Lancashire and South Cumbria Formulary Group
Terms of Reference

1. Introduction

The Lancashire and South Cumbria Formulary Group is a strategic platform for harmonising the 'legacy' formularies originating from places and trusts within Lancashire and South Cumbria. The Formulary Group is a subgroup of Lancashire and South Cumbria Medicines Management Group.

2. Aim

The Formulary Group aims to harmonise legacy formularies across all places and Trusts within Lancashire and South Cumbria ICS to produce a single Joint Lancashire and South Cumbria formulary to improve quality, safety and value of prescribing.

3. Objectives

a. The Formulary Group will produce, and implement a **work plan** to achieve harmonisation of formulary chapters across the Lancashire and South Cumbria health economy

b. BNF chapters (old style) will be **prioritised according to spend** and timely establishment of specialist clinical groups. **The 'big five' chapters, accounting for 67% of Primary Care spend will be key deliverables**.[1] The chapters and % spend are as follows:

   a. Cardiovascular system – 16%
   b. Endocrine system – 16%
   c. CNS – 15%
   d. Respiratory system – 12%
   e. Gastrointestinal system – 7%

c. The CSU support team will form a series of **clinical specialist groups** who will be engaged to review sections of the formulary containing major inconsistencies and **make recommendations to the Formulary Group**.

d. **The Formulary Group will approve formulary sections** for inclusion in the Lancashire and South Cumbria formulary.

4. Membership

The Formulary Group's Chair will be provided by the Lancashire and South Cumbria Integrated Care Board, administrative support and overall operational management of the Formulary Group meetings will be provided by the Midlands and Lancashire Commissioning Support Unit (MLCSU) Medicines Management Team.

Membership is specific to individual roles, but members who are unable to attend will be expected to send a nominated deputy where possible.

[1] The 'big five' chapters equate to 77% of items prescribed

- ICB Chief Pharmacist Co-chair
- Acute Chief Pharmacist Co-chair
- GP x 1
- Acute Trust deputy chief pharmacist or senior delegate x 2
- ICB locality lead x 2
- CSU support people x 2-4 depending on topic
- +/- Specialist Clinician(s) depending on topic
- Additional member co-opted as per needs of group

5. Secretariat

Papers and agendas will be circulated around five days before each monthly meeting. Meetings will normally be documented on an action log with brief details of decisions made.

6. Principles of Harmonisation

The aim for harmonisation will be to define a single recommended formulary position for each drug/indication (where relevant) for the whole ICS. Any different area/local formulary recommendations or RAG status across the ICS will only be agreed where there are defined and documented reasons for not producing a single approach. Inclusion of drugs within clinical guidelines will be considered alongside the separate formularies, the same principles will be applied. The stages of the process are explained in detail in the **Appendix**, briefly alignment will be approached as follows:

1	Identify drugs/indications where formularies are aligned into the **Matched** list	These drugs/indications will be listed for support by the Clinical Reference Group(s) then prepared for ratification by the Formulary Group ('grandfather' procedure)
2	Identify drugs/indications with differing but positive approval RAG ratings compared to LSCMMG, categorise:	
	a) **Minor**, effectively cosmetic 'tweaks' to allow alignment with current LSCMMG position	RAG ≡ RAG, grandfather with Formulary, after consultation at Clinical Reference Group(s)
	b) **Moderate** discrepancies compared to LSCMMG position	RAG ≠ RAG, CSU to make proposal for discussion at Clinical Reference Group following 2 week consultation with localities, where feasible. In case of agreement, a position will be proposed for adoption/if major issues revealed, Clinical Reference Group(s) to be consulted before ratification at Formulary Group
	c) **Major** discrepancies compared to LSCMMG position	RAG ≠≠ RAG, detailed discussion at Clinical Reference Group(s) with outcome to be discussed for ratification decision at Formulary Group

7. Clinical Specialist Groups

The clinical group will aim to have a clinical specialist chair as 'clinical champion' to ensure credibility and legitimacy with clinicians.

The group will review major inconsistencies and make recommendations to the Formulary Group to resolve any issues identified.

The clinical specialist groups will aim to have the following members (depending on topics identified)

- 1 specialist clinician from each of the four Trusts (Lancashire Teaching Hospitals Trust, Blackpool Teaching Hospitals Trust, East Lancashire Hospitals Trust, University Hospitals of Morecambe Bay Trust) and/or Lancashire and South Cumbria NHS Foundation Trust
- Up to 2 General Practitioners
- Up to 4 specialist clinicians (e.g. specialist pharmacists)
- Additional Primary Care representatives, as required. This could include practice based pharmacists/nurses.

8. Timescales

Once the methodology is established, and depending on capacity, it is estimated that each chapter will take around three months to complete. After initial data sifting and categorisation, etc, the group will normally move on to the next chapter around on month after initiation of the current chapter. This means that, after the start up period, a chapter should be produced each month.

9. Prioritisation of and provision of additional information for drugs

The formulary will inevitably contain multiple instances of drugs within some classes of medicines. When this occurs, there could be opportunities to provide information within the formulary allowing prescribers to prioritise drug choice.

a. Which drugs to prioritise

Prioritisation may be carried out on a case by case basis, taking the following into account:

- Current alignment of prioritised medicines – the 'Principles of Harmonisation' would usually be followed to determine alignment of prioritised medicines. This will include consideration of established clinical guidelines, etc.
- Prescribing data to indentify current practice
- Potential financial advantage of providing information on prioritisation (and considering information will most likely only be relevant to new initiations of a class of drug)
- Potential clinical advantage of providing information on prioritisation
- Amount of background work required to enable a prioritisation recommendation
- Impact on overall formulary/chapter timescale
- Steps required to ratify prioritisation. This could be, for example:
    - Adoption of already aligned positions at Formulary Group
    - Production of New Medicine Review type document to be consulted on and reviewed at LSCMMG

b. Method for prioritsation

If a decision is taken to minimise the number of options available within a drug class, the following will be taken into account to support prioritisation of a drug:

