NHS Greater Glasgow & Clyde Therapeutics Sub-Committee Processes related to the Therapeutics Formulary

1. BACKGROUND

NHS Greater Glasgow and Clyde supports the introduction of new and existing products that allow its population to benefit from advances in non-drug treatment. At the same time there is a need to achieve the maximum benefit for patients from the significant spend on existing medicines and non-drug items. In addition to these advances in treatment, changing demographics and increasing public expectations place growing demands on the NHS. Despite ongoing review of services and prescribing to maximise efficiency, gaps may emerge between patient / clinician demand and the ability of the NHS to provide within available funding allocations.

New products are constantly being developed and added to the Scottish Drug Tariff and therefore can be prescribed in the community. Historically a formulary has only been established for medicines and support from the SMC has provided guidance to health boards in developing their formularies to direct doctors and prescribers on appropriate and cost effective medicines. There is no equivalent organisation for non drug prescribed products and medical devices. Advice has often been directed from acute services specialists to the GPs. In addition patients have also been made aware of therapeutic non drug products and requested them from GP surgery staff who lack expertise and knowledge on the appropriateness of the request to individual patients. The increased number of independent non medical prescribers (nurses and Allied Health Care Professionals) has resulted in a migration away from GPs to NMPs in primary care to prescribe non drug devices. "Transforming nursing roles – developing district nursing in NHS Scotland" will further reinforce the role of NMPs is prescribing non drug treatments. (http://www.gov.scot/resource/doc/311667/0098354.pdf. Healthcare quality strategy 2010)

There is a strong desire and necessity to reduce inequality of provision of treatments across the NHS in Scotland and eliminate 'post code prescribing'. The process by which new products are managed must be transparent, consistent and explicit to ensure clinicians, managers and the public have confidence in the process and the decisions made.

Established as a subcommittee of the Area Drug and Therapeutics Committee (ADTC), the Therapeutics Sub-Committee (TSC), as a part of its remit, considers non-drug products identified via the Drug Tariff and/ or the relevant Technical User Groups (TUGs) and which can be accessed in the acute sector and that are prescribed in the community by GPs or non-medical prescribers. See Appendix I (Therapeutics Committee Work Stream Process).
Clinicians are advised not to prescribe a new product until the local processes for clinical and cost effectiveness review has been completed. Clinicians are encouraged to alert the TSC of new products for review in the first instance and to consider patient safety and appropriate use of products by following the Therapeutics Formulary inclusion process in appendix 2.

Further details on the subcommittee are contained in the appropriate Terms of Reference Document. Members and local expert advisors are required to declare any interest in relation to the products under consideration, competitor products, and the associated clinical suppliers.

Therapeutics Formularies

There was an identified need to develop a variety of formularies to take into account the wide range of non drug devices and products which are routinely prescribed, within a clear governance framework to support safe, clinical, cost effective prescribing. In the hospital setting the formulary for all products is decided through the Dressings and Sundries Formulary Group supported by NHSGGC procurement. The products are made available on the acute ordering (Pecos) system in a stratified way with only designated departments and wards provided the necessary authorisation for ordering relevant products to their area of expertise. In the community there are currently some specialist formularies for wound dressings and for urinary catheters and supplies. Most dietetic products have currently been included in the NHSGGC Drug Formulary. The Therapeutics Formulary would only include products that are used in Acute, Mental Health and Community settings and are available on an NHS prescription. These products cost the NHS a considerable amount of money. This cost is expected to continue to increase due to demographic and organisational changes in health care delivery, with the majority of therapeutic formularies cost accessed via prescribing in community.

2. THE PROCESS

Products are available through two sources:

National contracts

The acute services seek their supplies of products through the procurement department, this works closely with the National Distribution Centre (NDC) where contracts and prices are determined through a national contract bidding process. Following awarding of contracts, regional health board areas select a list of products for use in the acute based setting on these awards. The national contract system for managed care settings as in the case for drug procurement is a separate from the content with Scottish Drug Tariff which is linked to the English Drug Tariff. The managed service contracts are commercially sensitive and therefore the prices are not made public.

Scottish Drug Tariff

The Scottish Drug tariff lists products that are available in the community on an NHS prescription. Some of the dietetic supplements and substitutes are not in the Scottish Drug Tariff, but in the English Drug tariff, and still available in Scotland.

