East Lancashire Health Economy
Medicines Management Board

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Overarching Policy for the Managed Introduction of New Drugs

Priority Setting of Medicines (Policy Decisions)

East Lancashire Medicines Management Board

1/4/2020

East Lancashire Health Economy has a coordinated approach to managing medicines. This is a collaboration between Blackburn with Darwen (BwD) Clinical Commissioning Group (CCG), East Lancashire (EL) Clinical Commissioning Group (CCG) and East Lancashire Hospitals NHS Trust (ELHT). The overall aim is to take a Health Economy approach to the commissioning and use of medicines across the primary/secondary care interface, linking with Tertiary Centres and other specialist providers where appropriate.

NHS Blackburn with Darwen Clinical Commissioning Group
NHS East Lancashire Clinical Commissioning Group
East Lancashire Hospitals NHS Trust

Scope	Health Economy Wide (NHS ELCCG; NHS BwD CCG; ELHT)	
Classification	Policy	
Authors	Richard Lee – Senior Commissioning Pharmacist (2009) Dr Lisa Rogan – Head of Medicines Commissioning (2011;2013, 2016) Strategic Director of Medicines , Research and Clinical Effectiveness (2020)	
Reviewed	2011; 2013; 2016; 2020	
Review Date	April 2023	
Equality Impact Assessment ca rried out		Yes
Version Number	7	

Policy statement / Key objectives:
The objectives of this policy are to help constituent organisations:

1. Commission medicines and related services using the most effective and efficient management of resources
2. Provide unbiased, accountable commissioning, leadership and strategic co-ordination of the use of medicines
3. Commission services using medicines that focus on achieving improved clinical outcomes.

Supporting Information (NHS Confederation):
Priority Setting: An overview
Priority Setting: Managing Individual Funding Requests
Priority Setting: Managing New Treatments
Priority Setting: Legal Considerations
Priority Setting: Strategic Planning

- [1] Annex A of Payment by results: Implementation support guide 2006/07 (technical guidance). http://www.dh.gov.uk/PolicyAndGuidance/OrganisationPolicy/FinanceAndPlanning/NHSFinancialReforms/fs/en
- [2] Which includes a medicine, medical device, diagnostic technique, surgical procedure and other therapeutic intervention.
- [3] See Directions to Health Authorities, Primary Care Trusts and NHS trusts in England dated 11th December 2001 ("the 2001 Directions"). The 2001 Directions have been replaced by Directions to Primary Care Trusts and NHS trusts in England concerning Arrangements for the Funding of Technology Appraisal Guidance from the National Institute for Clinical Excellence (NICE) dated 1 July 2003 (as amended by Directions dated 24 September 2003, 13 February 2004, 30 September 2004, 30 August 2005 and 1 April 2006).

Introduction

"Need and demand for healthcare always exceeds the funding that is available to the NHS. This requires CCGs to prioritise needs into those that will be met and those that will not. The challenge lies in arriving at fair decisions which properly balance competing needs."

The NHS Confederation, 2007

Section 1

Purpose of the Policy

East Lancashire Health Economy has a coordinated approach to managing medicines which is collaboration between NHS Blackburn with Darwen (BwD) Clinical Commissioning Group (CCG) NHS East Lancashire (EL) Clinical Commissioning Group (CCG) [collectively identified as Pennine Lancashire (PL CCGs)] and East Lancashire Hospitals NHS Trust (ELHT). The overall aim is to take a Health Economy approach to the commissioning and use of medicines across the primary/secondary care interface, linking with Tertiary Centres and other specialist providers where appropriate.

All three organisations note their responsibilities in line with the guidance published in HSC 1999/176 which states:

"If a new intervention is not referred to NICE, this does not imply any judgement on whether the intervention(s) in question are clinically or cost effective. NHS bodies should continue to use existing arrangements to access the publicly available evidence and to determine local policies for the managed entry of the new intervention. The same principle should apply if an intervention has been referred to NICE but guidance is not yet available at the point at which the new intervention is first introduced".

This message has been reiterated in 'Best Practice Guidance ref: 7521' issued in December 2006 which states:

'It is not acceptable to cite a lack of NICE guidance as a reason for not providing a treatment. A key role of the NHS is to make decisions about the use of new interventions and this has always been the case, long before NICE was established.'

Clinical Commissioning Groups (CCGs) in Pennine Lancashire aim to commission the provision of high quality clinical care for the population equitably and consistently, based solely on clinical need and within the resources available. The best way to achieve this is by commissioning clear pathways of care which span the interfaces between primary and secondary care (and tertiary when required) and are supported by shared clinical protocols, policies and arrangements for audit and outcome evaluation. To achieve this aim and ensure that the commissioning of medicines is clinically led, joint decision making with the local main Acute NHS provider (ELHT) and Primary Care Takes place to ensure consistency of decisions between primary and secondary care,

which are ‘owned’ by clinicians across the system.

The commissioning of medicines in relation to specialist services commissioned by the NHS England is outside the scope of this policy.

This policy sets out the process for ratification of recommendations relating to new and existing medicines, and to provide reassurance that the process is **consistent, predictable, open and transparent**.

Section 2

Prioritisation and In Year Service Developments

The successful introduction of new medicines results in patients having smooth and timely access to new medicines, when funding has been agreed following a formal prioritisation process that is in line with the organisation’s strategic policy.

Prioritisation, which is how relevant organisation’s aim to make their decisions, is a complicated process, which takes a comprehensive view of a treatment and sets its priority against existing services and other potential service developments.

In a system that operates with fixed budgets and unmet healthcare need, prioritisation of medicines is essential which takes into account the clinical and cost effectiveness whilst also linking this to the opportunity costs and/or affordability.

Section 3

Population Decision Making vs. Individual Cases

Consideration of new drugs/technologies will take place within established commissioning frameworks of the NHS after consideration by the appropriate committees including NICE, Regional Medicines Optimisation Committees (RMOCs) and the local Lancashire and South Cumbria Medicines Management Group – LSCMMG).

The introduction of new medicines on an ad hoc basis risks inequity since the treatment may not be offered openly and equally to all with equal clinical need. There is also the risk that diversion of resources in this way will de-stabilise other areas of health care which have been identified as priorities.

