be submitted.

Items that cannot be claimed as personally administered include dressings used in minor surgery, hormonal implants, nebulas, catheters, clinical reagents etc.

Items that are personally administered do not attract a prescription charge. If a prescription is provided, a prescription charge would be payable (unless patient is exempt).

## **24. DOCTORS PRESCRIBING FOR THEMSELVES OR THEIR FAMILIES**

- 24.1 It is poor practice for doctors and their families to be registered at the doctors own practice. Unless there are exceptional circumstances, doctors and their families should register with a GP outside the family. Doctors who believe they and/or their family cannot avoid being registered at their own practice should contact their Responsible Officer.
- 24.2 Doctors (or any other prescribers) should not prescribe for themselves or their family. Prescribers must not treat themselves or family members other than in an emergency, or other exceptional circumstances (which should be discussed with the prescribers Responsible Officer).

## **25. PRESCRIBING FOR VISITORS FROM OVERSEAS**

- 25.1 Patients entitled to NHS treatment in primary care, including the provision of any necessary prescriptions are as follows:
- A person intending to be resident in this country for six months or more (registration with a practice is necessary)

- Patients from the European Economic Area in possession of a European Health Insurance Card (EHIC)
- Patients (from any country) who require immediate, essential treatment, which the treating doctor deems cannot reasonably be delayed until the patient returns home (EHIC not required).
- Patients from EEA member states holding an E112 (entitles the patient to seek treatment of a specific condition and prescriptions for this condition only).
- Patients from EEA member states holding an E128 (entitles the patient to seek NHS treatment for all conditions on same basis as UK residents)
- Patients allocated by the CCG.
- Refugees (those whose applications to reside in this country have been approved) and asylum seekers (those who have submitted an application and are awaiting a decision).
- This list is not exhaustive. Please check an individual's situation before providing or declining NHS care as special conditions may apply. Further information is available from the Overseas Visitors section of the Department of Health website.

25.2 Patients who do not fall into these categories may be offered and charged for private care, including the provision of private prescriptions where necessary.

25.3 Where appropriate, patients should be encouraged to register, permanently or as a temporary resident, with a general practice to receive NHS care.

## **26. DISPOSAL OF UNWANTED MEDICINES**

26.1 All pharmacies are obliged to accept unwanted medicines from patients, including dressings and medicines considered as hazardous (e.g. hormonal preparations, oral cytotoxic medicines etc.) as an essential service under the national Pharmacy Contract. Patients presenting at a GP practice with such items should be asked to return them to their local pharmacy for disposal. This also applies to patients who are resident in a residential home, however nursing homes providing nursing care to patients are required to make their own waste disposal arrangements.

26.2 Pharmacies are not able to accept sharps waste from patients e.g. insulin needles or medicines contained in pre-filled syringes etc. Patients who are prescribed such items should also be provided with a sharps bin and be instructed in how to use it safely and where to return it when full. Patients prescribed insulin needles and other items requiring disposal in a sharps bin in primary care should be prescribed an appropriate sharps bin on prescription and be advised to return to their GP practice when full. N.B. North Derbyshire CCG commissions a home care delivery service for patients prescribed methotrexate pre-filled syringes under a shared care arrangement. This service includes the provision and collection of hazardous waste bins by the home care company

A joint Derby and Derbyshire sharps collection service for housebound patients is available. See link below:

<http://www.derby.gov.uk/environment-and-planning/recycling-rubbish-and-waste/clinical-household-waste/>

## **27. MEDICINES DONATIONS OVERSEAS**

27.1 The Environment Agency support the views of the Royal Pharmaceutical Society of Great Britain, the World Health Organisation and Department of Health that patient returned waste medicines should not be exported for re-use overseas as the recycling of such medicines is regarded as unsafe due to concerns over the quality of the returned medicine and the difficulties in managing these medicines at the receiving end.