Product assessment process

New products added to the Scottish Drug Tariff would be considered non-formulary unless or until a formulary appeal process has been undertaken.

A request to assess a product may come from clinicians, specialist or via the central prescribing team where advice has been sought regarding the prescribing of this product. The person requesting the inclusion of the product in the formulary will be directed to the flow chart in Appendix 2. Product information will be gathered and a determination of need for the product will be investigated as per the 'Formulary Inclusion Process' appendix 2. A Form CH1: NHS GGC Health Board Request for Changes to the NHSGGC & Therapeutic Formulary should be completed and presented as per appendix 2. A report subsequently would be submitted to the Therapeutics Sub-Committee (TSC) and request for therapeutic liaison and contact made with the relevant specialists or specialist group who would be asked to review the product. A member of the TSC may be assigned to liaise with the appellant as per flow chart Appendix 1.

The TSC member will liaise with the appropriate general manager or equivalent to ensure a financial impact assessment positive or negative on current expenditure identified. Where the appellant is part of a specialist group the TSC member will liaise with this group. Examples of Specialist groups: Diabetes Prescribing Group, Oral Nutritional Sub-group.

Published evidence will be sought to support the assessment of the product, this will then be critically evaluated and a summary of the evidence prepared.

A summary of available benefit evidence and cost-effectiveness is prepared for each product to be reviewed including relevant background information, e.g. local prescribing data. For products accepted for use by NDC/Scottish Drug Tariff, local experts are asked to review the advice document and consider the local implications for NHS Greater Glasgow and Clyde as a whole.

Any products considered for reviewed in acute care, via D&S should be brought to the attention of the Therapeutics Committee if they have an impact on primary care i.e. patient could be discharged to primary care with a non formulary product or due to pricing structure may have a negative economic impact in primary care prescribing budget.

This may require discussion with other clinicians, managed clinical networks or specialist interest groups. Patient number estimates and potential budget impact are reviewed from a local perspective. Potential risk management issues are also highlighted. Advisors are generally lead clinicians based in acute care but where relevant may be General Practitioners or specialist practitioners.

At each Therapeutics committee meeting, a Formulary status is agreed including any proposed restrictions that are decided. Restrictions may be in terms of the prescriber (e.g. specialist initiation only), for selected patient groups or selected clinical areas. Decisions on some non-drug products may be deferred to allow development of a treatment protocol.

Possible Local Non- Drug Formulary status decisions:

Possible Formulary status classes:
Core and Non Core / Preferred List and Total Formulary for areas:-

- Acute & Community
- Acute Only
- Community Only
- Deferred to allow further consultation
- Non Formulary

Clinicians could appeal this decision through the Therapeutics Formulary inclusion process (but not until one year has elapsed from the original TSC decision).

The Therapeutics Sub- Committee will report its decisions every six months to the ADTC, Advice from ADTC members on a non- drug formulary decision may be sought in certain circumstances where there are possible training requirements that may impact on implementation.

Where the guidance has significant service implications or substantial cost implications in excess of an agreed threshold of £3000per patient/year which equates to £230per patient/month, it is referred to the Prescribing Management Group Primary Care (PMG-PC) and/or the Dressing and Sundries Committee for further consideration.

3. COMMUNICATION

It is important to have a system that can efficiently and effectively communicate decisions. In particular early communication to clinicians of products not recommended for prescribing can prevent a pattern of utilisation that may later result in difficulties in discontinuation.

After each Therapeutics Committee meeting the decisions will be communicated to the relevant specialist group or directorate and to Primary Care then published in the relevant Medicines Update and the Formulary website (www.ggcprescribing.org.uk).

