NHS
Cheshire and Merseyside

New Medicines Subgroup: NICE TA Process

Cheshire and Merseyside Area Prescribing Group (APG)

Situation	Actions
1. Drug launched and is for NMSG action	Grey statements will not be routinely issued, unless subgroup identify need, on a case-by-case basis (e.g. where further information is required for clinicians or patients)
	a) Subgroup agree grey statement not required: • Subgroup Chair to co-ordinate updates to legacy formularies • Grey RAG in formulary, pending publication of NICE TA. Hyperlink to NICE. • Grey RAG summary to next APG meeting for information only • No requirement to circulate for APG consultation
	b) Subgroup agree need for grey statement: • Subgroup Chair / nominated subgroup member to author • Draft grey statement produced. Hyperlink to NICE and include any other relevant information • Grey statement to be proof read and uploaded • Subgroup Chair to co-ordinate updates to legacy formularies • Grey statement to next APG meeting for information only, ICB approval not required • No requirement to circulate for APG consultation

<table>
<tr><td colspan="2">2. FAD/FDG / TA published
Go to situation 3
For drugs relevant to APG pathways, the Subgroup Chair will inform FGSG at the point of FAD publication</td></tr>
<tr><td colspan="2">3. Is drug recommended by NICE?
If no – go to situation 4
If yes – go to situation 5</td></tr>
<tr><td rowspan="3">4. Drug <u>is not</u> recommended by NICE
(negative FAD/FDG / TA)</td><td>• Provisional Black RAG assigned
• Black statements will not be routinely issued, unless subgroup identify need, on a case-by-case basis (e.g. where further information is required for clinicians or patients)
• Author to bring proposal to NMSG, using Black RAG report
• NMSG agree RAG and need for statement
• Not necessary to ‘information gather’ from LMC and LPC</td></tr>
<tr><td>Negative FAD/FDG - when TA published return to situation 2
Negative TA – continue with situation 4</td></tr>
<tr><td>• Bring RAG report / statement back to NMSG when TA published.
• Author completes Decision Support Summary (DSS) if required for black statement. DSS not required for RAG report.
• Agree final APG document and DSS.
• Prepare for APG:
  ○ DSS included (if required).
  ○ Subgroup Chair / nominated deputy to present at APG
• Black RAG report / statement taken to APG for recommendation.
• Black RAG report / statement sent to ICB for approval.
• For Black RAG reports, there will be no statement to upload. A Black RAG will be assigned in the formulary</td></tr>
</table>

	with a link to the TA. Subgroup Chair to co-ordinate updates to legacy formularies after ICB approval is received. • For Black statements, the statement will be uploaded and formulary updated by after ICB approval is received. Subgroup Chair to co-ordinate updates to legacy formularies.
5. Drug <u>is</u> recommended by NICE (positive FAD/FDG / TA)	Determine RAG – see **situation 6** [and **situation** 7]
6. Drug is not suitable for primary care prescribing [e.g. tariff-excluded high cost drug with commercial arrangement, for specialist use only; in-tariff drug, for specialist use only]	• Subgroup Chair informs author of FAD/FDG / TA publication • Provisional **Red** RAG assigned • Red statements will not be routinely issued, unless subgroup identify need, on a case-by-case basis (e.g. where further information is required for clinicians or patients, or implementation information is required) • Author to bring proposal to NMSG, using Red RAG report • NMSG agree RAG and need for statement • Identify any areas for further investigation i.e. within trusts • Not necessary to routinely 'information gather' from LMC and LPC • Chair to escalate any potential issues / barriers to ICB ↓ **<u>TAs with 90 day implementation deadline</u>**: • Bring RAG report / statement back to NMSG when TA published, including any feedback from further investigation (if relevant). **<u>TAs with 30 day implementation deadline</u>**: • In a situation where the implementation deadline will breach if the TA is delayed to the next NMSG meeting, the proposal / statement can be progressed straight to the APG meeting if the subgroup have already considered the proposal / statement from the FAD/FDG

