Hertfordshire and West Essex (HWE) Area Prescribing Committee (APC)
Terms of Reference (TOR)

Purpose	The HWE APC is a strategic local decision-making group with responsibility to promote rational, evidence-based, high quality, safe and cost-effective medicines use and optimisation across Hertfordshire and West Essex ICS, in order to ensure equity of access to medicines for all patients. Best available evidence is central to all decision making. The HWE APC does not have authority to make decisions where there is an impact on expenditure for the ICS, either directly as drug costs or as service costs unless as part of a mandatory NICE technology appraisal (TA). APC recommendations for non-mandatory NICE TA items that have an estimated cost pressure will be considered at Executive level, in the context of ICS strategic priorities before they may be implemented in any way that impacts the finances of the ICB. The APC provides a forum for local stakeholders to consider and make recommendations in ways that are robust, transparent, consistent and take account of regional and national recommendations using an explicit ethical framework and decision-making criteria (see Appendix for ethical framework). There will be a systematic approach to whole therapeutic areas, not only looking solely at single drugs in isolation from the care pathway; there will be consideration of other health-system costs to support and facilitate service redesign. Service redesign recommendations can and will be made but this is outside scope of the HWE APC. The HWE APC is part of a system-wide approach to supporting evidence-based investment, and disinvestment, in line with the strategic priorities of the Integrated Care System and Integrated Care Board. In this task the APC's activities will be coordinated with those of the HWE strategic Medicines Optimisation Group, HWE Priorities Forum and Long-Term conditions groups, recognising the "opportunity cost" of each decision on services for similar or different groups of people in the HWE system of health and social care. The APC will promote the widest levels of clinical engagement. This will extend beyond the scope of any clinical membership and should involve clinicians from all professional backgrounds. The APC will include Medicines Safety and other agreed sub-groups as standing agenda items. Appropriate procedures will be put in place where changes in use of medicines need to be made urgently e.g. for implementation of decisions to reduce antimicrobial resistance or medicines safety. HWE APC deliberations and decisions will take account of: evidence of clinical effectiveness; cost effectiveness and deliverability in HWE

	setting, including consideration of service delivery requirements; safety and patient/individual factors.
Membership and attendees	**Members** • Consultant in Public Health (1) C*hair.* *If the chair cannot attend they may nominate a deputy chair to act as chair in their absence.* • Pharmacists from HWE ICB: Chief Pharmacist; Clinical Effectiveness Lead; Medication Quality and Safety Lead; Integrating Pharmacy and Medicines Optimisation in primary care Lead; Financial Assurance, System Integration & Innovation Lead (5) • Chief Pharmacist from acute trusts, mental health and community services – ENHT, PAHT, WHHT, HPFT, EPUT (2), CLCH, HCT (8) • Consultant Chair of Acute Trust medicines decision-making group, Medical Director (or medical delegate) from acute trusts – ENHT, PAHT, WHHT (3) • GP Clinical Prescribing Leads – HWE ICS, SWH, ENH, WE (4) • Lead Pharmaceutical Advisor Clinical Effectiveness from HWE ICB (1) Professional secretary **N.B. All members <u>must</u> have a nominated deputy.** **Regular Attendees** • Admin support (ICB) • Patient representative – one per place (3) • Consultant Chair of medicines decision-making group or Medical Director from mental health and community services – HPFT, EPUT (two members representing community services and mental health), CLCH, HCT (5) • Local Medical Committee representative (2) • Local Pharmaceutical Committee representative, one from Community Pharmacy Hertfordshire , one from Community Pharmacy Essex (2) • Consultant in Public Health (*if not chair*) • Chair of subgroups (as needed) (if not a member/attendee in another capacity) • Pharmacists who have developed papers with the clinical staff may attend the whole meeting • Pharmacy team representatives from other local stakeholders including: Essex Child and Family Wellbeing Service (Virgin Care Services); NELFT NHS Foundation Trust In addition to regular committee members/attendees, other clinicians are invited to attend to provide expertise, necessary to the deliberations of the Committee. They will be asked to leave before the final decision-making process, and must complete a declaration of interests (DOI) form in advance of the meeting. Chair and secretary shall have the right to co-opt other specialists (e.g. contracts/finance leads) to the committee or to arrange for them to attend a meeting, if required, without voting rights. Other Healthcare professionals may attend the meetings as observers at the discretion of the chair but must complete a DOI form, agree to

