Corby Clinical Commissioning Group

Nene Clinical Commissioning Group

Guidance on Medicines not Routinely Commissioned

Introduction

NHS Nene CCG and NHS Corby CCG expect consideration of new drugs/technologies to take place within the established planning frameworks, for example NPAG or the annual commissioning round. This enables clear prioritisation against other demands for funding and the development of implementation plans which will allow access for all patients with equal need. NHS Nene CCG and NHS Corby CCG will not introduce new drugs/technologies in an *ad hoc* basis through the mechanism of individual case funding. To do so risks inequity, since the treatment will not be offered openly and equally to all with equal need. There is also the risk that diversion of resources in this way will de-stabilise other areas of health care which have been identified as priorities by NHSN. This guidance covers the following topics:

1. **The role of NPAG**
2. **The role of NPMG**
3. **Low Clinical Priority Drugs**
   - **3.1. Double red drugs**
   - **3.2. Vitamins and food supplements**
   - **3.3. Products not in the BNF**
4. **Requests to prescribe complex and/or off-license medicine regimes**
5. **Continuation of Drugs following a clinical Trial**
6. **NHS medicines following Private Consultation**
7. **Requests to Continue Funding for Treatments Commenced 'at risk' by Providers or by Others (Including Patients)**
8. **Medicines for foreign travel purposes**
9. **Prescribing medicines for use outside of the UK**
10. **Prescribing of Borderline Foods and Dietary Products**

1. The role of the Northamptonshire Prescribing Advisory Group (NPAG)

NPAG meets bi-monthly and considers any medicines which have been granted a new marketing authorisation or in the process of applying for authorisation in areas which will have a significant impact on primary care. As the aim of the group is to promote rational, cost effective prescribing across Northamptonshire clinical staff from the primary and secondary care healthcare organisations within the county are represented on the group

The group categorises the drug, or particular indication(s) by a Traffic Light System depending on

- Evidence base for clinical and cost effectiveness
- Clinical responsibility
- Patient safety
- Ensuring appropriate usage
- Ensuring efficient usage (clinical and cost)
- Willingness to provide shared care information
- Availability of suitable monitoring mechanisms in general practice
- Patient convenience and preference

The drugs are categorized into one of the following groups:

DOUBLE RED

These are medicines that are less suitable for prescribing and are not recommended in primary or secondary care due to the lack of good evidence for clinical- or cost-effectiveness, or due to the availability of more suitable alternatives. These medicines will not be included in the CCGs' prescribing guidelines or formulary or the Hospitals Trust Formulary and are not available in secondary care.

Approved by NPMG May 2012
Revised August 2014

Some double red drugs have specific prior approval criteria relating to their use and will be approved if these criteria are met. Clinicians should complete a Prior Approval Drug Form, which can be found on Pathfinder at http://nww.pathfinder-rf.northants.nhs.uk/nene/therapeutics/prior-approval/

and submit it to Priorapproval.northants@nhs.net.

Some double red drugs are not routinely commissioned and are only available via an Individual Funding Request (IFR). The requesting clinician must be able to demonstrate that the patient is "exceptional", as per the IFR policy.

http://www.neneccg.nhs.uk/indivi/

The list of double red drugs, including the agreed criteria where prior approval is applicable can be found on Pathfinder at

http://nww.pathfinder-rf.northants.nhs.uk/media/2906057/prior-approval-criteria-for-double-red-drugs.pdf

RED
These are medicines that should be initiated by specialists only and prescribing retained within secondary care; a GP would not normally be expected to have the clinical knowledge to undertake this specialised care, even with the provision of written guidelines. Therefore, GP initiation or continuation of treatment of RED medicines is not recommended.

AMBER
Broadly, a specialist medicine may be classified as amber if it is not normally prescribed by GPs, but the GP would normally be clinically competent to undertake associated specialised care if provided with appropriate guidelines, while the specialist initiating the treatment retains responsibility for monitoring the progression of the condition being treated.

The amber category can be split into two sections, defined as follows:
AMBER 1: These are medicines that require significant monitoring and the decision to treat with an AMBER medicine should be made by specialists only. Prescribing may be transferred to a GP under a shared care agreement. Therapy should either be initiated and the patient stabilised by the specialist, or the specialist may recommend the initial dose for the GP to prescribe while continuing to monitor the patient closely during the stabilisation phase; this will be specified in the shared care protocol e.g. for leflunomide and all other DMARDs. Amber 1 medicines attract a "near patient testing fee" under the GP Local Enhanced-Service Contract

AMBER 2: These are medicines that require little or no monitoring by the GP, but should be prescribed in general practice only after they have been recommended following specialist referral. The request to share care should still be made by the hospital consultant using the Shared Care Request Letter, but a shared care protocol is not required as little or no monitoring is required. However, GPs must still be provided with the required information by the hospital consultant; the duration of treatment must be specified and the possible consequences of treatment that would necessitate stopping treatment must be identified.

GREEN
These medicines are appropriate for initiation in both primary and secondary care. Prescribing is appropriate within licensed or local recommendations

GREY
This is a holding category for drugs that have not been formally assessed by NPAG and awarded a traffic light designation. Grey medicines, or those not included elsewhere, are those that NPAG has not assessed for therapeutic use and prescribers should refrain from prescribing where possible.

2. Northamptonshire Prescribing Management Group (NPMG)
NPMG meets bi-monthly to monitor prescribing performance and identify opportunities to improve prescribing efficiency within NHSN as well as undertaking certain governance functions.

Prescribing advisers and GP Prescribing leads from each locality are represented on the group.

