



Prescribing Dilemmas A Guide for Prescribers

This report has been prepared by a multiprofessional collaborative group, with support from the All Wales Prescribing Advisory Group (AWPAG) and the All Wales Therapeutics and Toxicology Centre (AWTTC), and has subsequently been endorsed by the All Wales Medicines Strategy Group (AWMSG).

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CONTENTS

1.0 INTRODUCTION	2
2.0 CLINICAL RESPONSIBILITY	2
3.0 PRIVATE REFERRAL	2
3.1 Patients who request to be referred privately	3
3.2 Top-up payments	3
4.0 PRIVATE PRESCRIPTIONS	3
4.1 Following a private consultation	3
4.2 For NHS patients	4
4.3 For a branded product	4
5.0 PRESCRIBING OF MEDICINES FOR AN UNLICENSED USE	4
6.0 PRESCRIBING OUTSIDE NATIONAL GUIDANCE	5
7.0 PRESCRIBING DURATION	5
8.0 PRESCRIBING OF BORDERLINE FOODS AND DIETARY PRODUCTS	6
9.0 COMPLEMENTARY MEDICINE AND ALTERNATIVE THERAPIES	6
10.0 COMMON AILMENTS	7
11.0 FERTILITY TREATMENT	8
11.1 Prescribing information	9
12.0 MEDICINES FOR THE TREATMENT OF ERECTILE DYSFUNCTION	9
12.1 Treatment of erectile dysfunction	9
12.2 Use in management of other clinical conditions	.11
13.0 PRESCRIBING FOR ONESELF OR FAMILY	.11
14.0 VISITORS FROM OVERSEAS	.12
15.0 TRAVEL ABROAD	.12
15.1 Immunisation for travel abroad	.13
15.2 Malaria chemoprophylaxis	.14
15.3 Controlled drugs: implications for patients	.15
16.0 VACCINES FOR OCCUPATIONAL HEALTH PURPOSES	.15
16.1 Hepatitis B vaccine	.16
APPENDIX 1: TRAVEL RELATED VACCINES AND OPTIONS FOR PRIVATE OR NHS SUPPLY THROUGH GENERAL PRACTICE	18
DEEEDENCES	20

1.0 INTRODUCTION

This document provides guidance for health professionals regarding prescribing situations not covered by the NHS, including private care and private prescriptions, unlicensed medicines, prescribing outside national guidance, prescribing duration, foodstuffs, complementary medicines and alternative therapies, common ailments, fertility treatment, erectile dysfunction, prescribing for self and family, visitors from overseas, travel and occupational health vaccines.

The information has been collated from various resources including those produced by former local health boards (LHBs) and trusts, the General Medical Council (GMC) and Welsh Government.

2.0 CLINICAL RESPONSIBILITY

Legal responsibility for prescribing lies with the prescriber who signs the prescription¹. It is important that prescribers prescribe drugs or treatment, including repeat prescriptions, only when they have adequate knowledge of the patient's health, and are satisfied that the drugs or treatment serve the patient's needs².

Please note that throughout this document reference has been made to general practitioners (GPs); however, the comments should equally apply to non-medical prescribers who have responsibility for prescribing in the relevant areas.

Independent prescribers (nurse/pharmacist/optometrist/physiotherapist/chiropodist/podiatrist) may prescribe for any medical condition within their area of competence.

Nurse independent prescribers and pharmacist independent prescribers in Wales can prescribe a controlled drug within their clinical competence and unlicensed medicines on the same basis as other independent prescribers. Optometrists/physiotherapists/chiropodists/podiatrists cannot prescribe unlicensed medicines or controlled drugs³. All prescribers are encouraged to report suspected adverse drug reactions using the Yellow Card reporting scheme⁴.

At the interface between hospitals and GPs, 'prescribing responsibility will continue to be based on clinical responsibility. This is good medical practice and is in the best interests of the patient'. Systems should be in place to ensure such responsibility can be accepted, with health boards and local statutory organisations representing various health professionals, e.g. local medical committees (LMCs), working together to identify deficiencies in local arrangements and providing mutually acceptable solutions.

3.0 PRIVATE REFERRAL

A large number of patients opt to have some or all of their investigations and/or treatment privately. Some use private health insurance, whilst others are willing to pay to be seen more quickly, or for the added convenience or comfort of receiving their care in private facilities.

In addition to the increasing emphasis on patient choice within the NHS, it is also recognised that patients are entitled to choose whether they receive their treatment within the NHS or privately. There has been a blurring of the boundaries between NHS and private treatment, with patients switching freely between the two sectors.

Whilst administratively convenient but not always practical, treatment is defined by 'episodes of care', which may be either continuous or consist of a series of treatment and care episodes, some of which may be funded by the patient and some by the NHS.

3.1 Patients who request to be referred privately

Such patients are expected to pay the full cost of any treatment they receive in relation to the care provided privately; consultation fees, diagnostic tests, drugs prescribed or treatment provided by a clinician in the course of a private consultation should be at the patient's expense⁵. Patients should be informed of this expectation prior to referral.