It is recognised that there may be individual cases where a patient’s needs cannot be met through existing care pathways. CCGs have arrangements in place for considering individual cases where a referral outside existing pathways may be appropriate. This may include consideration by an Individual Cases Panel.

Section 4

Purpose of the East Lancashire Medicines Management Board (ELMMB)

The East Lancashire Medicines Management Board (ELMMB) will act with mandated authority under the scheme of delegation from the Boards of the three constituent organisations (NHS BwD CCG, NHS EL CCG and ELHT).

The East Lancashire MMB will provide a forum for review and approval of recommendations from the RMOCs and the Lancashire Medicines Management Group (LSCMMG) and other relevant groups and/or individuals relating to the use of medicines. The group will provide a forum for discussion and understanding of how recommendations will fit into local clinical care pathways and CCG commissioning priorities whilst ensuring equity in access to medicines and optimisation of medicines use. The ELMMB will make recommendations to commissioning groups and provider organisations for adoption in order to ensure the best use of medicines and associated resources across the health and social care system. The ELMMB will ensure that processes underpinning local decision-making about medicines and treatments are consistent with the NHS Constitution and in accordance with common law. Member organisations of the ELMMB will receive and consider the recommendations and decisions of the Board through their own governance processes.

The full terms of reference for the East Lancashire Medicines Management Board (MMB) can be found in *Appendix 1.*

Section 4a
Principles that underpin the decision making process

Newly developed, newly licensed, newly indicated, or unlicensed* drug-based treatments or interventions will only be commissioned in the presence of a formally agreed and funded local policy which is in line with NHS funded clinical research trials in which the CCGs would be obliged to fund excess treatment costs. `

* *i.e. without a licence covering the indication concerned in the UK.*

Decisions will also be made on the potential for disinvestment where this is appropriate, to make additional resources available.

Stakeholders will prioritise requests for funding of medicines, or changes to established medicine-based treatments through delegated authority to make recommendations to the host organisations against the following criteria:

i. **Legality *(is it lawful?)***
Ensure that any decision taken on the commissioning of medicines is within its legal powers and complies with the principles of the Human Rights Act (which *do not* impose on the Commissioning Organisation a duty to provide comprehensive health care).

ii. **Safety (*'first do no harm')***
Ensure decisions are not complicit in exposing patients to unsafe healthcare and will look to licensing authorities such as the Medicines Healthcare Regulatory Agency (MHRA), EMEA and FDA, and other resources such as

NICE and the BNF for guidance.

iii. **Clinical Effectiveness *(does it work?)***
Recommend medicines following a review of the best available evidence. The MMB will prioritise interventions that produce the greatest clinical benefits for the population.

iv. **Cost Effectiveness *(is it an efficient way of using resources?)***
Recommend medicines that yield the greatest benefits relative to the cost based on the best available evidence. This balances the clinical and cost effectiveness of a service or treatment.

v. **Equity – Including Equality and Diversity *(is it a fair way of using resources?)***
Endeavour to ensure that where medicines are commissioned, they are available to all suitable patients who will gain the most benefit from them, taking into account the requirement to balance the needs of the individual and those of the population.

vi. **Accessibility *(can people get to the service?)***
Whenever possible ensure that recommended medicines are equally accessible to all the people they serve.

vii. **Affordability *(do we have the resources to pay for it?)***
Make recommendations on affordability in light of the totality of resources available to stakeholders. Where issues of affordability arise, the recommendations of ELMMB may require additional advice and input from individuals or groups from within the constituent organisations before a final decision is made by the Board.

Section 4b
Principles for Commissioning of Health and Healthcare

CCGs have a statutory duty to promote the health of the local community, and a duty not to exceed their annual financial allocation. These legal requirements mean that difficult choices have to be made and such decisions must be supported and enabled by a clear and equitable ethical framework.

The principles for the commissioning of health and healthcare have been agreed by commissioning organisations across Lancashire and are reproduced in *Appendix 2.*

Section 4c
Appraisal of End of Life Medicines

ELMMB may be asked to appraise life-extending medicines licensed for terminal illnesses affecting small numbers of patients, which, following appraisal, are deemed to have an incremental cost effectiveness ratio in excess of the upper end of the range normally approved by the MMB (in line with the NICE thresholds), but which may offer demonstrable survival benefits over current NHS practice**.**

NICE have amended their advice to their appraisal committees, and ELMMB will also follow this advice in full. This supplemental guidance for ELMMB can be found in *Appendix 3.*

In short, the NICE *Guide to the Methods of Technology Appraisal* recognises that there will be circumstances in which it may be appropriate to recommend the use of treatments with higher incremental cost effectiveness ratios (ICERs). It states (with reference to NICE's standard appraisal criteria) that: *Above a most plausible ICER of £30,000 per QALY gained, the Committee will need to identify a stronger case for supporting the technology as an effective use of NHS resources.* The purpose of this supplemental advice is to indicate to the NICE Appraisal Committees, RMOCs and subsequently ELMMB, the circumstances in which it may be appropriate to recommend the use of life-extending medicines licensed for small populations with terminal illnesses.

Section 4d
Experimental or Unproven Treatments

Definitions

Experimental and unproven treatments are medical treatments or proposed treatments where there is no established body of evidence to show that the treatments are clinically effective. They may include the following:

- Treatment is still undergoing clinical trials for the indication in question
- The evidence is not available for public scrutiny.
- Treatment does not have approval from the relevant government body.
- Treatment does not conform to an established clinical practice in the view of the majority of medical practitioners in the relevant field.
- Treatment is being used in a way other than that previously studied or for which it has been granted approval by the relevant government body.
- Treatment is novel, rarely used, or unknown and there is a lack of evidence of safety and efficacy.
- There is some evidence to support a case for clinical effectiveness but the overall quantity and quality of that evidence is such that the commissioner does not have confidence in the evidence base and/or there is too great a measure of uncertainty over whether the claims made for a treatment can be justified.

Effectiveness means the degree to which objectives which have been identified in advance are achieved.

C*linical effectiveness* is a measure of the extent to which a treatment achieves the pre-defined clinical outcomes in a target patient population.

A treatment is *efficacious* if it has been shown to have a beneficial effect in a carefully controlled and optimal environment. It is not always possible to have confidence that data from clinical trials will translate in clinical practice into the anticipated or any meaningful health gain for the target patient population of interest. This is the difference between disease orientated outcomes and patient orientated outcomes. For example a treatment might have demonstrated a change in some physiological factor which is used as a proxy measure for increased life expectancy but this relationship might not be borne out in reality.