3. Low Clinical Priority Drugs

- **Double red drugs (see above)**
- **Vitamins and food supplements;**

This would include most vitamin preparations (unless for an identified condition for which there is good clinical evidence e.g.vitamin D for diagnosed deficiency) such as co-enzyme Q10**.**

3.3 "Toiletry" products and others not within the BNF

NHS Nene CCG and NHS Corby CCG supports prescribers not to prescribe a product on an NHS prescription if the product is not considered an "appliance" and it is not listed in the BNF.

For example, many products normally considered as "toiletries" would come under this rule.

4. Requests to Prescribe Complex and/or Off-license Medicine Regimes

GPs may sometimes be asked to prescribe complex medicine regimes by specialist clinicians, for example in the area of mental health. This may occur particularly with patients in long-term residential care.

In these cases the GP may be familiar with the individual drugs, but may not feel that it is within their clinical scope to prescribe them in combination. The combinations may result in the drugs being used in an off-license way.

This may also include drugs used for a novel unlicensed indication (not described in BNF or BNF for children or where the prescribing is not "custom and practice") and drugs at doses higher than the licensed maximum.

The GMC provides guidance to GPs in the area of off-licence prescribing
http://www.gmc-uk.org/guidance/ethical_guidance/prescriptions_faqs.asp#10

The GMC also advises (taken from the document at the above link)

> 25. Where a patient's care is shared between clinicians, the doctor with the responsibility for the continuing management of the patient must be fully competent to exercise their share of clinical responsibility.
>
> 26. If you are the doctor signing and issuing the prescription you bear responsibility for that treatment; it is therefore important that, as the prescriber, you understand the patient's condition as well as the treatment prescribed and can recognise any adverse side effects of the medicine should they occur.
>
> 27. There should be full consultation and agreement between general practitioners and hospital doctors about the indications and need for particular therapies. The decision about who should take responsibility for continuing care or treatment after initial diagnosis or assessment should be based on the patient's best interests rather than on the healthcare professional's convenience or the cost of the medicine.

GPs should not be pressured into taking on prescribing for patients when they feel it is beyond their scope of clinical practice. GPs will be supported by the Prescribing and Medicines Management team, when such a decision to decline to prescribe is taken**.**

5. Requests to Continue Funding for Patients Coming Off Drugs Trials

NHS Nene CCG and NHS Corby CCG do not expect to provide funding for patients to continue medication/treatment commenced as part of a clinical trial. In line with the Medicines for Human Use (Clinical Trials) Regulations 2004 and the Declaration of Helsinki, the responsibility lies with those conducting the trial to ensure a clear exit strategy from a trial AND that those benefiting from treatments provided within the trial setting will have ongoing access to those treatments. The initiators of the trial (provider trusts and drug companies) have a moral obligation to continue funding patients benefiting from treatment until such time as NHS Nene CCG and NHS Corby CCG agree to fund through the annual commissioning round. Where the treatment is not prioritised through the annual commissioning round, the responsibility remains with the trial

initiators. The Research Ethics Committee should require this assurance as part of the approval for the trial.

6. NHS medicines following private consultation

6.1 The responsibility for prescribing rests with the doctor who has clinical responsibility for a particular aspect of the patient's care. Where, for instance, an NHS doctor refers a patient (privately or otherwise) to a consultant for advice but, when appropriate, retains clinical responsibility, he/she should issue the necessary prescriptions and at NHS expense provided that these are not for red or double red drugs.

6.2 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 as NHS referrals. However, there is no obligation for the GP to prescribe the recommended treatment if it is contrary to his/her normal clinical practice or CCG guidelines/formularies. By prescribing a clinician assumes clinical responsibility for the treatment. If the GP declines to accept prescribing, the consultant should retain prescribing responsibility or suggest an alternative therapy for the GP to consider. Another option, if appropriate, may be for the patient to be referred to an NHS specialist to provide the treatment.

6.3 If the medication recommended is part of a special NHS arrangement or is a RED drug on the traffic light classification then the patient should be referred to the appropriate NHS service. Treatment in respect of sub-fertility is a case in point and therefore GPs should **not be asked to prescribe.**

7. Requests to Continue Funding for Treatments Commenced 'at risk' by Providers or by Others (Including Patients)

The provider trust's decision to commence treatment in advance of any decision by NHS Nene CCG or NHS Corby CCG to fund is a clear risk taken by the trust and/or patient. NHS Nene CCG and NHS Corby CCG accept no responsibility for the decision taken by the provider trust in these circumstances.

In considering a request for funding NHS Nene CCG and NHS Corby CCG will apply the criteria set out in this policy as it would for any other request, and accords no special privileges because the unfunded drug was given by a provider trust.

8. Medicines for foreign travel purposes

- **Immunisation**
- **Prophylaxis including Malaria**

Please see "Guidelines for Medicines used during Foreign Travel" which can be found on Pathfinder at http://nww.pathfinder-rf.northants.nhs.uk/media/2909152/guidlines-for-medicines-used-for-foreign-travel-august-14-1-.pdf

9. Prescribing medicines for use outside of the UK

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10. Prescribing of Borderline Foods and Dietary Products

10.1 Prescribing of borderline foods and dietary products should comply with the recommendations of the Advisory Committee on 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 safely be prescribed, that patients are adequately monitored and that, where necessary, expert hospital supervision is available."

10.2 A complete list of conditions can be found in the BNF or Drug Tariff Part XV. Most conditions can be included in the following categories: -
Metabolic disorders

- Gastrectomy
- Malabsorption states
- Malnutrition (disease-related)
- Liver disease
- Inflammatory Bowel Disease
- Specific skin disorders
- Renal failure
- Dysphagia

Prescriptions should be endorsed “ACBS”.

10.3 Nursing and residential homes will have stopped routinely requesting oral nutritional supplements from their GP since 2010. Such patients should only obtain oral nutritional supplements following agreement by a NHS Nene CCG and NHS Corby CCG dietitian.