3.2 Top-up payments

Top-up payment, where the patient typically pays to receive a medicine (e.g. a cancer drug which has not had National Institute for Health and Care Excellence [NICE] or All Wales Medicines Strategy Group [AWMSG] approval) but then returns to NHS care, may be seen as different to private care, where the patient pays for all ongoing treatment. There is no legal barrier to top-up payments for medicines not routinely funded for use in Wales; a letter was sent to health boards in March 2011 advising the adoption of the *Improving the Availability of Medicines for Patients in Wales – Top-up Payments* Implementation Group Report⁵ recommendations. The *Medicines Funding in the NHS* report recommends that patients opting for top-up treatment should not lose their entitlement to NHS treatment⁶. However, health boards have the power to charge for associated monitoring and care (excluding unpredictable events)⁵. There are also recommendations relating to procedural issues that should be considered when top-up treatment packages are introduced⁵.

4.0 PRIVATE PRESCRIPTIONS

4.1 Following a private consultation

A private consultant (i.e. the person providing the private opinion, which may be a physician, dentist or other healthcare consultant) may see a patient privately in order to give an opinion to an NHS GP regarding diagnosis or further management. Alternatively, the consultant may treat a private patient for whom they will continue to have clinical responsibility and will personally determine the ongoing treatment for that particular condition. Until the consultant discharges the patient, this remains an episode of care. In this case, the consultant should prescribe privately for their private patient, and a GP may refuse to prescribe on the NHS in such a situation, as they do not have the clinical responsibility for managing that particular condition. It is advisable that GPs inform patients of this possibility before referral. The GP must, however, continue to provide NHS treatment and prescriptions for other conditions for which they retain clinical responsibility².

Exceptions to this (i.e. continuing to provide NHS treatment where they retain clinical responsibility) would be where prescribing a medication would be outside the competence of the prescriber, in which case the prescriber must make arrangements for appropriate care²; where the prescriber considers that the treatment would not be of overall benefit to the patient, in which case the prescriber must explain this to the patient and include the option to seek a second opinion⁷; or where the medication is generally not provided within the NHS (e.g. a drug listed under Part XVIIIA of the NHS Drug Tariff⁸).

The GMC advises that it is good medical practice to "contribute to the safe transfer of patients between healthcare providers", "share all relevant information with colleagues involved in your patient's care" and "when you do not provide your patients' care yourself... be satisfied that the person providing care has the appropriate qualifications, skills and experience to provide safe care for the patient". If the consultant considers that an emergency NHS prescription is required it is important that they contact the GP to share this information and to gain the agreement of the GP. Patients should be informed that unless it is an emergency prescription requests would be subject to the usual delay for routine prescription requests as specified by the practice.

For a specific condition, where a private consultant recommends a medication that is more expensive without good evidence that it is more effective than that recommended by the NHS, health board prescribing advice should be followed by the NHS GP. This advice should be explained to the patient, who will retain the option of purchasing the more expensive medicine via the private consultant.

4.2 For NHS patients

A GP may issue a private prescription for any item in circumstances where the medicine is not available on the NHS. These circumstances are where:

- The item is listed in Schedule 1 of the National Health Service (General Medical Services Contracts) (Prescription of Drugs Etc.) (Wales) Regulations 2004 as amended (the so called "blacklist")⁹. This list of products may also be found in part XVIIIA of the NHS Drug Tariff.
- The item is listed in Schedule 2 of the National Health Service (General Medical Services Contracts) (Prescription of Drugs Etc.) (Wales) Regulations 2004 as amended (the so called "SLS list") and where its use is for persons or purposes other than those specified in the Schedule⁹.
- The product is a travel vaccine, e.g. Japanese encephalitis vaccine, yellow fever vaccine (if at a yellow fever vaccination centre) (see section 15.1).
- The product is being prescribed in connection with travel and is for an anticipated condition (e.g. antibiotics for travellers' diarrhoea or acetazolamide).

4.3 For a branded product

Where NHS policy recommends that a generic medicine is used and a patient requests the branded equivalent, a private prescription cannot be issued if the patient is being treated within the NHS, unless the product cannot be prescribed on the NHS as specified above in "the blacklist".

Whilst issuing an NHS prescription for patients who request a branded equivalent is not prohibited, practices should be aware that this could be considered an example of inappropriate or excessive prescribing as stated in the GMS contract¹⁰.

5.0 PRESCRIBING OF MEDICINES FOR AN UNLICENSED USE

The GMC defines 'unlicensed medicines' as medicines used outside the terms of their UK licence (sometimes referred to as 'Off Label' use⁶) or which have no licence for use in the UK¹¹. Although prescribing unlicensed medicines is not recommended, the GMC states that "you may prescribe unlicensed medicines where, on the basis of an assessment of the individual patient, you conclude, for medical reasons, that it is necessary to do so to meet the specific needs of the patient"¹¹.

The following extract is from the GMC 'Good practice in prescribing and managing medicines and devices' (2013)¹¹:

"When prescribing an unlicensed medicine you must:

- a. be satisfied that there is sufficient evidence or experience of using the medicine to demonstrate its safety and efficacy
- b. take responsibility for prescribing the medicine and for overseeing the patient's care, monitoring, and any follow up treatment, or ensure that arrangements are made for another suitable doctor to do so
- c. make a clear, accurate and legible record of all medicines prescribed and, where you are not following common practice, your reasons for prescribing an unlicensed medicine" ¹¹.

Points for consideration: (See GMC guidelines for full version¹¹)

Prescribing unlicensed medicines may be necessary where:

- a. There is no suitably licensed medicine that will meet the patient's need
- b. A suitably licensed medicine is not available
- c. The prescribing forms part of a properly approved research project¹¹.

