Terms of Reference
County Durham & Tees Valley Area Prescribing Committee

1. Role

The Area Prescribing Committee will be responsible for the clinical decision making and advice in relation to prescribing and medicine management in services commissioned by the CCGs in County Durham and Tees Valley plus North Yorkshire CCG and provided by County Durham and Darlington Foundation Trust (CDDFT), North Tees & Hartlepool NHS Foundation Trust (NTFHT), South Tees NHS Foundation Trust (STFT), Tees Esk and Wear Valley NHS Foundation Trust (TEWVFT), and the Local Authorities in County Durham & Tees Valley, and all general practice members of the CCGs.

2. Remit

The principles for local decision making about medicines (LDM) are set out in the Department of Health document published in January 2009, Defining Guiding Principles for processes supporting Local Decision Making about Medicines and this underpins - NICE Good practice guidance – developing and updating local formularies Dec 2012.

2.1 Patient Safety

- Ensure patient safety is incorporated as a specific issue in all decisions and recommendations made, including the safety aspects of the way medicines are used in practice.
- Consider the impact of MHRA Alerts, patient safety alerts and other guidance on medicines usage.
- Support safe medicines usage across care interfaces; this may include, identifying the need for and/or developing shared care protocols and treatment guidelines, contributing to traffic light systems, discharge prescribing arrangements, the use of unlicensed medicines.
- Review of existing guidelines from either Durham or Tees Valley should have consistent engagement across the entire new geography. Where available in either CCG existing guidelines should be used as a basis for review across the whole APC geography.
- Contribute to national and local systems for reporting and learning from adverse events.

2.2 Commissioning

- To oversee, set direction, and ratify outputs from subgroups.
- To develop and maintain a shared formulary across participating organisations in County Durham and Tees Valley.
- North Yorkshire will produce a separate formulary with York but work alongside CD&T APC to help maximize/optimise consistency for the North Yorkshire population.
- To ensure that all applicable medicines with current NICE Technology Appraisals (NICE TAs) are available to patients and correctly listed on the APC formulary

and to provide advice to the CCGs to support the implementation of NICE guidance and other national guidance where it relates to the use of medicines.

- To establish and maintain a system for new medicine requests from healthcare professionals. Requests will be assessed on patient safety, clinical effectiveness, cost effectiveness or resource impact, strength of evidence, place in therapy relative to available treatments, national guidance and priorities, local health priorities, equity of access, stakeholder views.
- To review and maintain existing shared care agreements plus identify and develop any new shared care agreements.
- Horizon scan, plan for and manage the introduction of, and disinvestment in, medicine in the local health economy within available resources.
- Ensure that decisions taken about medicines usage are consistent with wider commissioning frameworks, for example, the annual commissioning round and prioritisation frameworks.
- Consider patient pathways and work with commissioners and contractors to ensure that systems are in place to manage high-risk medicines and treatments, within the context of existing (and future) contracting arrangements with primary care contractors and other providers.
- Advise on the management of the financial implications of medicines usage across the health community incorporating the QIPP agenda.
- Highlight to commissioners and providers, the potential impact (cost saving or cost generation) of medicines usage.
- Make recommendations to commissioners and providers about medicines linked to care pathway design and changes in service delivery.
- Establish/contribute to commissioning policy for which medicines, devices and appliances will be used across a health community (for example, by formulary development).
- Contribute and feedback to organisations producing national guidance on medicines.
- Approve changes to the Out of Hours Services Formulary for the North East Ambulance Service.

2.3 Governance

- Ensure that robust standards and governance arrangements underpin area wide decision-making/advice related to medicines.
- Provide local guidance for appropriate working with the pharmaceutical industry, including guidance for Clinical Commissioning Groups and non-medical prescribers, within national frameworks.
- Develop effectiveness measures against the main priorities of the APC (e.g. prescribing data).
- Ensure recommendations, once agreed, are formally adopted in contracts via existing processes and implementation is reviewed by an implementation and monitoring plan.
- Develop/contribute to quality standards around medicines usage to be included in provider contracts and advise on medicine related CQINN targets.