- Treatments which are judged experimental or not to be of proven effectiveness will not routinely be recommended for funding; and

- Funding for individual patients or groups of patients within trials or unstructured 'evaluation' of new treatments will not be supported.

ELMMB will strive to fulfil the requirements of the R&D Concordats to which the CCGs may be subject however the CCG will take the final decision as to affordability after it has taken into account competing demands.

ELMMB will be prepared to consider recommending the funding of a clinical trial or to sponsor a patient(s) into an existing on-going trial but funding cannot be guaranteed. The ability of the CCG to support R&D is influenced by:

- **Capacity constraints within the CCG management resource**. This is particularly an issue where the trial has to be 100% commissioned by CCGs. This can be a labour intensive process and CCGs are not currently resourced to do this.
- **The research priorities of the clinical community**. However desirable a trial, clinical or R&D support, there can be no guarantee that a given evaluation is a research priority for the clinical and R&D community, on whom commissioners are dependent for delivering a trial.
- **Financial constraints**. Any trial has to be prioritised against competing needs.

Although ELMMB may make a recommendation on the priority of the funding request, the final decision rests with the CCG.

All decisions regarding clinical trials will be in line with the individual primary and secondary care research policies and research governance frameworks.

Section 5

Proactive review of New Technologies

The Lancashire Medicines Management Group (LSCMMG), through horizon scanning, will identify and prioritise medicines at and prior to launch. For some new medicines assigned a high priority, a member of the Lancashire Medicines Management Group, or other outside commissioned individual or organisation will produce an evidenced based review of the medicine. The Lancashire Medicines Management Group (LSCMMG) will liaise with key stakeholders within its constituent organisations, and outside, to gain additional expert clinical advice and input into the draft recommendations contained within the 'New Drug Review' that will be considered by the LSCMMG.

New medicines requests will be submitted to the LSCMMG for consideration, review and development of recommendations or which will subsequently be submitted to the East Lancashire Health Economy Medicines Management Board (ELMMB) for final ratification and adoption. There may be some recommendations from LSCMMG that are ratified through the Lancashire and South Cumbria Joint Committee of CCGs (LSC JCCCGs) in line with delegated authority. ELMMB will consider the recommendations from the Lancashire and South Cumbria MMG with respect to local implementation, impact on local care pathways and CCG commissioning priorities. The Lancashire and South Cumbria Medicines Management Group may resubmit additional information to the East Lancashire MMB if appropriate.

The CCGs and/or providers may work collaboratively with other NHS organisations in clusters or networks, to consider the funding of drug-based interventions or treatment, and other commissioning priorities to reduce duplication of effort. Recommendations from such advisory groups, where they relate to medicines should be considered by the LSCMMG, who with delegated authority to make recommendations will be able to assign priority to them. The East Lancashire MMB recognises the work carried out by these advisory groups and networks, and will endeavour to support their recommendations where they are in line with the principles for decision making and the commissioning of healthcare and local affordability.

Section 6

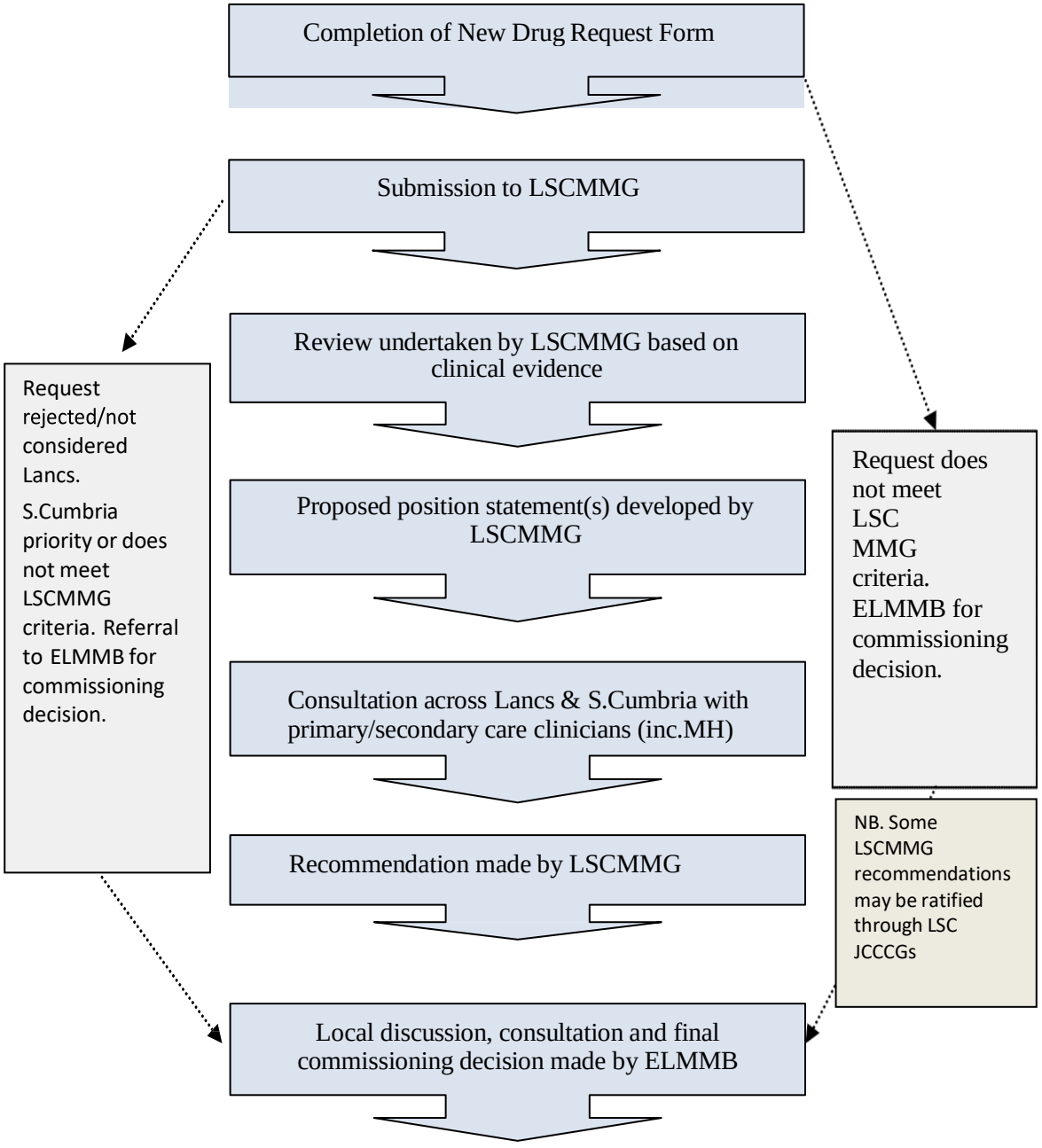
Making an application for a medicine to be reviewed and prioritised by the ELMMB