Information for patients

- a) You must give patients (or their parents or carers) sufficient information about the medicines you propose to prescribe to allow them to make an informed decision.
- b) Some medicines are routinely used outside the terms of their licence, for example in treating children. In emergencies or where there is no realistic alternative treatment and such information is likely to cause distress, it may not be practical or necessary to draw attention to the licence. In other cases, where prescribing unlicensed medicines is supported by authoritative clinical guidance, it may be sufficient to describe in general terms why the medicine is not licensed for the proposed use or patient population. You must always answer questions from patients (or their parents or carers) about medicines fully and honestly.
- c) If you intend to prescribe unlicensed medicines where that is not routine or if there are suitably licensed alternatives available, you should explain this to the patient, and your reasons for doing so.
- d) You should be careful about using medical devices for purposes for which they were not intended¹¹.

Leaflet for unlicensed use of medications in children: www.medicinesforchildren.org.uk/search-for-a-leaflet/unlicensed-medicines/

Leaflet of use of unlicensed medication for pain:

www.britishpainsociety.org/static/uploads/resources/files/useofmeds_professional_final_pdf

6.0 PRESCRIBING OUTSIDE NATIONAL GUIDANCE

Whilst issuing a WP10 in circumstances which fall outside of the national/local 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 contract¹⁰.

National and local guidance will often clarify what prescribers should do for identified individuals, e.g. who to immunise against influenza. Prescribers may make a decision, on a case-by-case basis, to prescribe outside any national guidance or programme if there is a compelling clinical reason to do so.

If the case is made to immunise outside of the national programme, this is a GMS service. GPs should not offer their registered patients a private service.

7.0 PRESCRIBING DURATION

A 28-day repeat prescribing interval is broadly recommended; however, discretion should be used for individual patients or medicines. This should be coupled with a rigorous and effective medication review process¹².

People that are stabilised on their medicines and are suitable for longer prescribing intervals can be considered for repeat dispensing (28-day prescriptions for 6–12 months)¹².

8.0 PRESCRIBING OF BORDERLINE FOODS AND DIETARY PRODUCTS

In certain conditions some foods (and toilet preparations) have characteristics of drugs and the Advisory Committee on Borderline Substances (ACBS) advises as to the circumstances in which such substances may be regarded as drugs¹³.

Prescribing of borderline foods and dietary products should comply with the recommendations of the ACBS: ACBS recommends products on the basis that they may be regarded as drugs for the treatment of specified conditions. Prescribers should satisfy themselves that the products can be safely prescribed, that patients are adequately monitored and that, where necessary, expert hospital supervision is available¹³.

A complete list of products can be found in the British National Formulary (BNF)¹⁴ or Part XV of the NHS Drug Tariff¹³. Most of the conditions for which they can be prescribed fall into the following categories:

- dysphagia
- gastrectomy
- inflammatory bowel disease
- liver disease
- malabsorption states
- malnutrition (disease-related)
- metabolic disorders
- renal failure
- specific skin disorders

There are several areas where prescriptions for dietary products do not comply with the above recommendations, and the responsibility lies with individual GPs who may use their judgement to make exceptions to the above recommendations. This may occur following recommendations from a dietician, or for a medical condition requiring nutritional support for a defined period of time. An example of the latter would be a patient having had maxillofacial surgery, being discharged from hospital with a wired jaw and requiring nutritional support for six to eight weeks post-operation. Such a patient would be unlikely to receive adequate nutrition from a manageable volume of liquidised foodstuffs.

GPs are strongly advised against prescribing dietary products for patients (including in nursing or residential homes) outside the uses listed in this section, and using them as an alternative to liquidising/purchasing appropriate food.

AWMSG has resources to support <u>Prescribing Gluten-free Products</u> and the Prescribing and Supply of Sip Feeds.

9.0 COMPLEMENTARY MEDICINE AND ALTERNATIVE THERAPIES

Complementary and alternative therapies include, but are not limited to:

- acupuncture
- Alexander technique
- aromatherapy
- herbal medicine
- homoeopathy
- hypnosis
- massage
- nutritional therapy
- reflexology

Public Health Wales guidance on interventions not normally undertaken states:

'Complementary medicines/alternative therapies are generally NOT used by the NHS. They are occasionally used as a treatment as part of a mainstream service care plan (e.g. as part of an integrated multidisciplinary approach to symptom control by a hospital based pain management team) and as such will be used as part of an existing contract. On existing available evidence the LHB will not support referral outside of the NHS for these services. Prior approval is required on a case by case basis for any requests outside the above criteria. The request for referral would need to be supported by evidence of the clinical effectiveness of the treatment and be to appropriately trained and qualified practitioners with recognised qualifications.'15

'The evidence suggests that there are large numbers of complementary and alternative therapies that have not been subject to the trials used to establish the effectiveness of conventional clinical treatments. The evidence base is developing and up-to-date evidence on complementary therapies and alternative treatments can be obtained from the Cochrane library and specialist evidence of the NHS library.' 15–17

(Please note physiotherapists can decide to use alternative therapies as part of their treatment plan if they consider it appropriate.)

10.0 COMMON AILMENTS

From 1 April 2007, prescription charges for drugs and appliances no longer applied in Wales. However, the Minister for Health and Social Services, Welsh Government, advised:

"While [free prescriptions] will benefit everyone who currently pays for prescriptions in Wales, it should particularly benefit those people on modest incomes or who have chronic illnesses who may not have previously been eligible for free prescriptions under the complicated exemption system.

