1 Introduction

This Policy informs Trust prescribers where and how to access medication for their patients.

2 Scope

This policy applies to all Trust prescribers

3 Aims

This policy aims to ensure that all prescribers follow Trust policy when seeking to access medicines for their patients

4 Responsibilities

All Trust prescribers are expected to comply with this policy.

5 Formulary Drugs

Clinicians are expected to prescribe from within the range of products contained within the North of Tyne Formulary. Drugs are included within the formulary when, following consideration of evidence of benefits, harm and costs, they have received clinical and corporate governance approval from the North of Tyne Area Prescribing Committee and the Trust.

Consultants and GPs, Senior Dieticians and Nurse Consultants can submit requests for products to be added to the formulary, to the Area Prescribing Committee's formulary subcommittee (www.northoftyneapc.nhs.uk).

6 Non-Formulary Drugs

6.1 Where a patient, prior to admission to hospital, has been established on a non-formulary drug, the clinical team may be able to reasonably substitute a formulary alternative. Where this is not appropriate the ward may be able to
arrange to use the patient's own supply of medication. Where this is not feasible pharmacy will, in most cases, be able to order in a supply of the drug, when informed of the situation by the clinical staff.

6.2 There will be occasions when, in the clinical judgement of the prescriber, a patient should have treatment initiated and be provided by the Trust with a non-formulary drug. In these circumstances, where the case is considered by the Trust to satisfy clinical governance and corporate governance, then the drug will be provided to the patient. Requests for clinical governance approval of such “one off” applications (anticipated once only, certainly 3 or fewer requests per year) should be addressed, as described on the NHS Commissioning Board form, to the Chairman of the Trust’s Medicines Management Committee, Assistant Director of Pharmacy Medicines Management and Trust Formulary and Medicines Audit Pharmacist. Further guidance and copies of the form can be found on this link (under Formulary).

Clinicians should include information to support the request of relevant patient history, management plan, expectations for new treatment, previous treatment failures, evidence of peer support/MDT approval and plan of dose/number of doses for costing purposes. The Medicines Management Committee Chairman will in conjunction with the Assistant Director of Pharmacy Medicines Management and Trust Formulary and Medicines Audit Pharmacist decide whether the request satisfies Trust Clinical Governance having, for cancer chemotherapy, sought advice from the Committee’s oncology specialist. For complex requests he/she may seek views from relevant members of the Medicines Management Committee.

The Medicines Management Unit will then co-ordinate consideration for corporate governance approval.

In the event that the requesting consultant wishes to appeal against a decision that was made not to support the submission of an Individual Funding Request or approve individual supply of a non-formulary medicine, representation should be made to the Medicines Management Strategy Panel. The case should be set out in an email addressed to the Director of Pharmacy who will ensure it is added to the agenda the next meeting.

7 Corporate Governance

Immediate corporate governance approval can be given when funding of treatment is included within the payment by result tariff (PbR tariff). This approval can be given by the clinical director where cost is below the current threshold of £10,000 per annum.

For PbR tariff excluded treatments funding should be sought from the appropriate NHS Commissioner before treatment is initiated. In urgent cases where it is clinically inappropriate to wait for the decision from the commissioner the clinical director may
approve the treatment, again where cost is below the current threshold of £10,000 per annum.

In both cases i.e. PbR tariff included treatments or urgent PbR tariff excluded treatments, where the costs are above the current threshold of £10,000, Trust Executive approval is required for costs between £10,000 and £50,000 and Trust Board approval for those above £50,000 before treatment can commence.

The Medicines Management Unit will co-ordinate the submission to the responsible commissioner in conjunction with the responsible officer within the Trust Finance Department (Ext 31009).

8 **Access to investigational drugs at the end of clinical trials through an expanded access programme (EAP)**

Clinicians are encouraged to enter patients into relevant clinical trials of investigational drugs. Clinical and corporate governance of trials has been established through the regulatory processes which have ensured scientific validity, and an acceptable exit strategy. This should include arrangements for continuing supply of the drug to patients who are deriving benefit i.e. an exit strategy. The use of these medicines in patients exiting clinical trials is covered by Research Governance processes. This should include referral into the formulary process and the medicine and allow the free of charge use of the medicine until fully approved by the Area Prescribing Committee from both a clinical and funding perspective.

9 **Expanded Access (Compassionate Use) Programme**

As described above in paragraph 6, it is usual practice that the pharmaceutical company continues to provide its product free of charge for as long as it is clinically reasonable to continue treatment. The Trust’s view is that this principle should also apply to treatment provided through an expanded access (compassionate use) programme. No EAP will be entered into which does not have a satisfactory exit strategy. The pharmaceutical company must confirm, in writing, the proposed arrangements for the continued supply of the drug for each patient.

Any expanded access protocol must be able to demonstrate potential benefit to people with a serious disease for which there is no good alternative treatment, and who are not eligible for entry into a relevant clinical trial, or studies are closed to recruitment, and be designed to generate additional information about the drug, especially its safety.

Before discussion with the patient, the prescriber must present, the case for treatment to the Medicines Management Strategy Panel, presenting information of treatments which have failed, expectations for new treatment, and document what trial evidence is available.
Access to the expanded access programme is allowed only in limited circumstances and after satisfactory completion of clinical and corporate governance steps (advice on this or alternatives can be sought from the Trust Medicines Management Unit, Ext 31386) The documentation to request the use of an access programme to treat an individual or cohort of patients can be found at the following link.