The table and flowchart below outlines the process for requesting the ELMMB to review and prioritise a medicine. [NB. The new medicines request form can be found in Appendix 4]

Completion of Application
New Medicines Request Form is completed by the clinician/specialist in the relevant therapeutic area and submitted to LSCMMG via the CCG Strategic Director of Medicines, Research and Clinical Effectiveness or ELHT Medicines Information Pharmacist. Form must be fully completed with required signatures. All supporting evidence must be attached with the submission with clear indication highlighted. All sections must be completed including whether request is within or outside of license.
Submission of Application
Once New Drug Request form is completed, Strategic Director of Medicines, Research and Clinical Effectiveness or ELHT Medicines Information Pharmacist submits request to LSCMMG for review.
Assessment and Review by LSCMMG and /or ELMMB
LSCMMG prioritise request in accordance with LSCMMG scope and demand across Lancashire footprint. If considered low priority or outside of scope, request will be referred back to ELMMB for local review and decision. In this situation, ELMMB will consult with local clinicians and commissioners across both primary and secondary care and make a decision based on the clinical evidence and consultation responses. Further information may be requested from the clinician/specialist submitting the request. If request considered a priority by LSCMMG, a comprehensive review of the clinical evidence is undertaken and proposed policy position(s) is/are drafted. Further information may be requested from the clinician/specialist submitting the request. Requests outside of scope for LSCMMG (see www.lancsmmg.nhs.uk) will be reviewed directly through ELMMB and a decision made based on the clinical evidence and advice from relevant specialists and clinicians.

Consultation
Draft review/position statement is shared widely with each health economy across Lancashire and South Cumbria. This includes clinicians and specialists across each CCG and provider trust (including mental health), primary and secondary care. Other commissioners and providers are consulted such as LAs and tertiary centres where appropriate. The requesting clinician may be invited to attend in person to either the LSCMMG or ELMMB to present their case/request.
Collation of Responses
Responses from consultations are collated and summarised for discussion at following LSCMMG.
Recommendation by LMMG
LSCMMG members review the clinical evidence and consultation responses and make a recommendation to individual constituent organisations/ Area Prescribing Committees based on the information presented.
Commissioning Decision
The LSCMMG recommendation is discussed across the local health economy decision making group (ELMMB) and a final commissioning decision is made. There may be some recommendations from LSCMMG that are ratified through the LSC Joint Committee of CCGs.
Assignment of Traffic Light and Formulary Inclusion

East Lancashire Health Economy summary of process for the Managed Introduction and Approval of New Drugs and Treatments



Section 7

Appeal to the Board

Where an applicant wishes to challenge a decision of ELMMB, they may do so by making an appeal to the Executive Teams of the constituent organisations. They may wish to delegate the task to an Individual Case Panel who has had no involvement in the process outlined above.

The Executive Team or delegated panel will not review the clinical evidence base for the request but will be limited to inquiries about whether the ELMMB, in taking the decision, complied with this policy and all associated procedures. The board will therefore check the quality of the process and ensure that the ELMMB:

- Followed organisational policies and procedures
- Considered all relevant factors and did not take into account immaterial factors
- Made a decision that was not so unreasonable that it could be considered irrational or perverse in the light of the evidence.

The stakeholders will reassure all applicants of an impartial hearing.

Section 8

Prioritisation of Decisions by the ELMMB

When the ELMMB reviews a medicine where it feels it has sufficient information it will assign each intervention with a priority based on clinical and cost effectiveness as follows:

High Priority:	Clinical and cost effective, and warrants 'in year' funding for the drug-based intervention or treatment, in line with the recommendations for use made by ELMMB. These interventions will be assigned a **RED**, **AMBER**, or **GREEN** Traffic Light. The traffic light will be assigned in line with the recommendations in the Health Economy Joint Formulary (www.elmmb.nhs.uk) which describes where the responsibility for prescribing lies.
Intermediate Priority:	Clinical and cost effective, but concerns around affordability required it to be re-considered against other competing priorities for the next and subsequent financial year.To be resubmitted by the applicant as part the next prioritisation process for inclusion in the relevant Strategic Commissioning Plan.
Low Priority:	Either not sufficiently effective or cost-effective to warrant funding either in year, or in future years. Access to this treatment may only be requested in exceptional circumstances through the CCG Individual Funding Request (IFR) Policy. These interventions will be given a '**BLACK** Traffic Light' as described below.

Low Priority:	A formal request has not been made nor has it been identified through the horizon-scanning process. These interventions will not appear in the joint formulary until a formal review has been undertaken and will be assigned a '**GREY'** Traffic Light and should not be prescribe
On-going Review	A formal request has been made or an intervention has been identified through the horizon scanning process and work is currently on-going and is thus awaiting a formal traffic light decision. These interventions will be assigned a '**GREY UNDER REVIEW'** status and should not be prescribed until a formal traffic light has been assigned.

Section 9

Emergency/Urgent decisions on medicines

Secondary care providers may occasionally require access to a drug-based intervention or treatment in an urgent setting, which has not been approved for use within the health economy. In this setting, approval should be sought from the Medical Director of the provider and the Trust Chief Pharmacist .The use of medicines in this way will usually fall 'within tariff or contract'.

Where this is disputed, the funding of such medicines should be taken on at risk to the provider. Discussions with the CCG should follow, and not precede the decision to obtain the urgent intervention. Any requests should be brought to the next available LSCMMG where the clinical evidence will be reviewed and presented to MMB for discussion and official ratification if supported. This process should be fully documented.

Section 10

Current contracting and payment processes

Drugs are funded through a variety of routes and differ between providers and commissioners.