"This is the simplest and most effective way of resolving health inequalities and those inconsistencies in prescribing. The move removes all the unfairness surrounding the present outdated 1968 exemption system where, for example, a diabetes patient automatically gets all prescriptions free but a cystic fibrosis sufferer doesn't.

"It must be stressed though that the free prescription policy aims to provide medication for free that is only available with a prescription. Where patients already buy non-prescription medication over the counter they should continue to do so in the normal way. If patients change their behaviour radically this could have a detrimental impact on the NHS as a whole and indirectly on those patients who are in most need of the free prescriptions." ¹⁸

The GMC advises that prescribers "should prescribe medicines only if you have adequate knowledge of the patient's health and you are satisfied that they serve the patient's needs"¹⁹. Declining patient requests from the outset may deter patients from making similar future demands (e.g. requests for simple analgesia or for antibiotics for viral infections).

The <u>AWMSG Choose Pharmacy Formulary</u> offers advice on a defined list of common ailments.

11.0 FERTILITY TREATMENT

The latest policy in Wales for <u>Specialist Fertility Services</u> was issued by the Welsh Health Specialised Services Committee (WHSSC) in October 2015 and applies to residents of all seven health boards in Wales²⁰. The document sets out the circumstances under which patients will be able to access specialist fertility services, clarifies the referral process, and defines the criteria that patients must meet in order to access treatment. The document also includes a generic referral form.

The criteria for treatment in this policy are as follows:

Female age

Criteria – Women who are aged less than 40 years and who meet the access criteria are entitled to two cycles of in vitro fertilisation (IVF) with or without intra-cytoplasmic sperm injection (ICSI). However, if the woman reaches the age of 40 during the first cycle of treatment they will not be entitled to a second cycle of IVF.

Women aged between 40 and 42 years who meet the access criteria are entitled to one cycle of IVF with or without ICSI provided the following three criteria are also fulfilled:

- They have never previously had IVF treatment.
- There is no evidence of low ovarian reserve.
- There has been a discussion of the additional implications of IVF and pregnancy at this age.

Existing children

Criteria – IVF on the NHS is available for couples who do not have any living children (biological or adopted) or where one of the partners does not have any living children (biological or adopted). For single women/men – that the woman/man does not have any living children (biological or adopted).

Body mass

Criteria – The couple/single woman/single man must have a body mass index of between at least 19 and up to and including 30. Patients outside this range will not be added to the waiting list and should be referred back to their referring clinician and/or general practitioner for management where required.

Sterilisation

Criteria – Subfertility is not the result of a sterilisation procedure in either partner/single woman/single man (this does not include conditions where sterilisation occurs as a result of another medical problem). Couples/single women/single men who have undertaken a reversal should not be referred for treatment.

Smoking

Criteria – Where either of the couple/single woman/single man smokes the patient is not eligible. Only patients who agree to take part in a supported programme of smoking cessation will be accepted on the IVF treatment waiting list and must be non-smoking at time of treatment.

History of previous treatment

Criteria – For single patients, three or more IVF cycles by the patient will exclude any further NHS IVF treatment. For couples, three or more IVF cycles by either partner will exclude any further NHS IVF treatment. Previous cycles whether NHS or privately funded will be taken into account.

Subfertility

Criteria – Subfertility must be demonstrated before there can be access to NHS funded IVF treatment. Subfertility for heterosexual couples is defined as inability to conceive after 2 years unprotected intercourse or a fertility problem demonstrated at investigation. Subfertility for same sex couples/single women/single men is defined as no live birth following insemination at or just prior to the known time of ovulation on at least six non-stimulated cycles or a fertility problem demonstrated at investigation.

For same sex couples/single women/single men, the non-stimulated cycles may be achieved through a private arrangement or through NHS-provided IUI with donor sperm. Intra-uterine insemination (IUI) is not funded by WHSSC. Funding for IUI is the responsibility of the health boards. Where donor sperm is needed to undertake IUI, the donated sperm will be funded by WHSSC, but not the IUI procedure.

In women aged 40–42 years there is also no evidence of low ovarian reserve.

HFEA

Criteria – Patients not conforming to the Human Fertilisation and Embryology Authority (HFEA) Code of Practice will be excluded from having access to NHS funded assisted fertility treatment.

Change of Partner whilst waiting for IVF treatment

Criteria – If a couple consent to treatment but during the waiting period for treatment the couple break up then treatment cannot commence. If one or both of the partners wish to proceed with treatment with either a new partner or by themselves then the clinic that is providing the treatment needs to be notified. The new couple/individual will need to attend a consultation where the fertility history of the couple/individual needs to be reviewed, treatment options explained and discussed and if the couple/individual still meet the eligibility criteria consent to proceed with treatment.

IVF for veterans

Criteria – Armed Forces Personnel who have become infertile as a result of military action and are Armed Forces Compensation Scheme (AFCS) recipients are entitled to three full cycles of IVF treatment. All applications for this should be forwarded to Welsh Health Specialised Services via the All Wales IPFR process for consideration in line with guidance from the Independent Medical Expert Group. [This will be subject to the outcome of the IPFR consultation process.]

11.1 Prescribing information

There are three providers of specialist fertility services for Welsh patients. These are:

- Liverpool Women's NHS Foundation Trust
- Shropshire and Mid Wales Fertility Centre at Shrewsbury Hospital
- Wales Fertility Institute at Neath Port Talbot Hospital and Wales Fertility Institute at University Hospital Wales, Cardiff

It is not expected that GPs will prescribe treatments for these specialist fertility centres.

