APG subgroup document process

NHS Cheshire and Merseyside

Stage 1

Subgroup identifies either the need for a new document or the review of existing document.

Prioritisation

New document resulting from:

- Horizon scanning
- Formal application
- New drug
- Service need
- RAG change
- National guidance
- New indication or change of use
- Request from other subgroup

Proposed changes should be evidence based and referenced

Author and proof reader allocated

Author drafts first version and decision support summary (DSS)

Stage 2

Document and DSS discussed by subgroup

Author amends document as agreed

Stage 3

Draft document circulated for (re) consultation

Subgroup discuss feedback and DSS and agree responses

Subgroup member to feed back final response to consultees
Subgroup chair feed back to LMC / LPC / networks

Author amends document as appropriate

Stage 4

Final version reviewed by proof reader

Author amends document as appropriate

Recommendation and DSS submitted to APG for support

APG recommendations submitted to ICB for approval

APG / ICB decline: document goes back to subgroup with feedback at appropriate stage

Formulary updated in line with ICB approvals

ICB approvals reported to local leads.

Document checklist

New documents

- Formal applications from any APG member organisation are submitted using a new drug application form or a minor formulary amendment or RAG change request form and send to CSU secretariat via email address - mlcsu.cmapg@nhs.net for pre-screening and accuracy checking. Secretariat then submits to subgroup for review.
- Ad hoc applications can also be submitted by a member of any subgroup.
- Application discussed at subgroup meeting and priority agreed using the prioritisation criteria form. The application may be referred to a more suitable subgroup.
- Subgroup Chair to respond to applicant with an explanation of the outcome of the prioritisation.
- Where added to workplan, subgroup agrees an author and a date for the application to be considered.
- Subgroup decides if a policy statement, formulary entry or amendment, guideline or other format is appropriate, and a likely RAG designation where relevant.
- Subgroup Chair sends author the appropriate blank document template.
- Author to draft the document with proposed place in therapy and RAG designation according to APG criteria. Where there is specialist input from outside the subgroup membership, specialists must declare any interest.
- Author sends draft document to subgroup Chair by agreed deadline.
- Document discussed at subgroup meeting.
- Draft document amended by author as appropriate. Subgroup agree whether it wishes to see document with amendments at next meeting, or whether it is suitable for consultation with agreed amendments.

Existing documents

- Applies to harmonised documents. Legacy documents will be reviewed following the agreed ICB harmonisation rules.
- Author to update and track changes into original document unless a wholesale rewrite of is required in which case this will be stated in the consultation email. Multiple tracked changes to a paragraph might be better re-written as a whole new paragraph with the old paragraph struck through. Only track insertions and deletions, not formatting changes.
- The review process should include a literature search for any new evidence or national guidance. Check to see if there are significant SPC changes, new safety information, and updated costings. Where there is specialist input from outside the subgroup membership, the specialist must declare any interest.

All documents

- Author to send draft document to subgroup Chair for consultation process.
- CSU to forward to the specifically nominated organisational representatives, as part of monthly consultation email, to be discussed with or circulated to key stakeholders for their comments (four week consultation).
- Stakeholders send feedback directly to secretariat using the electronic form provided.

- CSU administration compiles a summary of stakeholder comments and sends to the author and other subgroup attendees.
- Author to review summary of stakeholder comments, propose feedback to individual comments, and amend document as appropriate.
- Author to send policy statement and summary of stakeholder comments and feedback form, with proposed feedback, to subgroup Chair by agreed deadline.
- The draft document, summary of stakeholder comments and feedback form, and proposed feedback are discussed at subgroup meeting. Subgroup considers whether document is ready for submission to APG, or re-consultation is required.
- The draft document and proposed feedback are amended by author as agreed with subgroup.
- Subgroup completes Decision Support Summary (DSS).
- Proofreader to check final draft of document and send comments to author
- Final amendments, as necessary, made by author
- Author to send the final document and stakeholder comments with feedback to the subgroup Chair.
- Subgroup Chair shares consultation feedback and subgroup responses with subgroup members for them to forward and as necessary discuss the outcome with their organisation commentator.
- Subgroup Chair submits documents to APG agenda.
- Presented at APG by subgroup Chair or agreed deputy.
- Final amendments, if necessary, by author or subgroup Chair.
- Final proof check by subgroup Chair who submits documents to ICB agenda.
- Subgroup Chair updates the formulary with ICB approved documents.
- MLCSU secretariat disseminates ICB approvals to local leads.

Guidance for proof reading APG policy statements

These documents are to support local decision-making recommendations, and therefore open to legal challenge, so it is important that a thorough proof read is undertaken. The following points should be considered when checking any APG policy statements:

- Format in line with correct template and correct fonts used (no smaller than font size 10, except where necessary for references)
- Factual content checked against given reference sources. This may include clinical studies/summaries, NICE guidance, SPC etc. Ensure content is referenced appropriately.
- Any costings correct and up to date. Drug Tariff or NHSBSA dm+d used where necessary and month/year stated.
- For NICE TAs, costing information from the NICE resource impact statement, resource impact report or resource impact template should be provided.
- Check general readability.
- Check grammar, punctuation, and spelling.
- Check that hyperlinks work and link to the correct documents or websites.

Note that version numbers, and header and footer dates will be added by CSU Medicines Management team.

Reference format

All sources should be cited and numbered in the order they appear in the text. Place the citation number in the text at the end of the appropriate sentence.

For studies, list the first three authors, followed by 'et al' if there are more than three. Give the full title of the article, using US spelling if in the original. This is followed by the title of the journal, year of publication, volume number and first and last page numbers. References to books should include names of the authors, any editors, the title, edition, place of publication and year. For references accessible via the web include a web address together with the date accessed.

For NICE TAs, a separate reference to the costing information should be provided if the resource impact statement or resource impact report has been used. It is not necessary to reference the NICE resource impact template separately as the template is used as a calculation tool and the reference would not be able to provide the exact figures used.

Examples of format for common types of references using human readable hyperlink:

1. Sanofi. Summary of Product Characteristics; Lyxumia 20 micrograms solution for injection, 05 May 2021. Accessed online 06 September 2022. National Institute for Health and Care Excellence.

2. National Institute for Health and Care Excellence. NICE Guideline 87; Type 2 diabetes in adults: management, 29 June 2022. Accessed online 06 September 2022.

3. Scottish Medicines Consortium. Dapagliflozin (Forxiga) for the treatment in adults of chronic kidney disease (AstraZeneca UK Ltd), 09 May 2022. Accessed online 06 September 2022.

4. European Medicines Agency. European Public Assessment Report; Lyxumia, 28 November 2012. Accessed online 06 September 2022.

5. Ollech J, Normatov I, Peleg N et al. Effectiveness of Ustekinumab Dose Escalation in Patients with Crohn's Disease. Clin Gastroenterol Hepatol. 2021 January ; 19(1): 104–110. Accessed online 06 September 2022.

APG subgroup short process flowchart