## APPENDIX 1: GENERIC MEDICINES

Generic medicines are the same as a branded medicine, for example Nurofen is the branded name for the medicine ibuprofen (the generic name). Generic medicines are made to the same standard as branded medicines so they are as safe and effective and of the same high quality as the branded medicines. Generic medicines contain the same ingredients and are identical in strength to the branded medicine, so they treat conditions in just the same way as a branded medicine.

There may be some difference in colour, shape or size which does not affect the medicine or the way it works.

Using generic medicines saves the NHS money which is used in other ways to benefit you, your family and other patients. The advice from the Department of Health is to use generic medicines where they are available.

For these reasons, your repeat prescription will change and you will now be prescribed generic medicines.

Remember, generic medicines:

- Have the same active ingredients as branded medicines
- Meet the same quality standards as branded medicines
- Are as safe and effective as branded medicines.

## APPENDIX 2: ITEMS THAT SHOULD BE PRESCRIBED BY BRAND NAME FOR PATIENT SAFETY REASONS

The following table has been compiled by UKMI (July 2013, partial update December 2013) and lists medicines that might be considered for brand-name prescribing. The table has been compiled using a number of sources. Specific references for individual medicines are included where appropriate.

BNF	Drug or drug class	Reason for considering brand-name prescribing	Specific references
<b>Chapter 1</b>			
1.1.1	Antacids preparations containing simeticone	To aid identification. Products contain multiple ingredients.	BNF
1.1.2	Compound alginates and proprietary indigestion preparations	To aid identification. Products contain multiple ingredients.	BNF
1.5.1	Mesalazine oral preparations	The delivery characteristics of oral mesalazine preparations may vary and should not be considered interchangeable.	BNF
1.6.1	Bulk forming laxatives	To aid identification. Products contain multiple ingredients.	-
1.6.4	Macrogols (polyethylene glycols)	To aid identification. Products contain multiple ingredients.	-
1.7.2	Compound haemorrhoid preparations	To aid identification. Products contain multiple ingredients.	-
1.9.4	Pancreatin supplements	To aid identification. Products contain multiple ingredients.	-
<b>Chapter 2</b>			
2.6.2	Diltiazem modified release (MR) preparations	MR preparations have different release characteristics and are not interchangeable.	BNF dm+d
2.6.2	Nifedipine modified release preparations	MR preparations have different release characteristics and are not interchangeable.	BNF dm+d

<b>Chapter 3</b>			
3.1.1	Formoterol dry powder inhalers	Patient familiarity with one brand is important; instructions for use vary between preparations.	dm+d
3.1.1	Salbutamol dry powder inhalers	Patient familiarity with one brand is important; instructions for use vary between preparations.	dm+d
3.1.3	Theophylline modified release preparations	MR preparations have different release characteristics and are not interchangeable. Theophylline has a narrow therapeutic index.	BNF
3.1.3	Aminophylline modified release preparations	MR preparations have different release characteristics and are not interchangeable. Aminophylline has a narrow therapeutic index.	BNF dm+d
3.2	Beclometasone dipropionate CFC-free pressurised metered dose inhalers	<i>Qvar</i> and <i>Clenil Modulite</i> are not interchangeable. <i>Qvar</i> has extra-fine particles and is approximately twice as potent as <i>Clenil Modulite</i> and CFC-containing beclometasone inhalers. The MHRA has advised that CFC-free beclometasone inhalers should be prescribed by brand name. This applies also to combination products.	BNF dm+d MHRA [8]
3.2	Beclometasone dry powder inhalers	Patient familiarity with one brand is important; instructions for use vary between preparations.	dm+d
3.2	Beclometasone and formoterol CFC-free metered dose inhalers	See beclometasone CFC-free metered dose inhalers, above.	BNF MHRA [8]
3.2	Budesonide dry powder inhalers	Patient familiarity with one brand is important; instructions for use vary between preparations.	-
3.4.3	Adrenaline (epinephrine) pre-filled syringes	Patient familiarity with one brand is important; instructions for use vary between preparations.	BNF dm+d
<b>Chapter 4</b>			
4.2.3	Lithium preparations	Preparations vary widely in bioavailability. Changing the preparation requires the same precautions as initiation of treatment. Lithium has a narrow therapeutic index.	BNF dm+d
4.4	Methylphenidate modified release preparations	MR preparations contain different proportions of immediate-release and modified-release methylphenidate.	BNF dm+d
4.7.2	Morphine oral modified release preparations	MR preparations have different release characteristics; Patient familiarity with one brand is important.	PCF4 [9]
4.7.2	Fentanyl patches	Patches are available as matrix and reservoir formulations; Patient familiarity with one brand is important. Reservoir patches must not be cut because damage to the rate-limiting membrane can lead to a rapid release of fentanyl resulting in overdose. If the prescriber intends the patch to be cut (NB: unlicensed and not recommended by the MHRA) then the prescription must specify a brand of matrix formulation patch.	PCF4 [9]
4.7.4	Botulinum toxin type A	Preparations are not interchangeable due to differences in potency.	BNF dm+d