- clinical effectiveness

- safety
- cost-effectiveness/value for money
- patient factors
- Ease of administration/ limited titration steps
- local health priorities

Any decision made should support consistent and affordable decision-making.

c. Sources of information

The following sources should be considered when making prioritisation decisions:

- Drug license details
- BNF guidance
- Relevant NICE guidance and guidelines
- Neighbouring country guidance: SMC (SIGN) and AWMSG
- Established clinical guidelines e.g. British Society for Rheumatology
- NICE ESNM
- SPS resources
- Local clinician opinion
- Local prescribing data

d. Full clinical review

If the sources of information listed above do not support a clear prioritisation, a review should be requested for LSCMMG consideration using established New Medicines Review methodology.

Appendix - Details of alignment process

Stage 1

Choose formulary chapter – based on spend/prescribing levels (Big 5). EPACT data will inform chapter choice.

A **'clinical' specialist group** will be identified and approached to collaborate on chapter (this will be done before the chapter is tackled, access to members will sometimes be deciding factor for a decision about which chapter to review), the clinical specialist group will include specialist clinicians, Trust representatives and primary care representatives, including GPs.

Output – clinical specialist group and chapter identified

Stage 2

When BNF chapter identified, cross check each drug listed locally against other local CCG/Trust based legacy formularies plus LSCMMG web site. GM and Mersey positions will be checked for information only.

Produce 4 lists of drugs in the following categories: Matched, Minor, Moderately matched and major discrepancies

a) **Matched** – All formularies align	RAG = RAG – add to matched list
a) **Minor**, effectively cosmetic 'tweaks' to allow alignment with all formulary positions or complete alignment	RAG ≡ RAG - see Stage 3
b) **Moderate** discrepancies – maximum 1 region does not match	RAG ≠ RAG - see Stage 4
c) **Major** discrepancies	RAG ≠≠ RAG - see stage 5

Output – 3 lists of drugs – matched / minor issues, moderate discrepancies and those with major discrepancies

Stage 3

The first list to be produced will be the '**Matched'** list. These drugs will be those matched across formulary i.e. listed with same RAG ratings across all formularies or where there are minor cosmetic differences across formularies. These drugs will be eligible for "Grandfathering" process. This list should not need further examination as there are no discrepancies and local procedures or LSCMMG will have reviewed attributes and agreed the RAG rating.

Output – Matched list produced for inclusion in netFormulary web page

Stage 4

The second list will be for drugs with '**Moderate'** discrepancies across formularies. This includes drugs that:

- may have a different RAG rating in a maximum of one area but there is universal agreement across all other formularies.
- have RAG ratings that are aligned but additional indications, qualifying criteria, localised text, etc listed.
- May simply not be listed in one region

This list of drugs will be split into:

1) Those where inconsistencies are expected to be:
   a) oversights,
   b) historic or
   c) simple omissions.

Microsoft Forms will be used for these drugs with the simple questions listed for basic responses. Two weeks will be given for responses, forms will be sent to the clinical group identified for the chapter.

2) Those where inconsistencies are considered minor, as above, but clarification via email would be preferable.

Two weeks will be given for email responses from clinical specialist group

The above process will refine the **Moderate** discrepancy list and split these drugs into one of the two previously defined categories:

- Drugs that can be added to the **matched** list and can follow the 'Grandfathering' process and
- Drugs that will fall into the **major discrepancies** category and will require discussion at the clinical specialist group.

Outputs – list of drugs added to grandfathering category and list of drugs to be added to the major discrepancies category

Stage 5

Major discrepancies will be discussed ideally at a meeting of the clinical specialist group, failing this email correspondence will be used – see process in stage 4.

Drugs in this category will be tabulated to show where differences have been identified and, where possible, additional context will be added to provide a greater understanding of differences across the region. A recommendation based on best available evidence will be made to assist group decision making.

A meeting of the clinical specialist group will be scheduled. This group will include representatives from all regions and will include General Practitioners, specialist clinicians, pharmacists (practice and hospital) and senior ICS representatives (e.g. Heads of medicines optimisation, senior hospital representative). Meeting will be held via Teams or face to face.

Each of the major discrepancies will be discussed and the aim will be to gain agreement via consensus.

Anything that requires additional consideration or consensus cannot be reached will be discussed at the Formulary Group. The Formulary Group will be presented with an outline of the issues raised plus a recommendation, for discussion at a Formulary Group meeting. Where the Formulary Group feel able to make a decision about a discrepancy, then this decision will be accepted as final.

By exception, if the Formulary Group feel unable to make a decision, the discrepancy will be discussed at LSCMMG using current procedures (usually New Medicines review or RAG change review process).

See appendix for criteria used to address prioritisation of drugs, should this become relevant for a particular clinical area.

Outputs – aligned list and list of drugs for discussion at Formulary Group

Stage 6

The matched drug list will be added to a draft netFormulary web page

Stage 7

The RAG populated netFormulary web page will be refined to consider additional guidance information to be included in the final upload.

The Morecambe Bay formulary will be the starting point for additional information. The information included by Morecambe Bay will be compared to the information uploaded in the East Lancashire and Central Lancashire formularies.

A similar stepwise approach as illustrated above for stages 3 to 5 will be taken for the additional information sections.

Representatives from each of the 3 formulary committees who were previously involved in producing information uploads will be sought to provide context and rationale for each information upload section.

Output – a draft netFormulary version of the chapter will be produced

Stage 8

The draft netFormulary chapter will be presented at the Formulary Group for ratification.