	not disclose private/confidential information (e.g. on medicines costs) and are not part of the decision-making process/do not have voting rights. **Chair** In the absence of the nominated chair, the Professional Secretary will identify another voting member of the Committee to deputise.
Key Functions	• Advise HWE Integrated Care Systems (ICS) on the potential commissioning and provision of new medicines and new indications for medicines (including medical devices used for the delivery of medicines some of which may be prescribable on an FP10 and wound care management products, incontinence and stoma appliances and nutritional support) including the financial implications. Devices which do not deliver medicines are out of scope of this committee. • Provide prescribing advice to HWE clinicians across primary, community, secondary care and tertiary care • Inform the development of and ratify local medicine-related clinical guidelines or pathways and shared care guidelines, co-ordinating care across primary, secondary and community care, working in partnership within the framework of HWE service management e.g. Long Term Conditions programme board • Approve changes (additions/deletions) to local formularies for all medicines that are prescribed in primary and secondary care, promoting consistency of formulary choices across the ICS. • Those medicines which are used and funded solely within community / secondary care and which are not designated as high cost drugs within the national contract and commissioned by the ICS or NHS England, are considered by each respective Trust's Drug and Therapeutics Committee or equivalent. APC will note these DTC recommendations and provide further recommendations if there is an impact on health budgets (drug or activity costs). • Make recommendations for and maintain the traffic light classification for prescribing responsibility (See Appendix for traffic light definition). • Contribute to monitoring the implementation of recommendations for effective and appropriate medicines utilisation to inform strategic prioritisation and investment within the ICS. • Work with local Provider medicines Committees across HWE and receive their meeting minutes or an output summary for information. • Review and critically appraise the evidence and place in therapy and make recommendations for the commissioning of new medicines or new uses of medicines which are not being considered by NICE. • Work with providers and other stakeholders to develop prescribing recommendations/guidance/agreed care pathways linked to formulary changes that take account of the secondary / community / primary care interface and the overall cost implications of primary, community and secondary care prescribing taking account of HWE ICS strategic priorities and processes for overall prioritisation of investment.

Continued **Key Functions** *Continued*	• Note NICE Technology Appraisal (TAs) Guidance recommendations that concern prescribing and medicines usage. Identify the potential costs of NICE TAs and comment on how these fit within existing options for treatment of the same conditions. • Designate traffic light status, and where appropriate work with other groups within the ICS to advise on these changes to medicines use which may affect pathway development and implementation. (**NB** NICE TAs may be added to the local Formularies prior to ratification by the APC as ICS/NHSE funding of these TAs is mandatory within specified timescales. Where there is uncertainty about traffic light status this will be designated as red status until discussed in relation to patient pathways, and at the HWE APC). NICE TAs for NHS England-commissioned medicines will be noted by the APC. • Note, advise and/or make recommendations on the implementation of medicine-related NICE Clinical Guidelines recognising in these processes that commissioners are not mandated to provide funding for all treatment recommendations within NICE guidelines and that expenditure on medicines cannot be agreed other than as part of delivering ICS strategic priorities. • Note the publications of the implementation of NICE Highly Specialised Technologies Guidance. • Note and comment on HWE APC work plan and priorities. • Support the East of England Priorities Advisory Committee (EoEPAC) and work with other neighbouring NHS organisations contributing to development, consultation, ratification and implementation of recommendations as appropriate. **NB** The APC would normally expect to adopt the EoEPAC recommendations with local amendments when required. • Support the Regional Medicines Optimisation Committee (East of England) by contributing to development and ratification of their recommendations (where supported). • Respond to and prioritise NHS policy developments impacting on prescribing and medicines use, including medicines safety issues. • Define and ensure the completion, analysis and reporting of data, demonstrating the outcomes of APC decisions across the health system, against anticipated place in therapy, understanding and sharing the reasons for significant variances where these occur. • Promote information sharing and good practice to facilitate safer medicines use. Make recommendations to stakeholder organisations in responding to and implementing relevant actions in response to safety alerts from organisations such as the MHRA and NHS Improvement Patient Safety Alerts. Share learning on significant events. • Consider and ratify recommendations of sub committees. • Communicate recommendations and outputs effectively to all relevant member and stakeholder organisations and promote appropriate implementation process.
Conflict of Interest[i]	Any conflicts of interest (potential or actual) must be declared, recorded and a report made available for public scrutiny. In the case of committee members and regular attendees they may be asked to leave the meeting during the decision-making process if a potential conflict of