- Monitor medicines use in the health community and feedback to local organisations.

2.4 Whole system approach

- Provide guidance on medicines management issues that have an effect on clinical practice and the overall delivery of healthcare in the local health economy.
- Provide a forum for informed discussion between clinicians, from both primary and secondary care, to ensure that the implications of any significant changes in practice on the management of healthcare resources are defined and understood.
- Facilitate local implementation of national and regional policy and/or guidance where it has implications across organisations (e.g. NICE guidance, Better Care, Better Value Indicators, regional specialist decision making groups and Local Clinical Network appraisals and recommendations).
- Advise on social and local authority issues relating to medicines management.
- Engage with new and emerging organisations/groups which will have an impact on medicines optimisation in the health community.
- Facilitate community-wide activity e.g. medicines safety or waste campaigns.

3. Membership

3.1. Membership of the group will comprise:

- Three representatives each from County Durham CCG and Tees Valley CCG e.g. 2xGP + Medicines Management Lead
- Two representatives from North Yorkshire CCG e.g. GP + Medicines Management Lead
- Two representatives from each Acute Trust e.g. Consultant + Chief Pharmacist
- Two representatives from TEWVFT e.g. Consultant + Chief Pharmacist
- LPC representative - 2 members representing both stakeholder LPCs
- LMC representative - 1 member representing all stakeholder LMCs
- Public Health representative - 1 member representing all stakeholder local authorities
- Lay/patient representative – 2 members – 1 from Tees and 1 from County Durham
- Finance representative - 1 member representing all stakeholder CCGs
- Commissioning representative - 1 member representing all stakeholder CCGs
- Chief Pharmacist, NE Ambulance Service
- Chair of Formulary & Guidelines Subgroup
- RDTC representative & Professional Secretary (non-voting)
- South Tyneside & Sunderland APC Professional Secretary (non-voting)

3.2 All nominated members to have delegated authority from employing/representative organisation to attend and participate in decision making/

3.3 Chair and Vice-Chair to come from membership with one to be from primary care and one from secondary care and then ratified by participating CCGs/Trusts.

3.4 The quorum is two thirds of voting members present including both County Durham CCG and Tees Valley CCG represented, and 2 Acute Trusts. TEWVFT to be present for any items pertaining to Mental health on the agenda.

3.5 A maximum of one third of Formulary Subgroup membership to be members of APC to ensure good governance with decision making.

3.6 All members of the committee will be expected to sign up to the relevant policy on declaration and register of interests.

3.7 Members may be excluded from decision making, where declarations of conflict of interest may compromise neutrality.

3.8 Other advisory specialists may be invited to attend where specific issues relating to their respective areas of responsibility are discussed (e.g. those submitting papers or pathways for approval)

3.9 The Area Prescribing Committee may agree to co-opt other clinicians or managers as and when necessary.

3.10 The Regional Drugs and Therapeutics Centre will nominate a Senior Pharmacist to act as professional secretary. Responsibilities of Professional Secretary:

- Coordinate agenda, minutes and actions
- Prepare evidence for consideration by the meeting if appropriate
- Facilitate the agreed work programme

3.11 It is the responsibility of each APC Member to ensure that they disseminate information/actions identified as necessary to other parts of their organisation, or to other organisations they may be representing in a timely manner, and feedback any comments received to the chair/professional secretary of the committee in respect to any consultations that are undertaken within the timescales agreed.

3.12 Members may resign from the committee at any time by communicating this to the Chair or Professional Secretary.

3.13 All members attending APC to represent an organisation or present a paper do so in a professional capacity, and all participants should be treated with courtesy, respect and consideration. Participants should only speak when they are invited by the chair and should raise a hand to be recognised as having something to say. A person should not be interrupted while speaking or asking a question.

4. Attendance

4.1 Participating organisations should appoint deputies to represent them when they are their nominated member(s) is/are unable to attend.

