Surrey Heartlands

MEDICINES MANAGEMENT GUIDE TO PRESCRIBING

Section 4 – Prescribing situations and issues (Clinical)

Contents

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4.1 INFERTILITY TREATMENT

IVF and other similar assisted conception methods are specialist services and access will normally be on the recommendation of a local NHS Consultant Gynaecologist and on some occasions from local NHS Consultant Urologist.

It is not considered appropriate that such treatment should be undertaken in primary care and alternative funded arrangements are in place.

Drug treatments are included in the cost of the package and will not be funded as separate elements by Primary Care clinicians.

The advice is not to prescribe fertility drugs, not only due to clinical concerns but also to prevent inequalities across ICBs. This also applies to patients wishing to change from private to NHS status.

It is important to note that it is not normally considered appropriate for patients to move repeatedly between the care of an NHS specialist and private sector provider for the clinical management of the same condition.

For further information refer to the Surrey Heartlands CLIN 5 Assisted Conception Policy (including Operating Procedures for managing Assisted Conception applications**)** which is available of the Surrey Heartlands website https://www.surreyheartlands.org/policies-and-processes

Further information can be found on the NICE website: www.nice.org.uk/guidance/cg156

4.2 PRESCRIBING DIAZEPAM FOR FLIGHT ANXIETY

Patients may attend their GP requesting that they prescribe diazepam for fear of flying or to assist with sleep during flights. Many GP practices have a policy that they do not prescribe any sedatives/hypnotics for these conditions and your practice may consider that this is the right option.

The BNF notes that

- The use of benzodiazepines to treat short-term ‘mild’ anxiety is inappropriate
- Benzodiazepines should be used to treat insomnia only when it is severe, disabling, or causing the patient extreme distress.

An NHS prescription should not be provided for medication which 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. It is therefore recommended that an NHS prescription is **NOT PROVIDED** for fear of flying, however in extreme circumstances a prescription may be considered where clinically appropriate. If a GP practice does agree to prescribe diazepam, they should document that a full risk assessment has been undertaken.

The GMC have guidance on handling patient requests for medicine you don’t think will benefit them and state that “If, after discussion, you still think the treatment or care would

not serve the patient's needs, you should not provide it. You should explain your reasons to the patient and explore other options that might be available, including their right to seek a second opinion". https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/good-practice-in-prescribing-and-managing-medicines-and-devices/deciding-if-it-is-safe-to-prescribe

When having discussions with patients it is important to note that the following apply to **both NHS and Private prescriptions**

- Sedative-hypnotics (e.g. diazepam) should not be combined with alcohol (which is commonly consumed by nervous flyers) because there is a risk of excessive sedation and respiratory suppression.
- Sedative-hypnotics (e.g. diazepam) should not be taken by individuals who may be called upon to make important decisions (e.g. parents responsible for the care of young children or in case of an in-flight emergency) because they can cause excess sedation and impair decision-making.
- Benzodiazepines (e.g. diazepam) may cause drowsiness, impair concentration and impair decision making which may impair a person's ability to drive when they reach their destination.
- The risk of adverse effects is increased in older adults, especially those who are older than 75 years
- Some countries may not allow the entry of certain types of medicines, and others may have regulations requiring specific permission for a medication to be brought in – for further information see the NaTHNac Travel Pro Website https://travelhealthpro.org.uk/factsheet/43/medicines-and-travel

There are a number of courses available to address fear of flying run by the airline companies that you may wish to direct patients towards. Air Travel - Fit for Travel

4.3 CLINICAL TRIALS / RESEARCH

All trials of medicines within Surrey Heartlands ICB should have gained Research Ethics approval and meet research governance criteria where appropriate.

Since the 31st March 2016, studies led from England and involving the NHS in England, should now use the NHS Health Research Authority (HRA) approval process.