Continued **Conflict of Interest** *Continued*	interest is identified. ICB policies will be adhered to under these circumstances. • Committee members/regular attendees to complete a Declaration of Interests form on appointment and then re-confirm at least annually. • The declaration of interests to be recorded in a register maintained by ICB, a copy to be available for each meeting and made publicly available on the ICB website. • At each meeting committee members/regular attendees are required to make any new declaration of interest or declaration relating to matters on the agenda, or to reconfirm current declarations on the Register of Interests are accurate and up-to-date. • Where a new declaration of interest or declaration relating to matters on the agenda are made the following should be recorded in the minutes of the meeting: o Individual declaring the interest. o At what point the interest was declared. o The nature of the interest. o The Chair's decision and resulting action taken. o The point during the meeting at which any individuals retired from and returned to the meeting - even if an interest has not been declared. Anyone developing or commenting on papers/guidelines must declare any potential conflicts of interest or a nil return. When papers are circulated for comment they are sent with a declaration of interest form for completion by anyone wishing to send comment or a request to respond with a nil return. All committee members/attendees or anyone involved with the development of papers/guidelines must adhere to their organisational policies on conflicts of interest, gifts, hospitality, commercial sponsorship, working with the pharmaceutical industry, fraud and bribery and secondary employment. Committee members/regular attendee will be required to make an annual declaration. Healthcare professionals must act in accordance with their profession's code of conduct. *Further Guidance, including for attending specialists* 1. Specialist/consultant advice is needed to help get a local opinion on recommendations, therefore the approach is to ensure that visiting professionals have the opportunity to contribute. 2. As vital to trust in decision-making, all participants need to be transparent about sponsorship and links to pharmaceutical companies and other organisations with potentially competing interests. NHS organisations and healthcare professionals should be aware of and comply with wider transparency initiatives such as the ABPI Disclosure UK scheme and NHS/ICS standards of business conduct