4.2 Other representatives may attend as and when agreed with the Chair.

4.3 Members may be co-opted as appropriate with the agreement of the majority of the current APC membership via email prior to the APC meeting if necessary

4.4 If a member is late or leaves early, a record must be made in the minutes as this could affect quorum. If the meeting becomes non-quorate then all decision from that point forwards will require ratification via email post-meeting from those members who left the meeting.

5. Declaration of Interests

5.1 Members and regular attendees must complete a 'declarations of interest' form on joining the group and renewed annually in September.

5.2 In addition members and attendees are required to declare any relevant interests relating to the agenda at each meeting.

5.3 Members may be excluded from decision making (to be judged by the Chair) where appropriate.

5.4 Members should also highlight where their organisation may have a potential conflict of interest with an agenda item.

5.4. Declarations of Interest will also be required from all those submitting papers, formulary application, and guidelines to the APC.

6. Decision Making

6.1 Recommendations will take into consideration both clinical and cost-effectiveness relative to other interventions commissioned for the population, as well as affordability and consequences of implementation.

6.2 Commercially agreed discounts or rebate schemes will only be considered once a decision based on clinical effectiveness is reached.

6.3 Decisions will be made on the best available evidence; ideally this will be fully published trial data only. Abstracts, conference posters, or clinical opinion, will not be used as the sole basis of a recommendation.

6.4 Recommendations are reached by consensus, taking into account declarations of interest. Any dissent against a recommendation will be noted.

7. Voting

7.1 It is recognised that there are very few occasions when recommendations are not unanimous and therefore the requirement for the group to vote may not be necessary. If there are conflicting opinions within the group, the recommendation will be put to a majority vote of quorate members present who are eligible to vote. An appropriate spread of stakeholder representation and members' interests is also required for the vote be valid.

8. Appeals

8.1 Anyone who wishes to appeal against the decision making process of the group with regard to the decision in question will be required to present substantial evidence as to the reasons behind their appeal.

8.2 The right to an appeal will be at the Chair's discretion.

8.3 Grounds for appeal are:

- Significant new clinical evidence available to support application or submission not considered as part of original decision making process.
- Decision appears to be based on inaccurate or incomplete information.
- The process for the handling of new drug requests has not been followed.

8.3 Applications for a medicine on which a decision has already been made can only be resubmitted to the group if substantial and significant new evidence becomes available.

8.4 The Professional Secretary should be contacted in the first instance.

9. Adoption of NICE Technology Appraised Drugs into the Formulary

9.1 If there is more than one NICE-approved medicine for a condition, the APC will not recommend that any one of them is used routinely in preference to the others (unless an order of preference is stated in the TAs or HSTs).

9.2 The APC will not recommend that a medicine that has not been assessed by NICE is used routinely in preference to a NICE-approved medicine.

9.3 The committee may however suggest to healthcare professionals that a particular medicine is preferred locally. Reasons for this could include cost, if a medicine is cheaper than other options, to reflect local clinical expert opinion or to achieve optimal stock control. Any such local recommendation must only be taken into account, however, after a patient and prescriber have discussed all treatment options and only if they have no preference about which medicine they want to use.

9.4 The APC will not make a recommendation on any drug due a NICE TA in the next 6 months.

10. Accountability arrangements

10.1 The Committee will report to the management executives of the County Durham CCG and the Tees Valley CCG, and the respective Trust Boards. The Committee will also report to the North Yorkshire & York Medicines Committee (being formed summer 2020), 10.2 The Committee will have delegated authority for decision-making from the respective constituent CCGs and Trusts.

10.3 The APC has the following limits for delegated authority for decision making:
Decisions below £200k across CD&TVCCGs
CDTVAPC have delegated authority to approve items up to this level.

Above £200k across CD&TVCCGs, but less than £250k per CCG
If a director from TVCCG is present at the meeting then are able to approve up to £250k for TVCCG using our delegated authority. Can also approve outside the meeting up to this level.