4.8.1	Antiepileptic drugs	<p>The MHRA has classified antiepileptic drugs (AEDs) into three categories of risk, based primarily on their therapeutic index and physiochemical characteristics (in particular solubility and permeability across membranes) indicative of potential differences between formulations.</p> <p>Category 1: Specific measures are necessary to ensure consistent supply of a particular product (which could be either a branded product or a specified manufacturer's generic product).</p> <p>Category 2: NB: By default, this category includes all AEDs not listed in categories 1 or 3. The need for continued supply of a particular manufacturer's product should be based on clinical judgement and consultation with patient and/or carer.</p>	MRHA [10,11]
		<p>Category 3: No specific measures are normally required and these AEDs can be prescribed generically and without specifying a specific manufacturer's product:</p> <p>NICE recommends continuity of the same brand, or the same generic preparation, for patients with seizure disorders, unless the prescriber (in consultation with the patient and their family or carers) considers this not to be a concern. (For individual antiepileptic agents, see below.)</p>	NICE [12]
4.8.1	Carbamazepine	MHRA Category 1 (see 'Antiepileptic drugs' above).	MRHA [11]
4.8.1	Ethosuxamide	MHRA Category 3 (see 'Antiepileptic drugs' above).	MRHA [11]
4.8.1	Gabapentin	MHRA Category 3 (see 'Antiepileptic drugs' above).	MRHA [11]
4.8.1	Lacosamide	MHRA Category 3 (see 'Antiepileptic drugs' above).	MRHA [11]
4.8.1	Levetiracetam	MHRA Category 3 (see 'Antiepileptic drugs' above).	MRHA [11]
4.8.1	Phenobarbital	MHRA Category 1 (see 'Antiepileptic drugs' above).	MRHA [11]
4.8.1	Phenytoin	MHRA Category 1 (see 'Antiepileptic drugs' above).	MRHA [11]
4.8.1	Pregabalin	MHRA Category 3 (see 'Antiepileptic drugs' above).	MRHA [11]
4.8.1	Primidone	MHRA Category 1 (see 'Antiepileptic drugs' above).	MRHA [11]
4.8.1	Tiagabine	MHRA Category 3 (see 'Antiepileptic drugs' above).	MRHA [11]