12.0 MEDICINES FOR THE TREATMENT OF ERECTILE DYSFUNCTION

12.1 Treatment of erectile dysfunction

The information in this section relates to the prescribing of medicines for the treatment of erectile dysfunction in Wales. The regulations governing the NHS prescribing of these and other medicines differ between Wales and England. The relevant regulations in Wales are the National Health Service (General Medical Services Contracts) (Prescription of Drugs Etc.) (Wales) Regulations 2004 as amended, Schedule 2 of which lists a number of medicines, which can be used only in specified circumstances. Schedule 2 of the regulations is reproduced in Part XVIIIB of the NHS Drug Tariff.

Alprostadil, sildenafil, tadalafil or vardenafil can be prescribed for the treatment of erectile dysfunction on NHS prescription in the following circumstances:

- A man who is suffering from any of the following:
 - diabetes
 - multiple sclerosis
 - Parkinson's disease
 - poliomyelitis
 - prostate cancer
 - severe pelvic injury
 - single-gene neurological disease
 - spina bifida
 - spinal cord injury
- A man who is receiving treatment for renal failure by dialysis.
- A man who has had the following surgery:
 - prostatectomy
 - radical pelvic surgery
 - renal failure treated by transplant.
- A man who has been diagnosed as suffering severe distress resulting from erectile dysfunction where the assessment has been made by a specialist service or GP under arrangements made with a health board to provide such assessments.

Prescriptions must be endorsed 'SLS' (generic sildenafil should continue to be endorsed 'SLS' in Wales).

For full advice on preparations available for patients with erectile dysfunction and restrictions see the 'In Wales' section in Part XVIIIB of the NHS Drug Tariff.

Additionally, men receiving a course of NHS drug treatment for erectile dysfunction on 14 September 1998 will continue to be eligible to receive treatment from their GP²¹.

Prescribing guidance relating to men whose impotence is causing severe distress has been updated in Wales, with AWMSG making the following recommendations^{22,23}:

- For patients who have been assessed as suffering from severe distress as a result of erectile dysfunction, guidance is amended to remove the restriction of specialist service supply, enabling GPs to prescribe the medication [for this indication].
- The assessment of severe distress resulting from erectile dysfunction may be undertaken by GPs or specialist teams. All health boards should have clearly defined commissioning arrangements for this assessment. A commissioned, specialist-led service will support equality of access to therapy and minimise conflict in the doctor–patient relationship.
- Once-daily preparations should only be considered in patients who anticipate frequent use of single-dose preparations (i.e. at least twice-weekly). This should be based on the clinician's judgement²² [and in accordance with local formulary advice].

The following criteria should be considered when assessing severe distress:

- Significant disruption to normal social and occupational activities:
- A marked effect on mood, behaviour, social and environmental awareness;
- A marked effect on interpersonal relationships²².

It should be noted that any patient who does not adhere to a category may have the treatment prescribed privately²².

The frequency of treatment will need to be considered on a case-by-case basis, but

prescribers may find it helpful to bear in mind that the average frequency of sexual intercourse in the 40–60 years of age range has been estimated as once a week. Prescribers may also wish to bear in mind that some treatments for impotence have been found to have a 'street value' for men who consider, rightly or wrongly, that these treatments will enhance their sexual performance. Excessive prescribing could therefore lead to unlicensed, unauthorised and possibly dangerous use of these treatments²¹.

The National Assembly for Wales advised prescribers that one treatment a week is appropriate for most patients treated for erectile dysfunction²¹. If the GP, in exercising clinical judgement, considers that more than one treatment a week is appropriate, they should prescribe that amount on the NHS²¹; the GP should not write a private prescription.

12.2 Use in management of other clinical conditions

Where a medicine has a UK or EU marketing authorisation both for the treatment of erectile dysfunction and for the treatment of another clinical condition, the medicine may only be prescribed for the treatment of erectile dysfunction in the circumstances described in 12.1. However, it may be prescribed to any patient for the treatment of any other clinical condition provided the product's UK or EU marketing authorisation is also for that use.

Prescriptions must be endorsed 'SLS'.

13.0 PRESCRIBING FOR ONESELF OR FAMILY

The GMC states that 'wherever possible you must avoid prescribing for yourself or anyone with whom you have a close personal relationship'24. Ideally, doctors, family and staff from a practice should be registered with, and treated by, another practice. This gives the doctor and their family members access to objective advice and avoids the conflicts of interest that can arise when doctors treat themselves or those close to them.

The following guidance applies to all prescribers, not just GPs.

The GMC states:

- Controlled medicines present particular dangers, occasionally associated with drug misuse, addiction and misconduct. You must not prescribe a controlled medicine for yourself or someone close to you unless:
 - no other person with the legal right to prescribe is available to assess and prescribe without a delay which would put your, or the patient's, life or health at risk or cause unacceptable pain or distress, and
 - the treatment is immediately necessary to:
 - save a life
 - avoid serious deterioration in health, or
 - alleviate otherwise uncontrollable pain or distress.
- If you prescribe for yourself, or someone close to you, you must:
 - make a clear record at the same time or as soon as possible afterwards.
 The record should include your relationship to the patient (where relevant) and the reason it was necessary for you to prescribe.
 - tell your own or the patient's general practitioner (and others treating you or the patient, where relevant) what medicines you have prescribed and any other information necessary for continuing care, unless (in the case of prescribing for somebody close to you) they object²⁴.