For CDCCG, if director from CDCCG is present at the meeting, or happy to approve outside the meeting, then the £250k applies in the same way as TVCCG above.

However, any of the directors can ask for the decision to be referred to their Executive Committee if they prefer not to use their delegated authority for any specific item. (e.g. if they feel they require further clinical support/buy-in to the decision from their organisations).

Decisions above £250k per CCG
Any items over £250k per CCG will need to be referred to the individual CCGs for Executive Committee approval.

For North Yorkshire CCG their upper threshold is proposed at £14K pa per decision for the Hambleton, Richmondshire & Whitby population.

10.4 Information will be shared with Local Professional Committees, the respective Clinical Quality Review Groups and the North East Commissioning Support Unit.

10.5 The Committee will receive the minutes of the Formulary & Guidelines Subgroup.

10.6 The Committee will receive the minutes of stakeholder Trust D&Ts and Primary Care Prescribing Committees

10.7 The Committee will provide an annual report to the constituent organisations.

11. Communication

11.1 An agenda will be produced and circulated electronically together with accompanying papers at least 7 days prior to the meeting.

11.2 Draft minutes, Decision Summary and updated Action Log will be circulated after the meeting to the members within 2 weeks and the minutes confirmed in the subsequent meeting.

11.3 Once confirmed, minutes will be posted on the APC Website.

11.4 The Decision Summary including formulary changes and guidelines approved at the meeting will be posted on the APC Website.

11.5 The agenda, annual workplans, minutes and recommendations/decision summary will be shared with South Tyneside and Sunderland APC as standing agenda items to aid information sharing and closer collaboration.

11.6 The full APC papers will be shared with the professional secretary of South Tyneside and Sunderland APC prior to each meeting to aid information sharing and closer collaboration.

12. Confidentiality

12.1 All members and attendees agree to keep detailed discussions confidential to allow free and full debate to inform unencumbered decision making. Discretion should be used when discussing meetings with non-attendees and papers should not be shared without agreement of the chair or professional secretary, to ensure confidentiality is maintained.

13. Frequency of meetings

13.1 Meetings will be held every two months on the 2nd Thursday of the month 9am to 11.30am via Microsoft Teams. Additional meetings may be arranged if deemed necessary.

