5.1: NON-FORMULARY PRESCRIBING POLICY

Covering directly provided services across NHS Greater Glasgow & Clyde (NHS GG&C)

1. BACKGROUND

A robust Formulary management system is well established in NHS GG&C as the focus for good prescribing practice. An evidence-based review process is conducted at national and local level to influence prescribing recommendations. Medicines successfully traversing this process are included in the Board Formulary and are intended to cover the vast majority of patient requirements, providing clinicians with a wide range of cost-effective prescribing options. Where circumstances dictate that a medicine should only be prescribed on a limited basis, the Formulary will specify these restrictions.

2. POLICY STATEMENT

Prescribing from the Formulary is consistent with good clinical practice. The need for prescription of medicines from outwith the Formulary (NF prescribing) is recognised, but it is expected that:

- formal treatment guidelines / protocols will exclude NF drugs
- NF status will apply to new medicines until accepted by the SMC and the ADTC
- NF prescribing will be restricted to exceptional circumstances only and will be subject to approval on a case by case basis via an Individual Patient Treatment Request (IPTR)
- if an IPTR is proposed in the best interests of an individual patient, the principles outlined below will be followed.

3. APPLICABILITY

This policy will apply to all directly provided NHS GG&C services, including the Directorates within the Acute Service Division and Partnerships. The intention is to ensure a fair and consistent approach for all patients referred to NHS GG&C clinicians for treatment. A complementary, related policy will apply to prescribing by independent contractors in primary care (see 5.4 Primary Care Non-Formulary Process).

A Health Board outwith NHS GG&C (home Board) may request NHS GG&C involvement in a patient's case and request either advice or advice and treatment.

- Where advice alone is requested, the home Board clinician retains responsibility for the patient's treatment including the choice of medicines to be prescribed. In such instances, the Formulary processes within the home Board apply.
- Where an NHS GG&C clinician is requested to undertake treatment, the NHS GG&C Formulary processes apply. This is the case in whichever setting or location the NHS GG&C clinician is providing the service, including outpatient clinics within the geographical boundary of the home Board. Application for use of a non-formulary medicine relates to the NHS GG&C Formulary and processes.
- Where treatment is shared e.g. with a surgical patient requiring chemotherapy, the relevant process will align with the person taking responsibility for the prescribing.
- In exceptional circumstances for medicines that cost >£25,000 per patient treatment episode (or treatment year for continuous treatment), the patient's home board will be involved in the IPTR process (see 5.2 Policy for the Management of Individual Patient Treatment Requests).

4. PRINCIPLES

- The policy will apply to all patients. There will be no differential or separate process for non NHS GG&C residents, whether referred for treatment from a neighbouring NHS Board area or treated by an NHS GG&C prescriber in the environment of the home Board.
- Each directorate or partnership will have a clear process to review IPTRs, within the framework established by this policy and will be responsible for ensuring its implementation and monitoring. Requests will only be approved where there is a clear and overriding clinical case that formulary prescribing is not possible and where the agreed referral criteria have been met. For those approved, the supply will be initiated with appropriate monitoring and

reporting. For those not approved, the supply will be declined (See 5.2 Policy for the Management of Individual Patient Treatment Requests),

- Three levels of NF medicines have been identified:
    1) NF medicines/indications/formulations which are not prescribed frequently enough, or do not carry a significant financial burden, are deemed Level 1 and do not warrant the completion of an IPTR request.
    2) Those NF medicines/indications/formulations that are of a low individual cost, but where the overall impact of prescribing amounts to a significant expenditure, are deemed Level 2. These warrant closer monitoring; brief documentation is required at this level via the IPTR process (Form IPTR 2).
    3) Those NF medicines/indications/formulations where even low levels of prescribing incur a considerable cost are deemed Level 3. Submission of a full IPTR (Form IPTR 3) is required at this level, with evaluation and approval for use by a Directorate IPTR Panel prior to prescribing. This is indicated as part of the 'IPTR List'. Directorates are able, via the relevant Associate Medical Director or equivalent, to request change to the applicable level of a particular NF medicine/indication/formulation on the IPTR list.

5. REFERRAL CRITERIA FOR AN IPTR

The referral criteria for submission of an IPTR are:

- That the patient's clinical circumstances (condition and characteristics) are significantly different from either:
    - The general population of patients covered by the medicine's licence (for medicines awaiting evaluation or non-submissions to SMC); or
    - The population of patients included in the clinical trials for the medicine's licensed indication as appraised by the SMC or NHS HIS

AND

- That these circumstances imply that the patient is likely to gain significantly more benefit from the medicine than would normally be expected.

The IPTR will only be upheld if both the above criteria are met.

Further information pertaining to the IPTR process can be found in 5.2 Policy for the Management of Individual Patient Treatment Requests

6. IPTR APPEALS

A consultant has the right to ask for a review of the process applied to an IPTR declined via a recognised appeal process. Each appeal must be supported by relevant documentation. The Board aims for appeals to be heard within 20 working days of submission by a Review Panel consisting of the Board Medical Director, the Head of the Pharmacy and Prescribing Support Unit (PPSU) or their nominees and a lay member. The Panel will be supported by the PMG Professional Secretariat (or nominee). Some circumstances may demand the input of an independent expert advisor. There is provision for participation by the patient and / or the patient's representative, should the patient wish this. The panel's decision will be final. However, if there are subsequent changes in national advice, or the patient's clinical condition materially alters in the opinion of the consultant to align with the exceptionality criteria, then a fresh application can be submitted to the Directorate. The patient may also wish to consider the option of payment for the medicine.
The complete process for Appeals is described in 5.3 Individual Patient Treatment Request Appeal Process.

7. COMMUNICATION

The outcome of the IPTR will be communicated to all relevant stakeholders timeously.

- For an IPTR, the applicant (the patient's Consultant) is the principal recipient of the feedback. If approved, the prescription will be dispensed. If rejected, then the applicant should be aware that the medicine will not be supplied and that the only option remaining is the Board based IPTR appeal (refer to 5.3 Individual Patient Treatment Request Appeal Process)

- For full IPTRs, where NHS GG&C is the host Board, the outcome of a decision will be communicated to the home Board Director of Pharmacy or Medical Director.

8. MONITORING AND REVIEW

Each Directorate should develop systems for monitoring and review of NF prescribing, which will engage with the individual prescriber and will identify any emerging patterns of use at service or directorate level. This will enable a comprehensive NHS GG&C wide approach to the review of NF prescribing, with PPSU providing system wide overview and advice with the support of ADTC and PMG processes.