HRA Approval brings together the HRA's assessment of governance and legal compliance with the independent ethical opinion by a Research Ethics Committee (REC). HRA Approval is for all project based research involving the NHS and Health and Social Care (HSC) that is being led from England

See more at: https://www.hra.nhs.uk/approvals-amendments/what-approvals-do-i-need/

Website (homepage): http://www.hra.nhs.uk/

4.4 PRESCRIBING OF BORDERLINE SUBSTANCES

In certain conditions some foods and toilet preparations have characteristics of drugs.

The Advisory Committee on Borderline Substances (ACBS) advises as to the circumstances when such substances may be regarded as drugs and can be prescribed on the NHS.

When prescribed under these circumstances the prescription should be endorsed “ACBS”.

Doctors should satisfy themselves that the products can safely be prescribed, that patients are adequately monitored and that, where necessary, expert hospital supervision is available.

A list of these preparations and the specific conditions that they can be used to treat are listed in part XV of the Drug Tariff.

Although this is a non-mandatory list, Nurse and Pharmacist Independent Prescribers should normally restrict their prescribing of borderline substances to items on the ACBS approved list. They should also work within the guidance of their employing organisation.

Patients or care providers (including nursing or residential homes) should not use ACBS dietary products for convenience rather than liquidising or purchasing appropriate foods. The ICB will support any prescriber wishing to refuse prescriptions of dietary products for patients in this circumstance.

Borderline substances are mainly foodstuffs but also include some toiletries, such as sunscreens. These may only be prescribed for skin protection against UV radiation in abnormal cutaneous photosensitivity, and only preparations that meet ACBS criteria should be used.

4.4.1 Prescribing gluten-free foods

To achieve a balanced diet, it is essential that patients include naturally gluten free carbohydrates in their diet. These include rice, potatoes, corn (maize), soy, buckwheat, millet, lentils, quinoa and amaranth.

A wide variety of gluten-free (GF) products are now readily available in supermarkets. It has been acknowledged that due to the price differential between GF breads and flours and the equivalent standard non-GF products, that locally a restricted formulary of approved products would be maintained to aid patient adherence to a gluten free diet. The recommendations include a limit to the quantities to be prescribed of up to a maximum of eight items of bread or flour per patient, per month.

Since March 2011 Surrey Heartlands ICB and legacy organisations have recommended a restriction of gluten-free foods to ensure the cost effective use of NHS resources and the equity of the supply of these products.

The approved list of bread, flour and bread mix agreed for funding by Surrey Heartlands ICB is available on the PAD in the “Prescription Request for Gluten-Free Foods Form”. (A summary on the background to the original 2011 Surrey guidelines is also available via this link). Guidelines : Gluten free (res-systems.net)

4.5 DRUGS REQUIRING SELECTED LIST SCHEME "SLS" ENDORSEMENT

The Drug Tariff (DT) Part XVIIIB: Drugs medicines and other substances that may be ordered only in certain circumstances lists drugs that are only prescribable on the NHS for specific groups of patients with specific conditions. Prescriptions should be endorsed with the reference "SLS":

Drug Tariff: https://www.nhsbsa.nhs.uk/pharmacies-gp-practices-and-appliance-contractors/drug-tariff

Details of restricted availability appliances (vacuum pumps and constrictor rings for erectile dysfunction) can be found in Part IX of the Drug Tariff beside the listing for the relevant appliance.

The following is a list of the drugs in England (please refer to the DT for circumstances in which the SLS endorsement is valid):

<table>
<tr><td>Clobazam</td><td>Nizoral cream</td><td rowspan="3">The following drugs for the treatment of erectile dysfunction (ED)#:
Alprostadil (Caverject, MUSE, Viridal, Vitaros)
Avanafil (Spedra)
*Tadalafil (Cialis)
Vardenafil (Levitra)
Viagra</td></tr>
<tr><td>Locabiotal aerosol</td><td>Oseltamivir (Tamiflu)</td></tr>
<tr><td>Niferex elixir 30ml paediatric dropper bottle</td><td>Zanamivir (Relenza)</td></tr>
</table>

#Prescribing of drugs for ED due to severe distress is not covered by the SLS criteria in England for ED and therefore the SLS endorsement is not valid on FP10 forms. However, generic sildenafil is now no longer in the SLS list meaning that restrictions on its use are lifted. It no longer needs to be annotated SLS and can be prescribed by GPs on FP10 for any cause of ED including severe distress.