CCGs directly fund drug costs outside of tariff;

- Some drugs known as *High Cost Drugs* are specifically defined as a range of drugs and devices and HRGs which are excluded from national mandatory PbR tariff where local commissioning arrangements should be made. These include most of the high cost drugs used in chemotherapy, anti-retrovirals and biologics.
- Via "innovation payments" where, in exceptional circumstances, new technologies (including drugs) are identified that demonstrate significant health improvement and have high financial or service implications.
- Through primary care prescribing budgets; some of this is secondary care initiated and primary care cover the on-going costs of long-term treatments.
- Through contracts outside of 'payment by results' (PBR), which includes those services not currently covered by PBR, or those locally negotiated through primary care commissioning or directly by the CCG.

Providers fund the use of drugs

- Within national tariff HRG (Health Resource Group) costs i.e. within tariff
- Within locally negotiated contracts outside of PBR

Where, an NHS doctor refers a patient privately to a consultant for advice he/she should issue the necessary prescriptions at NHS expense only where this is in line with CCG policy regarding those medicines as outlined in *Appendix 5***.**

Section 11

NICE

(Including Interventions Subject to Current or Pending National Institute for Health & Care Excellence (NICE) Technical Appraisal Guidance or Clinical Guidelines)

NICE issued directions which came into force on 1 January 2002. These Directions are referred to as the "Funding Directions" in this policy.

The 'Funding Directions' for Technology Appraisals
The Funding Directions provide NHS organisations with a period of three months within which to make a health care intervention available to NHS patients in recognition of the fact that it can take some time to put the necessary funding arrangements in place.

Stakeholder organisations should endeavour to ensure that any new treatments recommended by NICE are available as soon as possible after NICE issues Technology Appraisal Guidance. If it is possible for an NHS organisation to make the necessary arrangements without utilising the full three month period stipulated in the directions, it should do so.

Guidelines
The Clinical Guidelines produced by NICE are a valuable source of good practice but the NHS is not required to implement them in the way that applies to the technology appraisals.

The guidance on *"Managing the Introduction of New Healthcare Interventions in the Absence of NICE Technology Appraisal Guidance"* is stated in HSC 199/176**.** ELMMB recognises the messages from HSC 199/176 which have been reiterated in 'Best Practice Guidance ref: 7521' issued in December 2006 which states:

'It is not acceptable to cite a lack of NICE guidance as a reason for not providing a treatment. A key role of the NHS is to make decisions about the use of new interventions and this has always been the case, long before NICE was established.'

ELMMB will therefore assess all requests for funding of medicines in the same way, whether they are currently being reviewed by NICE or not, or whether they are currently covered by fully published NICE Clinical Guidelines.

Section 12

Cancer Drugs – Request, Appraisal & Funding

Review of cancer drugs is outside of scope of this policy, however all cancer drugs reviewed and approved through NICE Technology Appraisals are commissioned by NHSE in line with national recommendations. These appraisals are ratified through ELMMB and are included or excluded from the Health Economy Joint Formulary where appropriate.

A new approach to the appraisal and funding of cancer drugs in England came into force on 29 July 2016. The new system, which includes a Cancer Drugs Fund (CDF), replaces the previous fund, which closed on 31 March 2016. The new system is the product of partnership working between NHS England, NICE, Public Health England and the Department of Health.

Individual funding requests (IFRs) relating to cancer drugs will no longer be considered via the CDF process. All IFRs relating to cancer drugs will be considered using NHS England's single, national IFR system, which was updated in January 2016.

All previous Cancer Drugs Fund content has been archived.

Section 13

Orphan Drugs & Ultra Orphan Drugs

Consideration for funding of orphan and ultra-orphan drugs should initially be based on the same criteria of clinical and cost-effectiveness as those applied for other drugs. Where the guidance on appraising medicines at the end of life does not apply for a particular orphan or ultra-orphan drug, the guidance outlined in *Appendix 6* should be followed.

Appendix 1a: East Lancashire Medicines Management Board Terms of Reference

East Lancashire Medicines Management Board Terms of Reference

AIM

To act as the delegated body for approving recommendations and commissioning decisions in relation to medicines across the health economy in line with the responsibilities and terms of reference outlined below:

- To assess the evidence and evaluate the resource implications of the use of all medicines (including unlicensed medicines) prioritised for review by the Lancashire Medicines Management Group (LSCMMG) and other NHS bodies and clinicians. Requests from health care professionals will also be prioritised and reviewed by the Lancashire Medicines Management Group (LSCMMG) and ELMMB.
- To ensure that all recommendations are adequately considered at a Health Economy level with respect to: local clinical priorities; financial implications; clinical care pathways; service redesign issues and local demographics.
- With delegated authority from CCG Governing Bodies to develop and approve recommendations and policies on the use of medicines in both commissioning and de-commissioning of services where appropriate across the health economy.
- To provide a forum for discussion and resolution of prescribing issues at the Primary and Secondary Care interface.
- To develop, monitor and make recommendations to update the East Lancashire Joint Medicines Formulary, Joint Wound Care Formulary, anti-microbial and other relevant prescribing guidelines.
- To provide guidance on which prescribers should initiate and/or maintain prescribing of medicines through the 'Traffic Light Scheme'.
- To support a Health Economy approach to the implementation and monitoring of all NICE guidance relating to medicines, ensuring that all local policies and guidance is aligned accordingly.
- To support a Health Economy approach for approval of medicine related protocols and guidelines, shared care guidelines and integrated care pathways and ensure that recommendations can be facilitated and implemented within local infrastructures and care pathways prior to ratification by individual organisation's internal governance processes.
- To receive safety alerts through the Medicines Interface and Safety Forum from organisations such as the MHRA (e.g. Drug Safety Update) and make recommendations to the organisations in responding to and implementing relevant actions.
- To receive recommendations from the Medicines Interface and Safety Forum to improve quality of care for patients on admission and discharge by ensuring patients receive seamless care through integrated care pathways.
- To support risk management, audit and research relevant to medicines-related issues.
- To ensure that decisions of the committee are reported to stakeholder Governing Bodies and Boards via appropriate mechanisms.
- To identify sub groups to undertake projects as necessary.
- To receive minutes from all sub-groups for discussion and ratification where appropriate.
- To ensure compliance with the appropriate Clinical Negligence Scheme for organisations' requirements.
- To contribute to organisational assurance and evidence in relation to all medicines aspects of governance frameworks.
- To ensure communication links with the Lancashire Medicines Management Group (LSCMMG), Regional Medicines Optimisation Committees (RMOCs), Specialised Commissioning teams, Local Area Teams, NHSE, PHE, Lancashire and South Cumbria Foundation (LSCFT) Trust DTC, the Cancer Network DTC, the Cardiac Network, CCG prescribing groups and other relevant committees where appropriate.