4.8.1	Vigabatrin	MHRA Category 3 (see 'Antiepileptic drugs' above).	MRHA [11]
4.9.1	Apomorphine pre-filled syringe	Patient familiarity with one brand is important; instructions for use vary between preparations.	dm+d
4.9.3	Botulinum toxin type A	Preparations are not interchangeable due to differences in potency.	BNF dm+d
<b>Chapter 6</b>			
6.1.1	Insulins	Patient familiarity with the same brand is important; training is required in the use of specific devices for self-injection.	dm+d
6.4.1	Hormone replacement therapy oral preparations	Different brands of the same formulation are available. Patient familiarity with one brand is important.	-
6.4.1	Estradiol transdermal patches	Different brands of the same formulation are available. Patient familiarity with one brand is important.	-
6.5.1	Somatropin injection cartridges	Patient familiarity with the same brand is important and training is required in the use of specific devices for self-injection. Some somatropin preparations are licensed as 'biosimilar' medicines.	BNF dm+d
<b>Chapter 7</b>			
7.3.1	Combined oral contraceptives	Different brands of the same formulation are available. Patient familiarity with one brand is important.	-
7.3.2	Progestogen only oral contraceptives	Different brands of the same formulation are available. Patient familiarity with one brand is important.	-
7.4.5	Alprostadil injection	Patient familiarity with one brand is important; instructions for use vary between preparations.	dm+d
<b>Chapter 8</b>			
8.2.1	Azathioprine	Different formulations may vary in bioavailability; to avoid reduced effect or excessive side effects, it is important not to change formulation except on the advice of a transplant specialist.	BNF Eur Soc Org Trans [12]
8.2.1	Mycophenolate	Generic and branded preparations are considered bioequivalent but it may be prudent not to change formulation except on the advice of a transplant specialist. Mycophenolate mofetil and mycophenolic acid preparations are not interchangeable.	BNF Eur Soc Org Trans [12] PJ [13]
8.2.2	Ciclosporin	Preparations are not interchangeable and should be prescribed by brand-name to avoid inadvertent switching. It is important not to change formulation except on the advice of a transplant specialist. Ciclosporin has a narrow therapeutic index.	BNF dm+d Eur Soc Org Trans [12] MHRA [14]

8.2.2	Tacrolimus	Preparations are not interchangeable; care should be taken to ensure the correct preparation is prescribed and dispensed. It is important not to change formulation except on the advice of a transplant specialist. Tacrolimus has a narrow therapeutic index.	BNF dm+d MHRA [15]
8.2.4	Interferon pre-filled disposable injection devices  Peginterferon pre-filled disposable injection devices	Patient familiarity with one brand is important; instructions for use vary between preparations.	dm+d
<b>Chapter 9</b>			
9.1.3	Erythropoietins	Patient familiarity with the same brand is important and training is required in the use of specific devices for self-injection. Some epoetin preparations are licensed as 'biosimilar' medicines.	BNF dm+d
9.1.6	Granulocyte-colony stimulating factors	Patient familiarity with the same brand is important and training is required in the use of specific devices for self-injection. Filgrastim preparations have been approved as 'biosimilar'.	dm+d BNF
9.2.1	Oral rehydration salts	To aid identification. Products contain multiple ingredients.	-
9.5.1	Calcium salts	To aid identification. Products contain multiple ingredients.	-
<b>Chapter 12</b>			
12.3.5	Saliva replacement products	To aid identification. Products contain multiple ingredients.	-
<b>Chapter 13</b>			
13.1- 13.10	Preparations for skin and scalp conditions containing multiple ingredients	To aid identification. Products contain multiple ingredients. Also, potency of topical corticosteroid preparations is a result of the formulation as well as the corticosteroid.	-
<b>Chapter 14</b>			
14.4	Human papillomavirus vaccine	<i>Cervarix</i> (bivalent vaccine) and <i>Gardasil</i> (quadravalent vaccine) are not considered interchangeable.	BNF

**Limitations:** This list of medicines may not be comprehensive.



### ***APPENDIX 3: INFORMATION FOR PATIENTS FOLLOWING AN NHS REFERRAL***

When you are referred by your GP to an NHS specialist your medication may change.

Your specialist may give you a one-off prescription as part of your treatment and if appropriate may ask you to go to your GP so that you can get the medicines as part of your long-term care. If the GP does not feel able to accept clinical responsibility for prescribing the medication, the specialist will remain responsible for further prescriptions.

Your GP must have a full clinical report from the specialist before providing further treatment so you may not be able to get another prescription right away. The specialist should give you enough medicines until your GP has received the report but please speak to your practice if you are concerned that you will not have enough.

Local GPs have agreed to prescribe in line with local policies. If the recommendation from your consultant is for medicines that are not in line with local policies, then your GP may change the medication to be in line with the drugs used for NHS patients.