*****Tadalafil: there have been prescriptions for tadalafil (and previously for sildenafil generic licensed products for ED, which has now been removed from the above list), prescribed for pulmonary hypertension with an SLS endorsement. This is against the GP terms of service. GPs should contact the Medicines Optimisation Team if asked to prescribe these drugs for any indication other than erectile dysfunction.

4.6 DVLA : MEDICAL CONDITIONS, DISABILITIES AND DRIVING

Holders of a driving license should inform the Driver and Vehicle Licensing Agency (DVLA) of the following:

- If they develop a 'notifiable' medical condition or disability
- If a condition or disability has got worse since they obtained their licence

Notifiable conditions are anything that could affect the ability to drive safely. Patients can check if they need to tell the DVLA about their condition by viewing the A-Z listing on the website: https://www.gov.uk/health-conditions-and-driving. Alternatively the DVLA can be contacted directly:

DVLA drivers' medical enquiries: **Telephone**: 0300 790 6806

Postal Address: Drivers' Medical Enquiries, DVLA , Swansea , SA99 1TU

Email and Webchat services are also available

For additional information on contacting the DVLA please visit the website: https://www.gov.uk/contact-the-dvla/y/driving-and-medical-issues

Note: it is the duty of the licence holder or licence applicant to notify DVLA of any medical condition, which may affect safe driving. On occasions however, there are circumstances in which the licence holder cannot, or will not do so. The GMC has issued guidance applicable to such circumstances where a patient cannot, or will not notify the DVLA of a particular medical condition where DVLA guidance has stated that notification should occur: GMC Guidance: Confidentiality: patients' fitness to drive and reporting concerns to the DVLA or DVA https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/confidentiality---patients-fitness-to-drive-and-reporting-concerns-to-the-dvla-or-dva

4.7 PATIENT SPECIFIC DIRECTIONS (PSDs) AND PATIENT GROUP DIRECTIONS (PGDs)

4.7.1 Patient Specific Directions (PSDs)

A Patient Specific Direction is the traditional written instruction, signed by a prescriber for medicines to be supplied and/or administered to a named individual after the prescriber has assessed that individual on a one-to-one basis. As it is individually tailored to the needs of patients, it should be used in preference to a Patient Group Direction (PGD) wherever appropriate.

Examples of a PSD for a single named patient:

- The usual method for the supply and administration of vaccines in the routine childhood immunisation programme could be via a PSD. The authorisation for this is usually the responsibility of the GP or an independent nurse prescriber at the six to eight-week check and is recorded as an instruction in the Personal Child Health Record (PCHR or Red Book). This agreement allows immunisations to be given in GP surgeries or clinics.
- A prescriber (i.e. GP) could make an electronic written instruction for a patient to be administered a particular vaccine in a patient's medical record. This written instruction from the prescriber would constitute a PSD.

Example of a PSD for a group of named patients

A written and authorised instruction to administer a medicine to a list of individually named persons where each person on the list has been individually assessed by that prescriber. The prescriber must have adequate knowledge of each individual's health and be satisfied that the medicine to be administered serves the individual needs of each person on that list. An example would be a list of individuals to receive a seasonal influenza vaccine during a pre-booked vaccination clinic - a GP could print off a list of patients' names off the computer, write an instruction for them all to have a vaccination administered, then add the practice address, date and sign it.

The information required in a PSD for administration of a medicine at a minimum should:

- Name of the individual and/or other individual identifiers including age if a child
- Name, form and strength of medicine (generic or brand name where appropriate)
- Route of administration
- Dose
- Frequency
- Date of treatment/number of doses/frequency/date treatment ends as applicable.
- Signature of prescriber and date PSD written.