Minutes from the following groups go to the MMB:
Lancashire and South Cumbria Medicines Management Group (LSCMMG)
Pennine Lancashire Medicines Interface and Safety Forum (MISF) Lancashire
Care Drug and Therapeutics Committee (LCFT DTC)

Frequency of meetings:
Minimum of 8 per year; a quorum of 6 members is required, with representatives from the three stakeholder organisations (ELHT, ELCCG and BwD CCG)

Membership:
Chair and vice-chair elected from the membership. Nominated deputies (with full voting powers) should be sent where members are unable to attend, other members and guests by invitation.

- One Clinical Director – ELHT
- Strategic Lead for Medicines – ELCCG; BwD CCG or representative
- Four Practicing Consultants - ELHT
- Director of Pharmacy - ELHT
- Clinical Services Pharmacy Lead – ELHT
- Governance Pharmacy Lead - ELHT
- GP Members: ELCCG X 5 members; BwD x 2 members
- CCG – Senior Commissioning Pharmacist
- Medicines Information Pharmacist – ELHT
- Non-medical Prescribing Lead - ELHT
- Senior Pharmacist representative – LCfT
- Patient representative

Attendees: For specialist advice by invitation of the Chair

- CCG Commissioning Managers
- CCG Finance Managers
- ELHT Finance manager
- Contracting representatives from constituent organisations
- CSU – by invitation
- Alternative specialists to present business cases/audits/trials where appropriate

Organisational consciousness for ratification of recommendations:

- The East Lancashire Health Economy Medicines Management Board reports to the Pennine Lancashire Committees in Common (PLCiC) which subsequently reports to the CCG Governing Bodies.
- The ELMMB reports to ELHT Trust Board via the Patient Safety and Risk Assurance Committee.
- Copies of minutes will be sent for acceptance and approval to the relevant groups outlined above on behalf of the Governing Bodies.

REVIEW OF TERMS OF REFERENCE: Every 2-3 years or as required
Next review: April 2023

Appendix 1b: Terms of Reference for the Lancashire Medicines Management Group

Lancashire and South Cumbria Medicines Management Group (LSCMMG)

TERMS OF REFERENCE

AIM

The group will provide a platform for making consensus recommendations relating to the use of medicines and medical devices which are available on NHS prescription across the Lancashire and South Cumbria NHS footprint. To ensure equity in access, optimisation of use and the integration of medicines and prescribed medical devices into care pathways and the promotion of inter- and intra-professional collaborative working across organisations. The group will make recommendations to the Joint Committee of CCGs, Integrated Care Partnerships, commissioning groups and provider organisations for adoption to ensure the best use of medicines and prescribed medical devices and associated resources across the health and social care system in Lancashire and South Cumbria.

OVER-ARCHING FUNCTION

Ensure that processes underpinning Lancashire and South Cumbria-wide decision making about medicines and medical devices which are available on NHS prescription are consistent with the NHS Constitution and in accordance with common law.

CORE BUSINESS

- To consider the impact of all medicines and prescribed medical devices that involve primary care prescribing or relate to medicines excluded from PbR tariff on the business of commissioning organisations within Lancashire and South Cumbria including:
    - Receive and consider applications from clinicians for approval to use a new medicine or medical devices which are available on NHS prescription, or a new indication for an established preparation. Note: applications that require an urgent, clinical decision are to be dealt with through internal provider processes.
    - Horizon scan and plan for the introduction of new medicines and medical devices
    - Consider new indications and the revised use of existing medications and medical devices which are available on NHS prescription
    - Where applications are received through the Individual Funding Request process that relate to a cohort of patients, LSCMMG will consider the development of a commissioning position
    - Receive and consider applications from Chief pharmacists/CCG Medicines Leads for, specialist prescribed, PbR included medicines or medical devices which are available on NHS prescription, where this may significantly affect the patient pathway or have a significant impact on commissioners
    - Consider the use of unlicensed and or off label use of medication
    - Receive, consider and adopt all relevant National Institute for Health and Clinical Excellence (NICE) Technology Appraisals
    - Receive and consider all relevant National Institute for Health and Clinical Excellence (NICE) Clinical Guidelines
    - Receive, consider and implement where appropriate all Regional Medicines Optimisation Committee guidance
    - Receive and consider all Scottish Medicines Consortium and All Wales Medicines Strategy Group guidance
- To develop commissioning policies and commissioning pathways for medicines and medical devices which meet the criteria above.

- To provide pharmaceutical expertise and advice to the Lancashire and South Cumbria Integrated Care System
- To receive, consider and agree all externally funded services, staffing or interventions that may impact on prescribing (including any requests that are facilitated through wider NHS organisations)
- Facilitate a process to inform local decisions on the funding of those medicines and medical devices which are available on NHS prescription not considered by NICE, in accordance with the requirements of the NHS Constitution and Secretary of State Directions to the NHS on Local Decision Making.
- Engage relevant clinical opinion from stakeholder organisations in the development of proposals and recommendations on the management of medicines and medical devices which are available on NHS prescription, with particular focus on their place in therapy within care pathways, formulary status, and traffic light status.
- Engage representative patient opinion in the development of proposals and recommendations e.g. by consulting relevant patient interest groups as appropriate.
- Engage Local Authority public health representation in the development of proposals and recommendations as appropriate
- Engage Lancashire and South Cumbria Local Pharmacy Network representation in the development of proposals and recommendations as appropriate
- Make prescribing formulary recommendations for the use of medicines and medical devices which are available on NHS prescription incorporating recommendations from NICE and local commissioning decisions for high cost drugs. The methodology will include a Traffic Light system to ensure that the provision of care in respect of medicines management is delivered within the most appropriate care setting.
- Facilitate the production of shared care arrangements and treatment guidelines for the prescribing, supply and utilisation of medicines and medical devices which are available on NHS prescription within the most appropriate care settings across the Lancashire and South Cumbria health and social care system.
- Consider recommendations from NICE and MHRA Drug Safety Updates relating to the use of medicines and medical devices which are available on NHS prescription and advise on required amendments to prescribing formularies to facilitate the safe, effective and prompt implementation of advice.
- Consider how the impact of new medicines and medical devices which are available on NHS prescription affects policies relating to the commissioning of services. Consider potential service implications associated with the managed introduction of a new medicines or the use of an established medicine for a new indication
- Provide an overview of the uptake and adoption of any recommendations made by the group.
- Ensure that patient outcomes, effectiveness and safety considerations are at the forefront of recommendations made.