Continued **Conflict of Interest** *Continued*	3. It should be noted that public perception of conflict of interest can be damaging for NHS organisations, even if a perceived conflict is not believed to be of a significant magnitude. Therefore, a precautionary approach is recommended. Any visiting consultants/specialists invited and should only attend for their item. Presenting/attending specialists must declare any conflicts of interest or a nil return in advance of the meeting they are attending. The declaration will be included within the papers. This enables any conflicts of interest to be discussed properly prior to the meeting. Consultants or other professionals should be made aware beforehand that they can't just attend *ad hoc* and contribute to discussions on other agenda items. However, in practice there will be a proactive process and agenda items will be reviewed in advance to identify consultants who are attending anyway, who may add value by contributing to other items. Planned attendance means any perceived conflict of interest can be managed in a transparent way which acknowledges public concerns, but allows the consultant voice to be heard. It will also allow for items potentially connected in this way to be sequential on the agenda. 4. If a medicines optimisation staff member has developed a paper with a 'conflicted' specialist/consultant then the robustness of the paper could be called into question. In general, the current process provides mitigation for this issue as there is representation from medicines optimisation team members from other parts of the area, and they will review the documents independently. The consultation process and meeting also gives the opportunity to challenge. 5. Attending specialists will be asked to leave before the final decision-making process 6. Where an ICB medicines optimisation team presenter has (or is believed to have) a potential Conflict of Interest, they should be invited to attend and contribute to the discussion on the issues but they should not take part in the final decision making and they may be asked to leave the meeting when the decision making occurs. 7. APC committee members/attendees who have a competing interest may also be asked to leave when decisions are made (at the discretion of the chair). This needs to be planned for, so that quoracy can be achieved. 8. The final decision on how a Conflict of interest is managed rests with the committee chair. 9. The minutes/notes should say how conflicts of interest were managed so there is a clear audit trail.
Quoracy	The **Committee** will be **quorate** to make recommendations if at least the following Committee members or nominated deputies without competing interests are present:- ▪ Two GP Clinical Prescribing Leads ▪ Two provider representatives (one of which must be a medical doctor [Consultant] from acute trust) ▪ HWE ICB Chief Pharmacist or Lead Pharmacist

	▪ Chair or acting chair ▪ Professional secretary to the committee **N.B. All these members <u>must</u> have a nominated deputy.**
Continued **Quoracy** *Continued*	Should non-attendance by members / organisations result in the meeting not being quorate, the chair may determine that there are appropriate people present to make decisions and allow the meeting to proceed. • Some agenda items may be rescheduled if necessary. • All decisions made when the meeting is not quorate must be circulated by email and approved by enough members to achieve quoracy and a post-meeting record will be added to the notes. Quoracy will then be taken as agreed. • If a recommendation made during a non-quorate meeting is not endorsed by an absent member required for quoracy, then that recommendation will be brought back to the next committee meeting for discussion. Some papers may receive virtual consideration by the Committee. Recommendations agreed by this process will need to be noted at a full Committee meeting before they are issued. The same minimum quoracy is required to make virtual decisions.
Method For Reaching Final Recommendations	**At the meeting:** ▪ Committee to give views on the evidence presented and specialists' comments. ▪ Committee to make assessment against the ethical framework and make a commissioning recommendation. ▪ Generally it is expected that at the committee meetings recommendations will be reached by consensus. Should this not be possible and all work on the item has been completed, the Chair will determine that a vote of members will be required. A vote could be deferred to a subsequent meeting if the committee agree that further information / evidence and stakeholder feedback needs to be obtained. The process for voting is set out below: a) Eligibility – Voting Membership is as follows. Chair – Consultant in Public Health (or nominated deputy) Chief Pharmacist, HWE ICB (or nominated deputy) GP Clinical Prescribing Lead, HWE ICS (or nominated deputy) GP Clinical Prescribing Lead, WE (or nominated deputy) GP Clinical Prescribing Lead, ENH (or nominated deputy) GP Clinical Prescribing Lead, SWH (or nominated deputy) Clinical Effectiveness Lead Pharmacist, HWE ICB (or nominated deputy)

Continued

Method For Reaching Final Recommendations

Continued

Medication Quality and Safety Lead Pharmacist, HWE ICB (or nominated deputy)
Financial Assurance, System Integration & Innovation Lead Pharmacist, HWE ICB (or nominated deputy)
Consultant Chair of medicines decision-making group or Medical Director, ENHT (or nominated deputy or Chief Pharmacist)
Consultant Chair of medicines decision-making group or Medical Director, PAH (or nominated deputy or Chief Pharmacist)
Consultant Chair of medicines decision-making group or Medical Director, WHHT (or nominated deputy or Chief Pharmacist)
Chief Pharmacist, EPUT mental health services (or nominated deputy)
Chief Pharmacist, HPFT (or nominated deputy)
Chief Pharmacist, CLCH (or nominated deputy)
Chief Pharmacist, EPUT community health services (or nominated deputy)
Chief Pharmacist, HCT (or nominated deputy)