## **APPENDIX 4 - INFORMATION FOR PATIENTS CONSIDERING PRIVATE MEDICAL CONSULTATIONS**

When you see a private specialist you should be aware what may happen about medication you may need after the consultation.

### **1 Independent private referral**

People who refer themselves to a consultant independently of the GP (i.e. outside the NHS), whether in the UK or abroad, are expected to pay the full cost of any treatment they receive in relation to the care provided privately.

### **2 Private referral through your GP**

After a private referral made by your GP, your private specialist may give you a prescription. Sometimes you may only need one prescription. The prescription provided by your private specialist will be a private prescription and you must pay for the medication. If you need continued treatment you may be given just one private prescription (which you will need to pay for) and advised to return to your GP to see if further NHS prescriptions can be provided.

A NHS prescription to continue your treatment will only be provided if your GP considers there is a clinical need and that an NHS patient would be treated in the same way; there is no obligation for the GP to prescribe the treatment recommended by a private specialist. In order to judge your clinical need your GP must have received a full clinical report from the private specialist and therefore you may not be able to have a prescription immediately.

GPs have agreed to prescribe in line with local policies. If the recommendation from your private specialist is for treatment that is not in line with local policies, then your GP may change the medication to be in line with medicines usually recommended for NHS patients. If your GP feels the treatment is for a specialist area your GP can ask the specialist to remain responsible for the treatment and to provide further prescriptions which the patient will need to pay for.

## **APPENDIX 5 - UNLICENSED MEDICINES AND MEDICINES WITH LIMITED THERAPEUTIC VALUE**

Medicines are provided with a license by the manufacturers to ensure they are safe. Derbyshire CCGs advise GPs not to prescribe products that do not have a UK medicine product license.

Examples of items where there is no product license are:

Health supplements e.g. Antioxidants for Age-related Macular Degeneration (Ocuvit®, ICAPS®),  
Gamolenic Acid,  
Cod Liver Oil,  
Q10,  
Elena®,  
Progest Cream®,  
Herbal medicines e.g. Ginkgo Biloba, St John's Wort

Other unlicensed products not listed in official information sources such as the British National Formulary .e.g. co-proxamol

Please note this list is not exhaustive.

Your GP is reviewing prescriptions where unlicensed medicines have been provided. You may be recommended an alternative or you may be able to buy the product yourself.

## ***APPENDIX 6 – PRESCQIPP TRAVEL VACCINE BULLETIN***

### **Locally agreed Derbyshire position statement for when both hepatitis A and hepatitis B vaccination are required for patients travelling abroad.**

The combined hepatitis A and B vaccination is available on the NHS as a travel vaccine because it contains hepatitis A. However hepatitis B vaccination is not commissioned by the NHS as a travel vaccine and would require a private prescription when prescribed as a single agent. When both hepatitis A and hepatitis B vaccination are required for patients travelling abroad, prescribers are not obliged to give the combination product as a travel vaccine on the NHS but should take the following local agreement into consideration:

The Derbyshire LMC's view is that a GP must prescribe on an NHS FP10 anything they believe is in the patient's best interests to do so (with the exception of items on the NHS blacklist) and if they are acting within their competence. If a patient is travelling to a place (or undertaking activities while abroad) where hepatitis A and hepatitis B immunisation is in the patient's best interest then the GP should prescribe these vaccines in whatever way they feel is in the patient's best interest. This will be an individual decision that may depend upon the patient's circumstances. It is recommended good practice to record the reasons for prescribing either the combined vaccine on the NHS or the separate vaccines (hepatitis A on the NHS and hepatitis B privately) on each occasion.

The bulletin below has been developed by PrescQIPP to assist practices receiving requests from patients for travel immunisation, clarify national guidance on which immunisations may be prescribed on the NHS and which should be privately prescribed.

## Travel vaccines (DROP-List)

Annually over £5.3 million (ePACT April 2014) is spent nationally on vaccines that are potentially not suitable to be prescribed on the NHS as they are mainly used for travel.