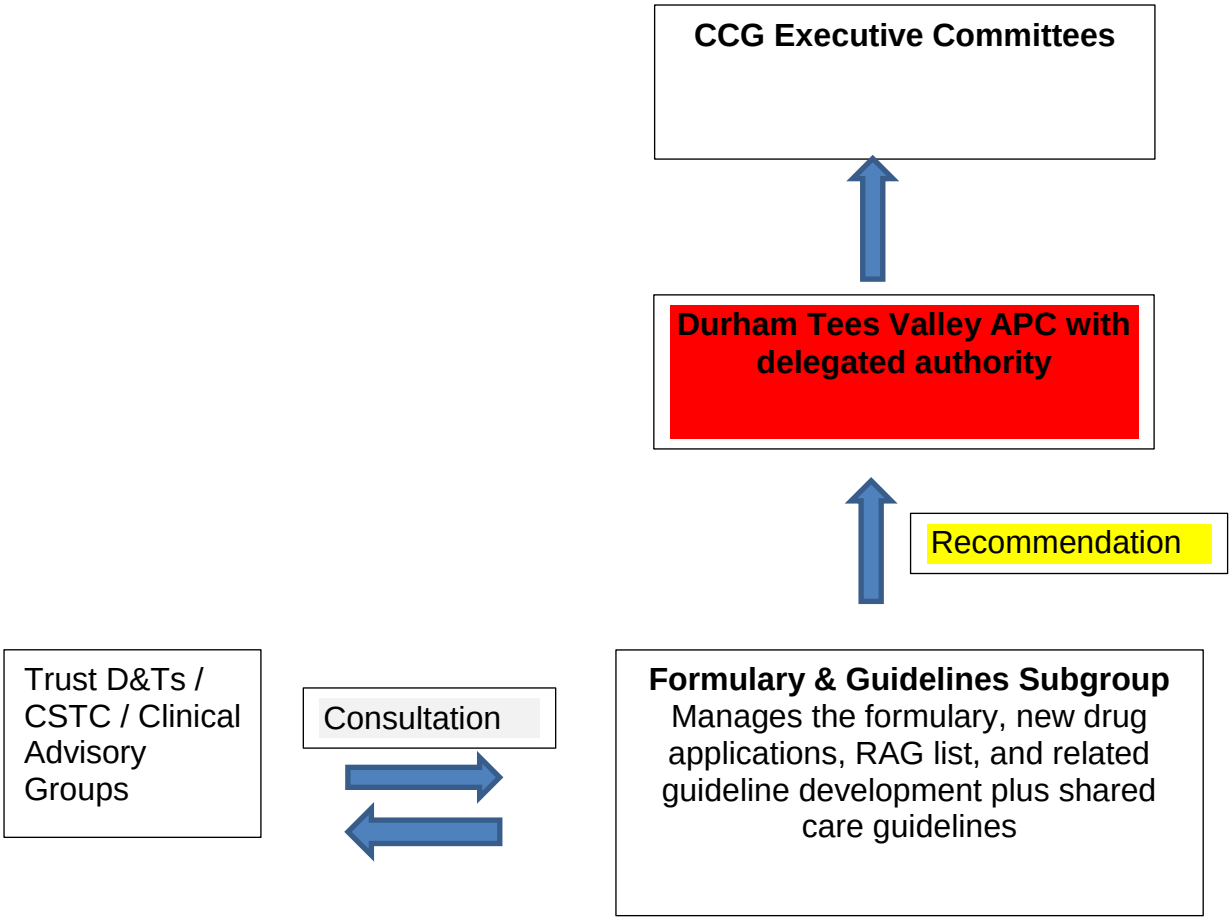
14. Sub Committees

14.1 Formulary & Guidelines Subgroup – this group considers new drug applications (for all prescribable products) and leads the development of the shared formulary. A recommendation to approve, defer or reject an application, with a summary of evidence, is presented to the APC. The approval of the APC is also sought for any proposed major change in policy.

15. Review

15.1 These Terms of Reference will be reviewed on an annual basis each year.

Appendix - County Durham & Tees Valley Area Prescribing Committee Reporting Structure



Membership:

Three representatives from each CCG e.g. 2xGP + 1x Medicines Management Lead (to be nominated by CCG with delegated authority)	6 members
Medicines Management Lead and GP Prescribing Lead from North Yorkshire CCG	2 members
Two representatives from each Acute Trust e.g. Consultant + Chief Pharmacist	6 members
Two representatives from TEWVFT e.g. Consultant + Chief Pharmacist	2 members
LPC representative	2 member representing all stakeholder LPCs
LMC representative	1 member representing all stakeholder LMCs
Public Health representative	1 member representing all stakeholder local authorities
Lay/patient representative	2 members (1 Durham + 1 Tees)
Finance & Commissioning representative	1 member representing all stakeholder CCGs
Chief Pharmacist, NE Ambulance Service	1 member
Chair of Formulary & Guidelines Subgroup	1 member
Professional secretary and RDTC representative (non-voting)	1 member
South Tyneside & Sunderland APC Professional Secretary (non-voting	1 member
Total	**27 members (25 voting and 2 non -voting)**

- Chair and Vice-Chair to come from membership and then ratified by CCGs/Trusts – suggest one be from primary care and one from secondary care
- The quorum is two thirds of voting members (i.e. 16 members) present including both County Durham CCG and Tees Valley CCG, and 2 Acute Trusts. TEWVFT to be present for any items pertaining to Mental health on the agenda.
- Max one third of Formulary Subgroup membership to be members of APC to ensure good governance with decision making.
- To meet on the 2nd Thursday of the month on alternate months (January, March, May, July, September, November) via Microsoft Teams.