Under no circumstances may an absent member vote by proxy, but they can delegate their vote in writing to an attending colleague. Absence is defined as being absent at the time of the vote. A vote may only take place if the Committee meeting is quorate.

a) Voting – At the discretion of the Chair all questions put to the vote shall be determined by oral expression or by a show of hands, unless they direct otherwise or it is proposed, seconded and carried that a vote be taken by ballot. If at least one-third of voting members present so request, the voting on any question may be recorded to show how each member voted or did not vote except where conducted by ballot.
b) Majority necessary to confirm a decision – every question put to the vote at a meeting shall be determined by a majority of votes of voting members present and voting. Voting members receive one vote only, e.g. if a voting member is deputising as the Chair of the meeting, they do not get a vote as the Chair and a separate member vote.
c) Casting vote – In the case of an equal vote, the Chair of the meeting shall have the casting vote.
d) Should a vote be taken the outcome of the vote must be recorded in the minutes of the meeting.
e) Abstaining from the vote – Voting members can choose to abstain from the vote. The abstaining member's vote may not be transferred to another voting member.
f) Concerns raised / dissenting views – A record shall be made in the minutes of the meeting of any concerns raised / dissenting views.

Committee Secretariat and setting the agenda	The Committee will be supported by a Professional Secretary and administrative staff employed by HWE ICB. All represented organisations on the Committee will be able to request agenda items for discussion at meetings. Items to be prioritised via the workplan.
Pre-Meeting Preparation	▪ Stakeholders to agree lead for evaluation document development as prioritised within the workplan. ▪ Local specialists to liaise with their provider pharmacy teams if they would like a treatment to be considered for use. This will be added to the workplan and prioritised accordingly. ▪ Evaluation papers to be sent out to provider pharmacy representatives, to obtain views of wider specialists, ideally 5 weeks but at least 4 weeks in advance of meetings. Provider pharmacy representatives are responsible for co-ordinating responses from relevant specialists within their Trust. ▪ Paper lead author should collate consultation comments and clarify points of discussion *prior* to the APC paper being finalised and circulated. ▪ Papers will be sent out to GP Clinicalprescribing leads, to obtain views of their practices, ideally 5 weeks and at least 4 weeks in advance of meetings. ▪ Final papers will be sent out to members/regular attendees at least 9 working days in advance of meeting. ▪ Members/regular attendees will read and review paperwork and bring comments to the committee for discussion.
Frequency of Meetings	A minimum of six meetings a year at approximately two-monthly intervals. Additional meetings may be held at the discretion of the Chair.
Duties and Responsibilities	**CHAIR** • The Chair should consider any known interests of members / attendees in advance and begin each meeting by asking for declaration of relevant interests. The Chair should take appropriate action in relation to declarations of interest. • Ensure the smooth and timely running of meetings. • Facilitate and ensure effective stakeholder participation. • Ensure process is followed and that the case supporting recommendations is consistent with the critical appraisal of the evidence and that the rationale for the recommendations are clearly captured for the record of the meeting. • Clarify and ensure that the rationale for each APC recommendation is documented and followed up. **MEMBERS/REGULAR ATTENDEES** • Commit to regular attendance at HWE APC meetings and their attendance to be regularly informed by the considered views of their service area / organisation and their peers. <u>Ensure nominated equivalent deputy in place if unable to attend.</u>