There has traditionally been a lack of clarity regarding the provision and charging for vaccinations for patients in at-risk groups, prior to travel and for occupational reasons. Most misunderstandings of the regulations are due to the confusion between the clinical advice for when to administer an immunisation for travel (as set out in the Green Book<sup>1</sup>) and the regulations indicating how practices are paid for it (as set out in the former Red Book<sup>2</sup>).

This bulletin has therefore been developed to assist practices receiving requests from patients for travel immunisation, clarify national guidance on which immunisations may be prescribed on the NHS and which should be privately prescribed. Supporting data, a briefing and a patient information leaflet are also available here:

<http://www.prescqipp.info/resources/viewcategory/263-travel-vaccines-drop-list>

Areas not covered by this bulletin include the childhood primary immunisation schedule, national vaccination programmes (including catch-up programmes) and vaccination as indicated under the advice of the Health Protection Agency.<sup>3</sup>

Provision of travel advice: NHS patients are entitled to receive advice on recommended immunisations and malaria prophylaxis free of charge.<sup>4</sup>

### Recommendations

- Vaccinations not allowed on the NHS should not be prescribed or supplied on the NHS for travel purposes. Patients should be charged for these vaccinations and associated costs.
- Hepatitis B vaccination is not commissioned under the NHS and this vaccination should be prescribed privately.<sup>1</sup>
- Local policy should be established to agree whether combined hepatitis A and B vaccination can be prescribed on the NHS for travel purposes or should be prescribed as separate component vaccines with the hepatitis A on FP10 prescription and the hepatitis B prescribed privately. This should be discussed with the Local Medical Committee (LMC).
- Cost of different products for the same vaccines should be considered. Single vaccines are cheaper than combined in the case of hepatitis A and typhoid.

### National guidance

#### Travel immunisations that can be given as part of NHS provision<sup>5</sup>

The following immunisations for travel are part of additional services under General Medical Services (GMS) and Personal Medical Services (PMS).<sup>4</sup> Patients should not be charged a fee for these specified travel immunisations if the service is provided to registered patients. Practices can opt out of this provision and refer patients to a travel clinic.<sup>6</sup>

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- Hepatitis A [infectious hepatitis] - first and second/booster dose
- Typhoid - first and any booster doses
- Combined hepatitis A and typhoid - first dose (second dose is Hepatitis A alone)

(Note: separate vaccinations are cheaper and more appropriate as they have different booster dosage schedules.<sup>7</sup>)

- Tetanus, diphtheria and polio combined vaccine
- Cholera.

Some vaccines are available on the NHS because they protect against diseases thought to represent the greatest risk to public health if they were brought into the country.

The vaccines for these are available at NHS expense in one of two ways:

- Purchased by the practice and personally administered payment claimed through FP34PD.
- Obtained by the patient on FP10 prescription. A prescription charge is payable to the pharmacy unless the patient is exempt. In this situation no claim for personal administration fees should be made through FP34PD.

### Travel immunisations that cannot be given as an NHS service<sup>5</sup>

The following immunisations are not remunerated by the NHS as part of additional services:

- Hepatitis B (single agent)
- Meningitis ACWY (quadrivalent meningococcal meningitis vaccine; A, C, Y and W135)
- Yellow fever
- Japanese B encephalitis
- Tick borne encephalitis
- Rabies.

The practice may therefore charge a registered patient for the immunisation if requested for travel. The patient may either be given a private prescription to obtain the vaccines, or they may be charged for stock purchased and held by the practice. The process of administration of the immunisation is also chargeable. Practices should give the patient written information on the immunisation schedule proposed and the charges involved at the outset of the process.<sup>8</sup> An FP10 (or equivalent NHS prescription) must not be used to provide these vaccines.

There is some ambiguity over the combined hepatitis A and B vaccination. Although the combination is prescribable on the NHS as a travel vaccine because it contains hepatitis A, hepatitis B is not commissioned by the NHS as a travel vaccine, so prescribers are not obliged to give the combination product as a travel vaccine on the NHS.