10 Training

Not applicable.

11 Equality and diversity

The Trust is committed to ensuring that, as far as is reasonably practicable, the way we provide services to the public and the way we treat our staff reflects their individual needs and does not discriminate against individuals or groups on any grounds.

12 Monitoring

<table>
<thead>
<tr>
<th>Standard / process / issue</th>
<th>Monitoring and audit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Data on Non-Formulary and EAP drug use will be collected prospectively to audit adherence to the policy at least once a year</td>
<td>Method: Medicines Management Unit, By: Medicines Management Committee, Committee: Medicines Management Committee, Frequency: Every two years</td>
</tr>
</tbody>
</table>

13 Consultation and review

This policy has been reviewed and agreed by members of the Medicines Management Committee.

14 Implementation (including raising awareness)

Changes to the policy will be published on the intranet and in the Trust Policy Newsletter.

15 References

1 The North of Tyne APC endorses NICE Technology Appraisals, NHS Commissioning Board Clinical Reference Group Decisions (CRGs) and previous NECDAG (pre 1st April 2013)/CRGs (post 1st April 2013) decisions in the case of cancer chemotherapeutic agents.
The Newcastle upon Tyne Hospitals NHS Foundation Trust

Equality Analysis Form A

This form must be completed and attached to any procedural document when submitted to the appropriate committee for consideration and approval.

PART 1

1. **Assessment Date:** 27th October 2015

2. **Name of policy / strategy / service:**
   - Access to Drugs Policy Trust-wide

3. **Name and designation of Author:**
   - Ian Campbell Assistant Director Pharmacy

4. **Names & designations of those involved in the impact analysis screening process:**
   - Ian Campbell Assistant Director Pharmacy

5. **Is this a:**
   - Policy [x] Strategy [ ] Service [ ]
   - Is this:
     - New [ ] Revised [x]
   - Who is affected
     - Employees [x] Service Users [ ] Wider Community [ ]

6. **What are the main aims, objectives of the policy, strategy, or service and the intended outcomes?** *(These can be cut and pasted from your policy)*
   - This Policy informs Trust prescribers where and how to access medication for their patients.

7. **Does this policy, strategy, or service have any equality implications?**  
   - Yes [ ] No [x]

   If No, state reasons and the information used to make this decision, please refer to paragraph 2.3 of the Equality Analysis Guidance before providing reasons:
   - The policy is used to inform prescribers how to access drugs for all patients who enter the Trust. Some groups of people with protected characteristics may require more expensive drugs than others; this is taken into account in the formulary process and drugs are prescribed based on medical need.
8. Summary of evidence related to protected characteristics

<table>
<thead>
<tr>
<th>Protected Characteristic</th>
<th>Evidence, i.e. What evidence do you have that the Trust is meeting the needs of people in various protected Groups relating to this policy</th>
<th>Does evidence/engagement highlight areas of direct or indirect discrimination? If yes describe steps to be taken to address (by whom, completion date and review date)</th>
<th>Does the evidence highlight any areas to advance opportunities or foster good relations. If yes what steps will be taken? (by whom, completion date and review date)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Race / Ethnic origin (including gypsies and travellers)</td>
<td>All prescribers undertake mandatory equality and diversity training</td>
<td>Some groups of people with protected characteristics may require more expensive drugs than others; this is taken into account in the formulary process and drugs are prescribed based on medical need.</td>
<td>No</td>
</tr>
<tr>
<td>Sex (male/ female)</td>
<td>As above</td>
<td>As above</td>
<td>No</td>
</tr>
<tr>
<td>Religion and Belief</td>
<td>As above</td>
<td>As above</td>
<td>No</td>
</tr>
<tr>
<td>Sexual orientation including lesbian, gay and bisexual people</td>
<td>As above</td>
<td>As above</td>
<td>No</td>
</tr>
<tr>
<td>Age</td>
<td>As above</td>
<td>As above</td>
<td>No</td>
</tr>
<tr>
<td>Disability – learning difficulties, physical disability, sensory impairment and mental health. Consider the needs of carers in this section</td>
<td>As above</td>
<td>As above</td>
<td>No</td>
</tr>
<tr>
<td>Gender Re-assignment</td>
<td>As above</td>
<td>As above</td>
<td>No</td>
</tr>
<tr>
<td>Marriage and Civil Partnership</td>
<td>As above</td>
<td>As above</td>
<td>No</td>
</tr>
<tr>
<td>Maternity / Pregnancy</td>
<td>As above</td>
<td>As above</td>
<td>No</td>
</tr>
</tbody>
</table>

9. Are there any gaps in the evidence outlined above? If ‘yes’ how will these be rectified?

No

10. Engagement has taken place with people who have protected characteristics and will continue through the Equality Delivery System and the Equality Diversity and Human Rights Group. Please note you may require further engagement in respect of any significant changes to policies, new developments and or changes to service delivery. In such circumstances please contact the Equality and Diversity Lead or the Involvement and Equalities Officer.

Do you require further engagement? Yes ☐ No [x]

11. Could the policy, strategy or service have a negative impact on human rights? (E.g. the right to life, right to respect for private and family life, the right to a fair hearing and the right to education?)
No, life promoting drugs are prescribed based on medical need

PART 2

Name: Ian Campbell

Date of completion: 28th October 2015

(If any reader of this procedural document identifies a potential discriminatory impact that has not been identified, please refer to the Policy Author identified above, together with any suggestions for action required to avoid/reduce the impact.)