Continued **Duties and Responsibilities** *Continued*	• Gather their service area / organisation's view (including specialists) on the evaluation and proposal including evidence for clinical and cost effectiveness in the papers circulated to the group in advance of the meeting. • Critically appraise the evidence, ethical framework considerations and test the rationale in the case for change, using their clinical and/or management knowledge to consider the impact on patient care. • Promote two-way communication between HWE APC meetings and relevant service area / organisation and communicate / champion decisions from HWE APC to their organisations for implementation. • Read relevant papers / discussion documents as supplied for the meeting prior to attendance at the HWE APC meeting so that discussions can be informed and as concise as possible, and agreement can be reached. • Undertake work as necessary between meetings. • Voting members to have the authority to make decisions on behalf of their constituent organisations or professional groups. Support decision making process usually reached by consensus. Voting members to vote when this cannot be reached. • Complete an annual declaration of interests (DOI) form and ensure the register is up to date. The Chair will request any additional declarations at the beginning of each meeting which might have a bearing on their actions, views and involvement in discussions within APC. • Attend training sessions related to APC functions and process.
Relationship to other bodies	The HWE APC makes recommendations to and receives guidance from to the whole health economy (ICB, place based groups and Trusts) about the use (including effectiveness, cost-effectiveness) and relative priority for funding of medicines.
Output and Communication	Recommendations from the HWE APC are actioned, communicated and presented in a variety of formats including: • Recommendations and outputs are added to Public Facing website and communicated to all stakeholders • Additions/deletions to Formularies • Blueteq forms updated/amended • Appropriate ScriptSwitch messages added • Summarised information issued to GP practices, Community Pharmacists, stakeholders and Committee Members / organisations and any other healthcare professionals who have asked to receive a copy of the recommendations. It is the responsibility of all Committee members to ensure that they communicate the APC recommendations in an appropriate manner to the organisation that they represent. Organisations should adopt, communicate and implement recommendations and update formularies accordingly.

Nature of decisions and reporting mechanisms	ICB's have budgetary responsibility for treatments that fall within ICS funding responsibility, for their populations. The ICB/ICS has a statutory duty to break even within their allocated annual financial budget. Except where a recommendation in respect to a particular treatment is laid down by the National Institute for Health and Care Excellence as a technology appraisal (TA), ICS's have to set their own priorities and policies at board level in order to guide their officers as to how the ICSs' resources should be allocated between conflicting demands for treatment or care. The HWE APC will make recommendations but recognises that it is without delegated funding authority. All outputs must be formally reported, prioritised and ratified by the HWE ICB Commissioning Committee or other agreed mechanism. Where a recommendation is both drug and activity cost neutral or cost saving, this may be implemented in advance of formal ratification. Outputs eg implementation resources, developed to support a recommendation previously made and not associated with an additional separate cost-pressure may be implemented in advance of formal ratification. Where a recommendation is for a NICE TA, drugs may be added to formulary in advance of formal ratification to allow for implementation within the mandated time scales. Commissioners have a statutory responsibility to comply with and make funding available to comply with NICE TA recommendations within the timeframe recommended in that guidance, usually within 3 months of the TA being published (1 month for fast-track TAs). Where a non-NICE TA recommendation has a cost pressure this must be reported for consideration before implementation. The recommendation will then be reviewed for prioritisation and consideration for affordability and formal ratification by the HWE ICB Commissioning Committee or other agreed mechanism. Where a decision is considered to be required urgently and a delay inappropriate (e.g. updated safety advice from MHRA or antimicrobial prescribing guidance from NICE and Public Health England) the proposed recommendations supported by ICB PMOT, and cost pressure information to be reported to and agreed with ICB Medical Director and ICB Chief Finance Officer (or deputies) before implementation, in advance of formal decision making. APC recommendations will be reported to Trust Drug and Therapeutics Committees (or equivalent) within HWE. As representatives from these Trusts participate in the APC decision-making process, APC decisions will be adopted by Providers within HWE.