Local policy should be agreed on whether hepatitis A and B combined vaccine can be prescribed locally on the NHS for travel or whether the hepatitis A alone can be prescribed on an FP10 and hepatitis B vaccine should be given and charged as a separate private vaccination.

### Private provision

The ambiguity on when to supply travel vaccines under the NHS or privately stems from the regulations regarding the charging of patients that are registered with the practice. Schedule 5 of the NHS regulations leaves the decision as to whether the practice levies a charge or not to the discretion of the practice.<sup>4</sup> The regulations do not impose any circumstances or conditions as to when these immunisations should be given on the NHS or as a private service. Practices have to ensure that their policy is non-discriminatory and that this is not done contrary to the Equality Act 2010 (formerly the Disability Discrimination Act).<sup>9</sup>

For travel vaccines not available on the NHS a charge may be levied for:<sup>4</sup>

- The vaccine
- Administration
- Private prescription writing.

The level of charges should be determined by the practice; it is advisable to develop a practice protocol available to patients in the form of a leaflet or section of the practice leaflet or website.

Patients should be advised to compare prices as there may be variation in the amount that individual pharmacies will charge to supply the vaccination. Alternatively, practices may choose to buy in the vaccine directly and charge patients for the cost of the vaccine.

Possible charges after vaccination:

- Post-vaccination serological testing in the case of Hepatitis B administration, if performed for travel reasons.
- Provision of certification of immunisation (for example, confirmation of Meningitis ACWY135 administration).

## Occupational health

Under the Health and Safety at Work Act,<sup>10</sup> employers must pay for protective measures such as immunisation. In occupations where there is a risk to health from any form of work related infection it is the employer's duty to assess that risk and, if present, to protect the workforce.<sup>11</sup>

## Costs

Cost of individual products as per BNF 67 (March 2014) are shown in table 1.<sup>7</sup> The lowest cost product or combination should always be supplied unless there is a clinical reason not to do so.

£5.3 million is spent on vaccines that should not be prescribed on the NHS and can be prescribed privately if required by patients for travel. Total savings available nationally are £5.3 million (ePACT, April 2014). This equates to £9,400 per 100,000 patients. This savings figure assumes a local commissioning policy not to prescribe Hepatitis A and B combined vaccination on the NHS.

The accompanying data pack shows prescribing data at CCG level and annual savings available for each CCG. The spend on the vaccines has been apportioned for travel and is an estimate.

## Summary

Table 1 on the following page clarifies the availability on the NHS for each vaccine. In the case of travel immunisation it shows the current BNF cost per vaccine and suggests the possible charges that can be levied.<sup>7</sup>

## Resources for further information

Further information on which vaccinations are necessary or recommended for the areas patients will be visiting are available on these two websites:

- Fit for Travel<sup>12</sup>
- National Travel Health Network and Centre (NaTHNaC)<sup>13</sup>

Further information on individual vaccines is available from the Summary of Product Characteristics (SPC) available at [www.medicines.org.uk](http://www.medicines.org.uk)

Some countries require an International Certificate of Vaccination or Prophylaxis (ICVP) before you enter.<sup>14</sup> For example, many tropical countries in Africa and South America will not accept travellers from an area where there is yellow fever unless they can prove that they have been vaccinated against it. Saudi Arabia requires proof of vaccination against certain types of meningitis for visitors arriving for the Hajj and Umrah pilgrimages. Providing a certificate of vaccination in such cases can be charged for.