14.0 VISITORS FROM OVERSEAS

Overseas visitors who are entitled to NHS treatment in primary care include, but are not limited to:

- A person intending to be resident in this country for six months or more (registration with a practice is necessary).
- Patients from within the European Economic Area in possession of a European Health Insurance Card (EHIC).
- Patients who require immediate, essential treatment, which the treating doctor deems cannot reasonably be delayed until the patient returns home (EHIC not required).
- Patients holding an S2 form (previously an E112) for specific treatment of a particular condition (and prescriptions for this condition only).
- Patients allocated by the health board.
- 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 contains the most common categories, but prescribers should check an individual's situation before providing or declining NHS care as special conditions may apply.

Patients who do not fall into these categories may be offered and charged for private care, including the provision of private prescriptions where necessary. Further advice for GPs on overseas visitors accessing NHS primary medical services is available from the GPC²⁵.

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

Further information is available from the <u>Overseas Visitors section</u> of the Health in Wales website²⁶.

15.0 TRAVEL ABROAD

Under NHS legislation, the NHS ceases to have responsibility for people when they leave the UK. However, to ensure good patient care, the following guidance is offered.

People travelling within Europe should be advised to carry the European Health Insurance Card (EHIC) at all times; this gives entitlement to local healthcare arrangements²⁷. Patients are advised to check specific entitlements and appropriate health advice prior to travel and obtain adequate travel insurance cover²⁸.

Guidance for GPs on risk assessment for travellers and appropriate advice is available from the <u>National Travel Health and Network Centre</u> (NaTHNaC) and <u>TRAVAX</u> websites^{27,29}.

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. If the patient is returning within the timescale of a normal prescription (usually one and no more than three months) then this should be issued, providing it is clinically appropriate. Patients carrying certain prescribed medication for their own personal use may require a doctor's letter or a personal licence²⁷. This will depend on the duration of travel, the type of medicine (e.g. codeine, Sativex®) and the country of travel. More information on the carrying of prescribed controlled drugs abroad for personal use is covered in section 15.3. Patients who require over-the-counter (OTC) medicines should check that the medicine is available OTC in the country of destination³⁰.

For longer visits abroad (e.g. more than three months), the patient should be advised to register with a local doctor in the destination country for continuing medication; this may need to be paid for by the patient. It is wise for the patient to check with the manufacturer that medicines required are available in the country being visited.

GPs are not required to provide prescriptions for medication that is requested solely in anticipation of the onset of an ailment whilst outside the UK, but for which treatment is not required at the time of prescribing (e.g. travel sickness, diarrhoea). Patients should be advised to purchase these items in the UK prior to travel; advice is available from community pharmacists if required. A private prescription may be provided for any prescription-only medicines if deemed appropriate and necessary, such as ciprofloxacin for traveller's diarrhoea (for use outside Asia). Patients should be advised about the appropriate use of self medication and when they would need to seek medical attention abroad.

Travellers should consider carrying a personal emergency medical travel kit tailored to their needs and their travel destination (advice on what to include is available from the NaTHNaC and TRAVAX websites). There are occasions where the traveller may wish to include prescription-only medicine (POM) items and/or plasma substitutes in their personal emergency medical travel kit. A private prescription is required for the former.

15.1 Immunisation for travel abroad

Immunisation against infectious disease (The Green Book)³¹ gives clinical recommendations for the use of vaccines, but does not identify those that are recommended to be NHS funded (see Appendix 1 for further information on NHS versus private supply options). Where no remuneration is available, either via the GMS contract or a local enhanced service for individual vaccines, NHS prescribing is generally discouraged in line with the intent of regulations, which enable GPs to charge their own patients for immunisations requested in connection with travel abroad.

Immunisations that are available for reimbursement under the new GMS contract must be provided free of charge to patients who require them³². Travel vaccines that are available via the NHS for which reimbursement is received include (see <u>BMA</u> for further information):

- Hepatitis A first and second/booster dose (6–12 months after first dose)
- Combined hepatitis A and B all doses
- Typhoid first and any booster doses
- Combined hepatitis A and typhoid first dose (second dose is with Hepatitis A alone)
- Tetanus, diphtheria and polio as given in the combined Td/IPV vaccine
- Cholera³²

A number of other travel-related vaccines, including hepatitis B and meningococcal A, C, W135 and Y vaccine, are not remunerated by the NHS as part of additional services, although the vaccine costs may be reimbursable. The regulations do not impose any circumstances or conditions as to when these immunisations should be given on the NHS or as a private service³². GPC guidance states that:

"This causes confusion, and the ambiguity stems from the regulations regarding the charging of patients that are registered with the practice. Schedule 5 of The National Health Service (General Medical Services Contracts) Regulations 2004 states that: 'The contractor may demand or accept a fee or other remuneration for treatment consisting of an immunisation for which no remuneration is payable by the [Local Health Board] and which is requested in connection with travel abroad'

This wording leaves the decision as to whether the practice levies a charge or not to the discretion of the practice, rather than the [health board]."33

In the case of hepatitis B vaccination, which is also available as a combination product, the practice may charge any patient a private fee for hepatitis B for travel, as long as it is not combined with hepatitis A, which must be given on the NHS³³. For more information on hepatitis B vaccination, see section 16.1.