WIDER CONTEXT

- Consider funding pathways and work with commissioners, providers and contractors to ensure that systems are in place to manage high cost medicines within the context of existing and future financial frameworks (for example PbR tariff exclusions).

- Highlight to stakeholder organisations the potential clinical, financial and service impact and benefits of medicines under review, for consideration as part of decision making processes.
- Support commissioning organisations in their processes for managing individual funding requests (IFRs) and exceptional case requests by making evidence-based policy recommendations where appropriate.
- Consider changes in service delivery that impact on medicines management across Lancashire and South Cumbria, promoting the integration of prescribing and medicines use issues with the mainstream commissioning process and wider healthcare service planning.
- Consider social and local authority issues relating to medicines management including relevant recommendations from joint Pharmaceutical Needs Assessments.
- Support risk management, audit and research relevant to medicines-related issues.
- Ensure that any recommendations made by the group are communicated to the relevant commissioning group and provider organisation for due consideration
- Identify working groups to undertake projects as necessary.
- Receive recommendations from working groups for discussion and ratification where appropriate.
- Ensure there are communication links in place with other relevant bodies, including Trust Drugs and Therapeutics Committees, health economy medicines management groups, Health and Wellbeing Boards, NHS England Area Team (including specialist commissioning team), Regional Medicines Optimisation Committee, Clinical Networks, CCG medicines management committees and other groups as appropriate.

SUB-GROUPS

The Lancashire Care NHS Foundation Trust Drug and Therapeutics Committee will provide expert advice in relation to the prioritisation and commissioning of mental health drugs, including formulary recommendations. Its membership will include commissioner representation.

Working groups (professionally supported by the Midlands and Lancashire Commissioning Support Unit) will be established to undertake specific pieces of work according to need

MEMBERSHIP

Membership will be representative of the stakeholder organisations across Lancashire and South Cumbria and include:

- Medical director of Integrated Care System (to act as Chair to the group')
- Integrated Care Partnership senior medical representation
- Integrated Care Partnership senior pharmacist representation
- Lancashire and South Cumbria Finance Representative
- NHS Trust / Foundation Trust senior medical representation
- NHS Trust / Foundation senior pharmacist representation
- NHS England Area Team representative

A review of membership will be undertaken annually. Where members have not attended for greater than 6 months, they will be removed from the distribution list in consultation with the organisations LSCMMG representative.

Members should:

- Commit to regular attendance of the committee to ensure continuity and balance of input into the formulation of recommendations
- Review the agenda and supporting papers in advance of the meeting
- Act as a representative of their organisation and ICP within the committee
- Send a nominated deputy to meetings if they are unable to attend
- Communicate discussions and recommendations back to the organisations they represent, enabling ratification of recommendations as appropriate
- Act as representative of the committee within their own organisation
- Declare any relevant interests relating to the agenda at each meeting and declare all pertinent interests through the Annual Declaration of interests process
- Undertake any post meeting actions, as agreed at the meeting
- Maintain the confidentiality of material marked as confidential, received in accordance with the business of the Lancashire and South Cumbria Medicines Management Group
- Update the Group on relevant business from stakeholder groups and organisations relevant to the business of the LSCMMG

In attendance

- Commissioning Support Unit Medicines Management lead / professional support
- Other relevant persons (including clinical experts) may be invited to attend the meeting for the purpose of providing advice and / or clarification to the group.
- Representation from North West Medicines Information Centre

FREQUENCY OF MEETINGS AND QUORACY

A minimum of 9 meetings per year will be held. A quorum of 8 voting members will be required, with a minimum representation of 4 of 5 Integrated Care Partnership health economies, 2 primary care representatives and 2 provider Trusts.

SCHEME OF DELEGATION AND VOTING The group has delegated authority to make *recommendations.*

In line with the strategic direction of the NHS Long Term Plan, to continue to develop Integrated Care Systems (ICS's), which will typically involve a single CCG for each ICS area all recommendations (medicines recommendations, NICE TAs, commissioning policies, commissioning pathways) will be considered and adopted by the Joint Committee of CCGs in accordance with its governance processes.

Clinical guidelines and shared care documents will be considered and adopted by individual Integrated Care Partnership health economies in accordance with their governance processes.

Where decisions of the group will have significant financial implications, the Finance Investment Group (FIG) will be consulted prior to the final recommendation being made to the Joint Committee.

Where decisions of the group will have significant service impact issues and require additional clinical consultation, the Care Professionals Board will be consulted prior to the final recommendation being made to the Joint Committee.

Recommendations will be made in accordance with stakeholder agreed principles for the commissioning of health and healthcare, taking into consideration evidence of efficacy, cost effectiveness, patient outcomes, safety, affordability and projected cost, and patient benefits. The group will promote treatments for which there is good evidence of clinical effectiveness in improving the health status of patients and is affordable.

When there are conflicting opinions within the meeting and a consensus agreement cannot be reached, the decision will be put to a majority vote. Voting will be on the basis of one vote per organisation, with the Chair having the casting vote.

APPEALS PROCESS

The Group will consider appeals against its recommendations. Appeals will be accepted from LSCMMG member organisations only. Appeals will be accepted within three months of the LSCMMG meeting at which a recommendation was agreed. The following grounds for appeal will be considered:

- that the LSCMMG process had not been appropriately followed; or
- that the LSCMMG's recommendation was perverse in light of the evidence considered.

Appeals should be submitted in writing, stating which of the above grounds forms the basis of the appeal. Appeals should be addressed to the Chair of LSCMMG and submitted via the MLCSU.medicinesmanagement@nhs.net email address.