Continued **Nature of decisions and reporting mechanisms** *Continued*	<u>Public Health Documents</u> HWE APC will review Public Health documents where there is an impact on medicines use across HWE but ratification processes for Public Health documents lie outside of HWE APC where the developing organisation is responsible for approval. Ideally public health documents should be brought to the committee and reviewed prior to final publication. It should therefore be noted that the purpose of HWE APC in relation to Public Health documents is not to ratify but rather review and advise.
Equality and Diversity	The HWE APC commits to have due regard to Equality, Inclusion and Human Rights considerations in its decision-making process and this is included in the Ethical Framework used by the Committee. (See Appendix – Associated Documents) <u>Equality Impact Process</u> APC paper author: • Considers any differential impact of the recommendations / guidelines on people with protected characteristics (neutral, positive and negative) • Completes an Equality Impact statement (this is in the form of a summary paragraph of text) within the APC paper including highlighting any actual (or likely) differential impact. The aim is to ensure that recommendations / guidelines: o have at least, a neutral impact on people with protected characteristics o identify negative or adverse impact and if it can be removed or reduced, and then plan to remove or reduce it or justify why it can't be removed or reduced o identify opportunities to promote equality • When paper is being consulted on in advance of APC meeting this is sent to HWE Equality and Diversity Lead for comment on the Equality Impact statement • HWE Equality and Diversity Lead will respond with comments concerning the statement including: if the statement is appropriate, proportionate and adequate, if further information / clarification is required and/or if a full Equality Impact Assessment is recommended. (If it is thought to have a major impact – standard Equality Impact Assessment paperwork to then be completed): o Comments are included in the APC paper o Any further information/clarification is provided to HWE Equality and Diversity Lead and subsequent response included in the paper o Full Equality Impact Assessment undertaken in liaison with HWE Equality and Diversity Lead when recommended and included with APC paper • APC paper submitted to APC committee including Equality Impact statement and all comments and/or with Full Equality Impact Assessment when recommended.
Appeals Process	The HWE APC is willing to re-consider recommendations made if new significant drug information on efficacy, safety or cost is provided to the Committee.

<table>
<tr><td></td><td>Applicants can appeal the HWE APC decision where they believe the process has not been followed. The first appeal will be considered by HWE APC.

If applicants remain unhappy with the outcome of the first appeal, they can make a second appeal where Bedfordshire, Luton and Milton Keynes Area Prescribing committee will review the process of decision making.</td></tr>
<tr><td>Document history</td><td><table>
<tr><td>Version</td><td>3.0</td></tr>
<tr><td>Developed by</td><td>HWE ICB Pharmacy and Medicines Optimisation Teams and external Senior Specialist Pharmaceutical Adviser
09/06/2022 – minor updates agreed at HWE APC
02/02/2023 – updates to GP Clinical Prescribing Leads and HWE ICB PMOT to align with new structures
08/02/2024 - update to green RAG recommendation wording
18/04/2024 – updates to delegation approved by HWE ICB Commissioning Committee and Board.</td></tr>
<tr><td>Date ratified</td><td>18/04/2024 – APC (updates to delegation approved by HWE ICB Commissioning Committee and Board).
02/02/2023 at HWE APC and 09/03/2023 at HWE ICB Commissioning Committee</td></tr>
<tr><td>Review dates</td><td>every 2 years</td></tr>
</table></td></tr>
<tr><td>Context</td><td>The following publications have been considered for the development of the HWE APC Terms of Reference:
▪ The NHS Constitution for England

▪ Defining guiding principles for processes supporting local decision making about medicines Supporting rational local decision-making about medicines (and treatments)

▪ NICE Good practice guidance (GPG1) on developing and updating local formularies.</td></tr>
<tr><td>Review of the Committee</td><td>The committee will undertake a regular self-assessment to:
▪ Review that these Terms of Reference have been complied with and whether they remain fit for purpose;
▪ Determine whether its planned activities and responsibilities have been sufficiently discharged; and,
▪ Recommend any changes and / or actions it considers necessary, in respect of the above.</td></tr>
<tr><td>Clinical Responsibility</td><td>Decisions made by the APC are arrived at after careful consideration of the evidence available. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. However, the APC guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.</td></tr>
</table>

Appendix

Appendix 1 - Classification of new drugs and therapies (RAG rating)

DOUBLE RED – Not recommended for prescribing by either Community/Secondary/Tertiary or Primary care; NOT a priority for funding. Such a treatment should only be used in exceptional cases (refer to Individual Funding Request policy) and prescribing may be subject to challenge. Any treatment appraisals terminated by NICE will automatically be designated a "double red" category.