The following travel immunisations are not generally prescribed as part of an NHS service nor are they remunerated by the NHS if given for pre-exposure to travel:

- Japanese encephalitis
- rabies
- tick-borne encephalitis
- yellow fever³²

Practices may charge for both the prescription and the administration of these vaccines at their discretion³⁴.

Newer vaccines should normally be provided at NHS expense only if they are demonstrated to be of improved efficacy or when there is other compelling clinical advantage. Advice will be issued as new products arise.

No charge should be made to any NHS patient of the practice for providing advice.

15.2 Malaria chemoprophylaxis

Malaria chemoprophylaxis should not be provided on the NHS³⁴. A GP may provide medicines for malaria chemoprophylaxis via a private service and charge the patient for prescription and/or the supply of medication (pharmacy ['P'] medicines and POMs).

Patients can purchase some 'P' medicines for malaria chemoprophylaxis directly from the community pharmacy. Local community pharmacists also have access to up-to-date advice regarding appropriate prophylactic regimes and can advise travellers accordingly.

There is no NHS Regulation that prevents a GP prescribing drugs for the prevention of malaria at NHS expense. However, Welsh Office guidance in 1995 encouraged general practitioners to prescribe privately^{35,36}.

Patients should be advised to purchase sufficient prophylactic medicines to cover the period of their travel within an endemic area. Patients are advised to commence treatment one week before departure and continue treatment for four weeks after leaving the endemic area¹⁴. Exceptions are:

• mefloquine (Lariam[®]), for which prophylaxis should be started 2–3 weeks before

- mefloquine (Lariam[®]), for which prophylaxis should be started 2–3 weeks before travel to the endemic area so that if adverse events occur there will be time to switch to an alternative^{14,37},
- proguanil/atovaquone (Malarone[®]), for which prophylaxis should be started 1–2 days before travel to the endemic area and stopped one week after returning from the endemic area³⁸,
- doxycycline, for which prophylaxis should be started 1–2 days before travel to the endemic area³⁹.

The importance of mosquito nets, suitable clothing and insect repellents to protect against being bitten should be stressed. Travellers should be directed to the Public Health England document: *Guidelines for malaria prevention in travellers from the United Kingdom* 2014³⁷.

Remember the four steps to prevent suffering from malaria in UK travellers:

- Awareness: know about the risk of malaria.
- Bites by mosquitoes: prevent or avoid.
- Compliance with appropriate chemoprophylaxis.
- Diagnose breakthrough malaria swiftly and obtain treatment promptly.

15.3 Controlled drugs: implications for patients

Department of Health guidance recommends that, in general, prescriptions for controlled drugs in Schedules 2, 3 and 4 should be limited to a supply of up to 30 days treatment. Exceptionally (to cover a justifiable clinical need and after consideration of any risk) a prescription can be issued for a longer period, but the reasons for the decision should be recorded in the patient's notes¹⁴.

Patients who are travelling for less than 3 months and carrying less than 3 months' supply of prescribed controlled drugs listed under Schedules 2, 3, 4 Part I and 4 Part II to The Misuse of Drugs Regulations 2001, will not need a personal import or export licence to enter or leave the United Kingdom⁴⁰. They should carry a letter from the prescribing doctor with the carrier's name, travel itinerary, names of prescribed controlled drugs, dosages and total amounts of each to be carried⁴⁰.

Additionally, it is always advisable to contact the Embassy, Consulate or High Commission of the country to be visited regarding their policy on the import of controlled drugs, as the legal status of controlled drugs varies between countries.

Controlled drugs should be:

- carried in original packaging;
- carried in hand luggage (airline regulations permitting);
- carried with a valid personal import/export licence (if necessary; see below).

Persons travelling abroad (or visitors travelling to the UK) in excess of three months and carrying controlled drugs, or carrying more than three months' supply of controlled drugs, will require a personal export or import licence⁴⁰. A personal licence has no legal standing outside the UK and is intended to assist travellers passing through UK customs controls with their prescribed controlled drugs. Travellers are advised to contact the Embassy, Consulate or High Commission of the country of destination (or any country through which they may be travelling) regarding the legal status and local policy on the importation of controlled drugs⁴¹.

16.0 VACCINES FOR OCCUPATIONAL HEALTH PURPOSES

The provision of vaccines for occupational health reasons is the responsibility of the employer and not the patient's GP (unless private contractual arrangements have been made between the practice and the employer). The employer (not the patient) will have to make private arrangements for administration of the vaccine(s). This may be with a GP practice or an occupational health provider.

16.1 Hepatitis B vaccine

Occupation – Hepatitis B vaccinations for occupations as listed in the Green Book³¹ and BNF¹⁴ should normally be provided by the employer via their own occupational health provider or via private agreement with a practice. Categories are:

- NHS General Dental Practice employees*
- Primary care employees[†]
- Other occupational groups considered at risk[‡]. These include:
 - NHS Trust, private and charity health workers,
 - nursing home and old peoples' home staff,
 - prison staff, police, ambulance officers, morticians and embalmers.

Special consideration may need to be given to a patient who is at risk where the employer refuses to provide the intervention, or no occupational health service is available.

There are occasions where the vaccine is for occupational health reasons and the patient is from a group of patients identified as 'at risk'; it is then the responsibility of the GP to provide the vaccine if necessary and appropriate. See 'At risk' patients below.