	and no further issues have identified. The Chair will inform the subgroup if this action is taken.
	• If the FAD/FDG has not already been considered by the subgroup, it may be necessary to agree appropriate action with the subgroup and circulate the proposal / statement by email if necessary.
	• Author completes Decision Support Summary (DSS) if required for red statement. DSS not required for RAG report.
	↓
	• Costing information added from NICE resource impact statement / template
	• Agree final APG document and DSS.
	• Prepare for APG
	  ○ DSS included (if required).
	  ○ Subgroup Chair / nominated deputy to present at APG
	• Red RAG report / statement taken to APG for recommendation
	• For Red statement only - final amendments, if necessary, to be made by author or subgroup Chair
	• Red RAG report / statement sent to ICB for approval
	• For Red RAG reports, there will be no statement to upload. A Red RAG will be assigned in the formulary with a link to the TA. Subgroup Chair to co-ordinate updates to legacy formularies after ICB approval is received.
	• For Red statements, the statement will be uploaded and formulary updated by after ICB approval is received. Subgroup Chair to co-ordinate updates to legacy formularies.

7. Drug suitable for primary care prescribing [may include high cost drugs without a commercial arrangement e.g. rimegepant]	Subgroup Chair informs author of **FAD/FDG** publication • A draft statement should be developed from the provisional recommendations in the FAD/FDG to enable timely discussion. This is particularly important for TAs with a 30-day implementation deadline. • Provisional **Amber** or **Green** RAG assigned. • Author to bring draft FAD/FDG statement to NMSG. • NMSG agree RAG and draft statement content. • NMSG to identify any areas for further investigation.

	• Members must 'information gather' within organisations to agree RAG and identify any issues. • However, if it is another drug in class for an indication which has already received a positive TA and ICB approval, information gathering to agree the RAG is not required. The subgroup may need to consider the need for information gathering on a case-by-case basis if any other issues are identified. • Subgroup Chair to circulate email to subgroup for members to forward to relevant clinicians. Chair to circulate to LMCs and LPCs for feedback. ↓ **For TAs with 90-day implementation deadline:** • Bring draft TA statement back to next NMSG to discuss including feedback from 'information gathering.' **For TAs with 30-day implementation deadline**: • The NMSG will endeavour to adhere to the 30-day implementation deadline wherever possible, but understand that NHS Cheshire and Merseyside observe the 90-day statutory deadline. • Timescales will need to be considered with an aim of taking the draft TA statement to the next APG meeting. Consideration on a case-by-case basis may be required. **If the TA is due to be published after the next APG meeting**: Bring draft statement and DSS back to next NMSG to discuss including feedback from 'information gathering.' **If the TA is due to be published before the next APG meeting:** A short turnaround time will be required for organisations to gather and submit feedback. It may be necessary to agree draft TA statement, DSS, and subgroup feedback responses via email, for inclusion on the APG agenda. ↓
8. Drug is recommended by NICE (positive TA)	• Subgroup Chair informs author of TA publication • Author to bring draft TA statement and DSS to next NMSG (or agree by email, **as above**, if it is not possible to bring to next NMSG meeting). • NMSG address feedback from 'information gathering.' • Costing information added from NICE resource impact statement / template. • Agree final statement and DSS.

	• Final document to be proof read. • 'Information gathering' feedback finalised by Chair and circulated to subgroup members. • Members to feed back to stakeholders within their organisations. • Subgroup Chair to circulate feedback to LMC and LPC.
9. Prepare for APG	Subgroup Chair to include in agenda: • Statement • Informal 'information gathering' summary included in APG agenda • DSS  Subgroup Chair / nominated deputy to present at APG  Statement taken to APG for recommendation
10. Actions following APG	• Final amendments after APG, if necessary, to be made by author or subgroup Chair. • DSS to be updated by Chair following APG. • Statement sent to ICB for approval, including summary from the DSS for information. • Statement will be uploaded and formulary updated after ICB approval is received. Subgroup Chair to co-ordinate updates to legacy formularies. • Link to statement included in the APG approvals report. • APG approvals report circulated.