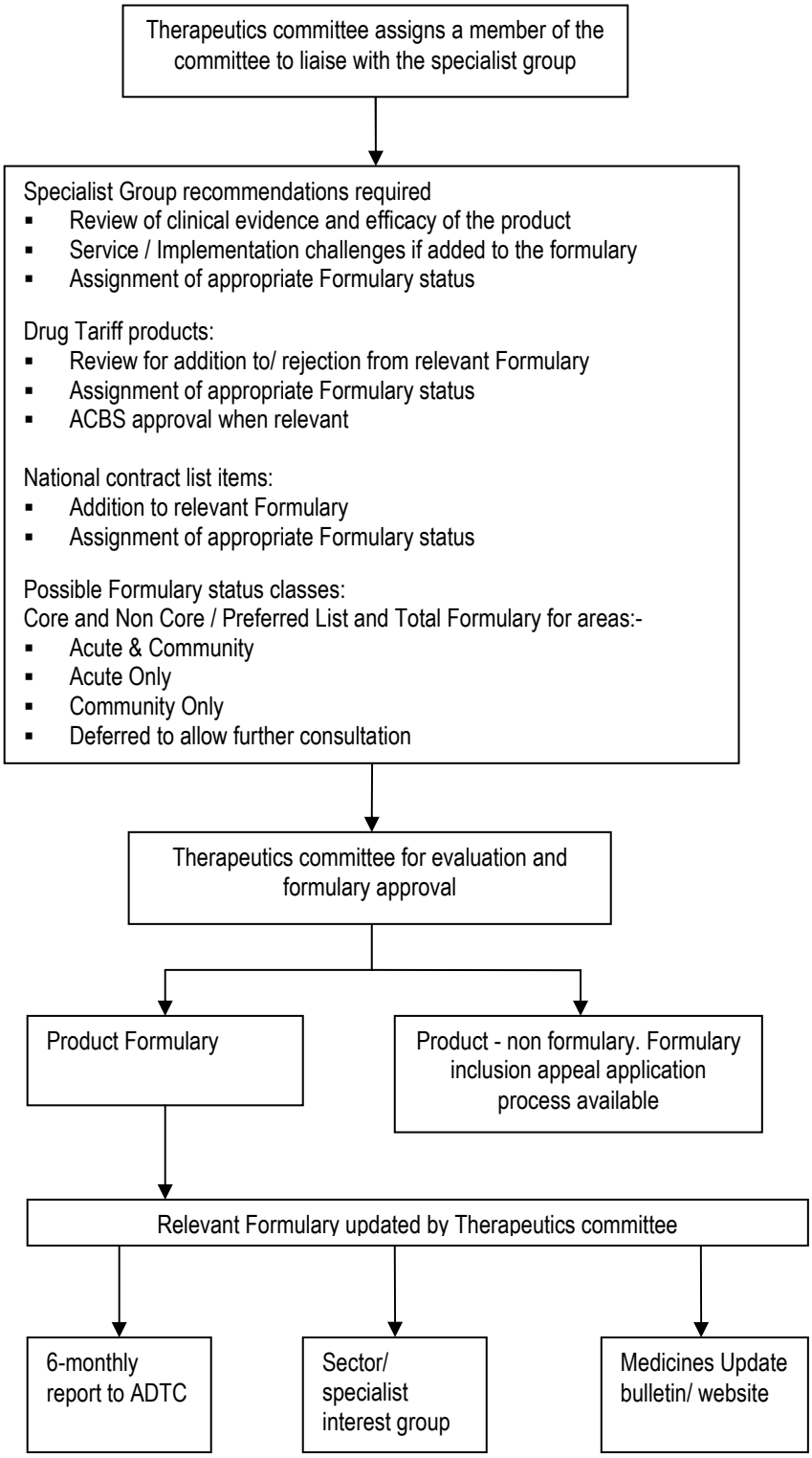
4. APPEALS

Local specialist prescribers or clinicians may complete a Therapeutics Formulary inclusion request for non- drug products (Form CH1 ADTC Therapeutics Sub-Committee). Requests to prescribe any Non-Formulary products should be addressed through the Non-Formulary process, which is currently in practice in the community. The process applies for products not on National Contract and will require the support of the budget holder.

5. MONITORING

Monitoring of "Formulary and Non Formulary" product activity will be shared with and/or sent to HSCP staff and managers by the prescribing leads and prescribing support pharmacists based on PRISMS reports. Support on use of therapeutic formularies can also be obtained from the non medical prescribing team and PPSU. A target list of non-Formulary products will be monitored within the acute sector. Further detail can be found on the Procurement staffnet site.

Work Stream Process for Specialist groups Diagram Appendix 1



New Non-Drug Product or Contract – Formulary Inclusion Process Appendix 2

FORMULARY APPLICANT RESPONSIBILITIES

THERAPEUTICS COMMITTEE RESPONSIBILITIES