Students – Prospective and current students of healthcare (e.g. medical, nursing, dental students) should be vaccinated by their educational organisation³³ and not in general practice, as, practically, the provision of vaccination might include prior blood screening to assess immunity status, and guidance from an appropriate specialist on whether vaccination is necessary. Students will also receive specific advice on how to avoid blood-borne infections, needle-stick injuries etc. If hepatitis B vaccination is given in general practice, it could deprive the students of the necessary and important occupational health induction they will get at their educational organisation prior to their hepatitis B immunisation. This will also include advice on hepatitis C, HIV etc.

'At risk' patients – Where the patient is identified as being 'at risk', it is the responsibility of the GP to provide the vaccine if necessary and appropriate. The GP should use either WP10 for supply through community pharmacy or personally administered item (WP34) to reclaim vaccine cost. There is no item of service fee. Examples of patients 'at risk' are provided in the BNF¹⁴ and Green Book³¹ and include:

- parenteral drug users,
- patients with multiple sexual partners,
- close family contact of a case or carrier especially infants.
- people with learning disabilities living in residential care,
- patients and carers of patients receiving frequent blood transfusions,
- foster carers of children at increased risk.

Travel – If a patient requests hepatitis B immunisation for travel abroad to areas of high prevalence and may be at risk, this should normally be a private service to patient, but for patients 'at risk', hepatitis B immunisation may be given if appropriate. Patient may be charged a fee to include cost of drug (plus VAT and on cost), dispensing fee and service provision. There is no item of service fee.

NHS General Dental Practice employees – Funding has been made available by the Welsh Government to reimburse the costs for the vaccination course for healthcare workers who may be at risk. Some areas may have NHS occupational health departments to assist making the vaccination available. Alternatively, where a dental employee is considered at risk following a risk assessment by their employer, a request for the vaccination should be given to the employee for the GP practice. A fee may be charged by the practice and the dental practice may claim the fee on presentation of a receipt to the health board.

[†]**Primary care employees** – Where a primary care employee is considered at risk following a risk assessment by their employer, a request for the vaccination should be given to the employee for the GP practice. The immunisation is free to the patient; the practice is asked to bear the service cost. A WP10 or WP34 can be used.

[‡]Other occupational groups considered at risk – The patient should not be charged. The employer can be charged to include the cost of the drug (plus VAT and on cost), dispensing fee and service fee.

Guidance on the provision of hepatitis B vaccinations is open to interpretation. NHS Choices states "GPs are not obliged to provide the hepatitis B vaccine on the NHS if you're not thought to be at risk. GPs may charge for the vaccine if you want it as a travel vaccine, or they may refer you to a travel clinic so you can get vaccinated privately"⁴². To date, there is no definitive advice on the use of the hepatitis B vaccine for occupational health or travel purposes as part of the service provided by NHS under the GMS, and the decision as to whether or not an NHS prescription for the hepatitis B vaccine is appropriate should be made on an individual patient basis, taking into account their clinical and occupational situation, and may depend on the views of the medical practitioner involved.

For further advice contact your local occupational health or public health teams.

APPENDIX 1: TRAVEL RELATED VACCINES AND OPTIONS FOR PRIVATE OR NHS SUPPLY THROUGH GENERAL PRACTICE

Vaccine	Private	NHS		
		WP34	WP10	Comments
Cholera	*	*	√	The vaccine is not indicated for most travellers, but may be appropriate for those who are unable to take adequate precautions in highly endemic or epidemic settings. This would include aid workers assisting in disaster relief or refugee camps, and more adventurous backpackers who do not have access to medical care ⁴³ .
Hepatitis A	×	✓	✓	All doses provided on the NHS. Refer to the Green Book ³¹ for guidance.
Hepatitis B	✓	✓	✓	Private prescription for travellers, pre exposure, and for occupational health purposes, unless they are in an at risk category as documented in the Green Book ³¹ . Check local policy.
Hepatitis A and B (combined)	×	✓	✓	All doses for the complete course are provided on the NHS. Regions of risk for hepatitis A apply.
Hepatitis A and typhoid (combined)	×	✓	~	All doses provided on the NHS. Refer to the Green Book ³¹ for guidance.
Japanese B encephalitis	✓	×	✓	Only one vaccine is licensed for UK use: Ixiaro® (Novartis Vaccines).
Meningococcal A, C, W135 and Y	✓	✓	~	Not routinely available on the NHS for overseas travel.
Rabies	1	×	√	Pre-exposure immunisation is recommended for some travellers. For occupational risk and bat handlers, the vaccine is obtained from the Department of Health. For more details of this, and post-exposure information see the Green Book ³¹ .
Tetanus, diphtheria and polio	×	×	✓	This vaccine (Revaxis®) is supplied centrally for the childhood vaccination programme but central stocks should not be used for adults.
Tick-borne encephalitis (TBE)*	✓	×	✓	TBE vaccine is used for the protection of individuals at high risk of exposure to the virus through travel or employment.
Typhoid	×	✓	✓	Refer to the Green Book ³¹ for guidance.
Yellow fever	1	×	×	Only available at designated centres. A listing of approved yellow fever vaccination centres in Wales may be found at: http://nathnacyfzone.org.uk/search-centres .

Electronic multi-vaccine claims

GP practices who submit monthly claims for administering multiple-dose vaccines are now able to do so electronically via the <u>Primary Care Services intranet site</u>. WP10 forms should not be submitted to Prescription Pricing Services in GP accounts for vaccines allowed via the WP34 claim form route.

NB GPs may prescribe privately and charge their registered patients for vaccine only if use is in association with pre-exposure related to travel abroad.

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