Where a PSD exists, there is no need for a PGD. For further information on Patient Specific Directions and the requirements for their writing and use see the SPS website https://www.sps.nhs.uk/articles/questions-about-patient-specific-directions-psd/

4.7.2 Patient Group Directions

A Patient Group Direction (PGD) is a written instruction for the supply or administration of a medicine where the patient may not be individually identified before presenting for treatment.

The supply and administration of medicines under PGDs should be reserved for the limited number of situations where this offers an advantage for patient care (without compromising patient safety). Careful consideration should be given to opportunities within the care pathway to use a prescription or a written Patient Specific Direction and also consider the use of exemptions

PGDs allow health care professionals specified within the legislation to supply and/or administer a medicine directly to a patient with an identified clinical condition without the need for a prescription or an instruction from a prescriber. The health care professional working within the PGD is responsible for assessing that the patient fits the criteria set out in the PGD.

The supply and/or administration of medicines under a PGD cannot be delegated – the whole episode of care must be undertaken by the health care practitioner operating under the PGD.

PGDs can only be used by the following registered healthcare professionals, as named individuals:

• nurses	• optometrists	• chiropodists/podiatrists
• midwives	• radiographers	• Dental hygienists/therapists
• pharmacists	• orthoptists	• dieticians
• paramedics	• physiotherapists	• occupational therapists
• prosthetists	• orthotists	• speech and language therapists

PGDs are legal documents and must follow the guidance set out in HSC 2000/026 and the good practice recommendations included within NICE MPG2 Patient Group Directions. This includes the requirements that:

- The PGD must be signed by a senior doctor and a senior pharmacist, both of whom should have been involved in developing the direction
- The PGD must be authorised by the commissioner (ICB / NHS England)
- PGDs should be drawn up and signed by a multi-disciplinary group involving a doctor, a pharmacist and a representative of any professional group expected to supply medicines under the PGD

- A senior person in each profession should be designated with the responsibility to ensure that only fully competent, qualified and trained professionals operate within directions
- All professions must act within their appropriate Code of Professional Conduct

A PGD can include a flexible dose range so the healthcare professional can select the most appropriate dose for the patient.

Medicines can be used outside the terms of their Summary of Product Characteristics (SPC) so called 'off-license/off-label' use, provided such use is supported by best clinical practice. The PGD should state when the product is being used outside the terms of the SPC and why this is necessary. However, unlicensed products which do not have a marketing authorisation in the UK, cannot be authorised under a PGD.

Black triangle (▼) vaccines used in immunisation programmes may be included in PGDs, providing they are used in accordance with the recommendations of the Joint Committee on Vaccination and Immunisation (JCVI). The PGD should state that a black triangle medicine is being included.

Information which must be included in a PGD is subject to legislation The Human Medicines Regulations 2012 (legislation.gov.uk) which specifies that each PGD must contain the following information:

- the name of the business to which the direction applies i.e. The local NHS England team
- the date the direction comes into force and the date it expires
- a description of the medicine(s) to which the direction applies
- class of health professional who may supply or administer the medicine
- signature of a doctor or dentist, as appropriate, and a pharmacist
- signature for organisational authorisation i.e. clinical governance lead
- the clinical condition or situation to which the direction applies
- a description of those patients excluded from treatment under the direction
- a description of the circumstances in which further advice should be sought from a doctor (or dentist, as appropriate) and arrangements for referral
- details of appropriate dosage and maximum total dosage, quantity, pharmaceutical form and strength, route and frequency of administration, and minimum or maximum period over which the medicine should be administered
- relevant warnings, including potential adverse reactions
- details of any necessary follow-up action and the circumstances
- a statement of the records to be kept for audit purposes

For further information on developing and using PGDs see the SPS website Patient Group Directions – SPS - Specialist Pharmacy Service – The first stop for professional medicines advice