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Table 1- Travel vaccines available/not available on the NHS

\*Epaxal® (hepatitis A vaccine) will be discontinued by Crucell, part of Janssen, during 2014<sup>15</sup>

VACCINE	AVAILABLE ON NHS FOR TRAVEL <sup>5</sup>	PRICE PER DOSE BNF 67 <sup>7</sup>	POTENTIAL CHARGES
Bacillus Calmette-Guérin (BCG)	NO	N/A	Referral to a respiratory clinic is recommended for tuberculin testing and follow up for all patients requesting vaccination.
CHOLERA	YES The vaccine is not indicated for most travellers.	Dukoral® £23.42 (2 dose pack)	NONE
DIPHTHERIA/TETANUS/ POLIO	YES Stock centrally funded by the Department of Health as part of the childhood immunisation programme must NOT be used for the purposes of travel.	Revaxis® £6.50	NONE
HEPATITIS A	YES	Havrix Monodose® £22.14 Havrix Junior Monodose® £16.77 Vaqta® Adult 1-mL pre-filled syringe £18.10 Vaqta® Paediatric £14.74 Avaxim® £18.10 Epaxal®* £23.81	NONE
HEPATITIS A/TYPHOID	YES Hepatitis A/Typhoid available on NHS, booster dosage not aligned so consider separate vaccines.	Hepatyrix® £32.08 ViATIM® £29.80	NONE



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VACCINE	AVAILABLE ON NHS FOR TRAVEL <sup>5</sup>	PRICE PER DOSE BNF 67 <sup>7</sup>	POTENTIAL CHARGES
HEPATITIS A/B	<p>Establish local commissioning policy</p> <p>Hepatitis B is not available on NHS for the purposes of travel.</p> <p>Local policy should be agreed on whether hepatitis A and B combined vaccine can be prescribed locally for travel or whether the hepatitis B vaccine should be given as a separate private vaccination.</p>	<p>Twinrix® 1-mL prefilled syringe (Twinrix® Adult) £27.76, 0.5-mL prefilled syringe (Twinrix® Paediatric) £20.79</p> <p>Ambirix® £31.18 (under 16 years only)</p>	<p>If policy agreed to charge privately for hepatitis B as a separate vaccine:</p> <ul style="list-style-type: none"> <li>• Private prescription</li> <li>• Cost of vaccine</li> <li>• Administration</li> <li>• Serological testing</li> </ul>
HEPATITIS B	NO	<p>Engerix B® £12.99 (prefilled syringe) (under 16 years £9.67)</p> <p>Fendrix® £38.10</p> <p>HBvaxPRO® £12.20 (under 16 years £8.95)</p>	<ul style="list-style-type: none"> <li>• Private prescription</li> <li>• Cost of vaccine</li> <li>• Administration</li> <li>• Serological testing</li> </ul>
JAPANESE ENCEPHALITIS	NO	<p>Ixiaro®</p> <p>£59.50</p>	<ul style="list-style-type: none"> <li>• Private prescription</li> <li>• Cost of vaccine</li> <li>• Administration</li> </ul>
MENINGOCOCCAL - MENINGITIS ACWY	NO	<p>ACWY Vax® £16.73</p>	<ul style="list-style-type: none"> <li>• Private prescription</li> <li>• Cost of vaccine</li> <li>• Administration</li> <li>• Certification</li> </ul>

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VACCINE	AVAILABLE ON NHS FOR TRAVEL <sup>5</sup>	PRICE PER DOSE BNF 67 <sup>7</sup>	POTENTIAL CHARGES
RABIES	NO	Rabipur® £28.80	<ul style="list-style-type: none"> <li>• Private prescription</li> <li>• Cost of vaccine</li> <li>• Administration</li> </ul>
TICK-BORNE ENCEPHALITIS	NO	TivoVac® £32.00 TivoVac Junior® £28.00	<ul style="list-style-type: none"> <li>• Private prescription</li> <li>• Cost of vaccine</li> <li>• Administration</li> </ul>
TYPHOID	YES	Typhim Vi® £9.30 Typherix® £9.93	NONE
YELLOW FEVER	NO Only available at designated Yellow Fever Vaccination Centre	N/A	SPECIALIST CENTRES ONLY

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### Additional PrescQIPP resources



Briefing



Data pack



Patient information leaflet

Available here: <http://www.prescqipp.info/resources/viewcategory/263-travel-vaccines-drop-list>

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