RED – Not recommended for prescribing in Primary Care (for prescribing by Community/Secondary/ Tertiary care as agreed) because of clinical or other issues and/or treatments are specialist national tariff excluded, or funding responsibility lies with NHS England; Prescribing may be subject to challenge.

AMBER INITIATION – Recommended for prescribing but only considered suitable for initial prescribing by specialists in Community, Secondary and Tertiary care (as agreed) with prescribing (and monitoring, where applicable) continued by GPs. A shared care agreement is not required here but the patient's GPs must be supplied with sufficient information on the prescribed medication. Examples fitting this category are where dose stabilization is needed, or where treatments are complex but the monitoring is not great enough to require amber protocol status.

AMBER PROTOCOL – Recommended for prescribing but only considered suitable for initial prescribing by specialists in Community, Secondary and Tertiary care (as agreed) with prescribing and monitoring continued by GPs and Primary Care Clinicians in conjunction with a Shared Care Agreement. The Shared Care Agreement must follow HWE APC Shared Care Principles in order for it to be accepted.

These amber categories must not be confused with the Amber category in the National Enhanced Service.

GREEN – Recommended for prescribing and treatment considered to be suitable for initiation in Primary, Community, Secondary or Tertiary care and continuation in Primary Care.
Prescribers must recognise and work within the limits of their competence and must maintain and develop knowledge and skills relevant to their role and practice, including prescribing and managing medicines. Green status does not mean that a treatment must be initiated by a prescriber if they consider it is not within the limits of their competence and they do not have the current clinical knowledge and skills. This may be particularly relevant for recently licensed/approved medicines/new indication(s) for existing medicine. Advice can be sought from an appropriate experienced colleague, or advice and guidance can be sought from an appropriate specialist to support a prescribing decision.

Any new drug or new indication is regarded as a Double Red drug until considered by HWE APC.
This excludes branded generics, hybrid (generic) inhalers and biosimilars – the decision to use a branded generic or hybrid (generic) inhaler lies outside of APC; the decision to use a biosimilar lies with individual provider Trusts providing the biosimilar and implementation adheres to the standards described in the Biosimilars Position Statement and/or contractual agreements with the commissioner.

Associated Documents

1. Template evaluation paper
2. HWE APC Ethical Framework

Abbreviations

APC: Area Prescribing Committee

CLCH: Central London Community Healthcare NHS Trust

DOI: Declaration of Interest

DTC: Drug and Therapeutics Committee

ENH: East and North Hertfordshire

ENHT: East and North Hertfordshire NHS Trust

EoEPAC: The East of England Priorities Advisory Committee

EPUT: Essex Partnership University NHS Foundation Trust

FP10: NHS Prescription form

HCT: Hertfordshire Community NHS Trust

HPFT: Hertfordshire Partnership University NHS Foundation Trust

HWE: Hertfordshire and West Essex

ICB: Integrated Care Board

ICS: Integrated Care System

LMC: Local Medical Committee

LPC: Local Pharmaceutical Committee

MHRA: Medicines and Healthcare Products Regulatory Agency

NHSE: NHS England

NICE: National Institute for Health and Care Excellence

PAHT: The Princess Alexandra Hospital NHS Trust

PMOT: Pharmacy and Medicines Optimisation Team

RMOC: Regional Medicines Optimisation Committee

SWH: South and West Hertfordshire

TA: Technology appraisal guidance (NICE)

WE: West Essex

WHHT: West Hertfordshire Hospitals NHS Trust

[i] For the purposes of the Herts & West Essex Area Prescribing Committee (HWE APC) the rationale used by the British Medical Journal will be applied when assessing whether matters may be a potential conflict of interest (a “Competing interest”)
See https://www.bmj.com/about-bmj/resources-authors/forms-policies-and-checklists/declaration-competing-interests and https://www.bmj.com/content/349/bmj.g7197