REPORTING ARRANGEMENTS

NHS Trust, Foundation Trust and CCG representatives are responsible for agreeing and ratifying Board level reporting arrangements within their own organisations, consistent with their own integrated governance arrangements and with regard to Regulatory requirements.

A six-monthly report will be provided to the ICS Board of the decisions of the group, any expected and actual cost impact and the planned work areas for the coming six months.

Recommendations and copies of the minutes will be sent to the Joint Committee of CCGs for ratification.

REVIEW OF TERMS OF REFERENCE

These terms of reference will be reviewed every 12 months, or sooner if circumstances dictate.

Date of last review: February 2019

Appendix 2: Principles for the Commissioning of Health and Healthcare

1. Introduction

1.1 This document sets out the principles underlying the commissioning decisions and policies of the Commissioning Organisation.

1.2 The context and rationale for this document is set out in "Commissioning Policies for Health and Healthcare – an Introduction".

1.3 This document and each commissioning policy is a separate public document in its own right.

Principles

1.4 Subject to its obligation to commission the majority of interventions which have been recommended by the National Institute for Health and Care Excellence in a Technology Appraisal Guidance[1], the Commissioning Organisation will **only** commission interventions which fulfil **all** of the following criteria:

- Appropriate
- Effective
- Cost effective
- Ethical

2. Appropriate

2.1 The Commissioning Organisation defines an appropriate intervention as

- One which has the intended outcome of preventing, diagnosing or treating a medical condition. The Commissioning Organisation defines a medical condition as any illness, injury or impairment in which there is an abnormality in the structure or function of the body or mind.

  OR

- One which ensures dignity at the time of death.

  OR

- One which has the intended outcome of preventing unwanted pregnancy.

  OR

[1] *Directions to Primary Care Trusts and NHS trusts in England concerning Arrangements for the Funding of Technology Appraisal Guidance from the National Institute for Clinical Excellence (as amended) - http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4075686.pdf*

- One which provides part of such services or facilitates for the care of pregnant women, women who are breastfeeding and young children as may be reasonably required[2].

2.2 The Commissioning Organisation categorises appropriate interventions as follows:

Category 1 ("Must Do's") Interventions:-

a) Those for which the intended outcome is to:

- preserve life;
- prevent or relieve pain, disability or physical discomfort;
- directly address the distress or disability associated with a diagnosed mental health condition; or
- maintain dignity at the time of death.

b) Vaccinations for those falling with the scope of a recommendation from the Joint Committee on Vaccination and Immunisation3.

c) Services or facilities which are reasonably required for the care of pregnant women, women who are breastfeeding and young children.

Category 2 ("Could Do's"): Interventions which fall within the overall definition of "appropriate" but for which the intended outcome or purpose is other than those in category 1.

2.3 The commissioning organisation will commission category 1 interventions provided the principles of effectiveness, cost effectiveness and ethical delivery are met.

2.4 In the light of competing demands for NHS resources, the commissioning organisation will only consider routinely commissioning interventions in category 2 if its financial position permits.

2.5 Any new procedures for which there is no budgetary provision in the current financial year may be placed in category 2 until such time as the budget can be prioritised.

2.6 It is a matter for the discretion of the commissioning organisation as to whether or not it will routinely commission any category 2 interventions as part of current or future commissioning rounds.

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[2] *s.3(1)(d) of the NHS Act 2006.*
[3] *Section 2a of the NHS Constitution.*

3. Effective

3.1 The Commissioning Organisation defines an effective intervention as one which is capable of achieving its intended outcome as demonstrated by research evidence, and of doing so without causing undue harm.

3.2 In assessing whether an intervention is effective the Commissioning Organisation will normally consider the content and quality of the available research and evidence.

3.3 A treatment of little benefit will not be provided simply because it is the only treatment available.

3.4 The Commissioning Organisation will not normally commission an intervention for which evidence of effectiveness is unavailable unless it is delivered as part of high quality research which complies with the Commissioning Organisation's Research Governance Framework

4. Cost effective

4.1 The Commissioning Organisation defines a cost effective intervention as one which represents good value for money in comparison with other possible uses of that money.

4.2 The Commissioning Organisation will not normally commission any intervention which does not meet any national or local cost effectiveness criterion that may be in force at the time.

5. Ethical

5.1 The Commissioning Organisation defines ethical healthcare as that which is provided justly and fairly according to need such that the health of the population is maximised within the resources available.

5.2 The Commissioning Organisation will commission interventions based on the health and healthcare needs of its resident population, as assessed by the Commissioning Organisation. In doing so it will seek to reduce health inequalities within the population.

5.3 The Commissioning Organisation commissioning policies in line with the Equality Act 2010 will not discriminate on the basis of age, sex, gender reassignment, sexual orientation, race, religion or belief, pregnancy and maternity, lifestyle, occupation, social position, financial status, family status (including responsibility for dependents), intelligence, disability, physical or cognitive functioning.

The commissioning organisations will apply the Human rights principles of Freedom, Respect, Equality, Dignity and Autonomy when developing and applying commissioning policies ensuring that they demonstrate a positive duty to meeting peoples human rights in line with the Human Rights Act 1998 and the NHS Constitution 2009.

All commissioning policies will be subject to robust equality analysis and if there is robust evidence that these factors affect the effectiveness of an intervention, the Commissioning Organisation may take this into account in its commissioning policy.

Where there are specific equality issues in relation to the application/implementation e.g. exceptions then these will be referred to the organisation's funding request panel for consideration.

5.4 The Commissioning Organisation will not commission a service simply because that service is commissioned by another Commissioning Organisation or Commissioning Organisations.

Appendix 3: Appraising end of life medicines

Introduction

LSCMMG and/or the ELMMB may be asked to appraise life-extending medicines licensed for terminal illnesses affecting small numbers of patients, which, following appraisal, are deemed to have an incremental cost effectiveness ratio in excess of the upper end of the range normally approved by the ELMMB (in line with the NICE thresholds), but which nevertheless offer demonstrable survival benefits over current NHS practice**. NICE offer the following advice to their appraisal committees and ELMMB will follow this advice in full (see below).**

National institute for Health and Clinical Excellence: Appraising life-extending, end of life treatments

1. Summary

1.1 This document sets out supplementary advice to the Appraisal Committees, to be taken into account when appraising treatments which may be life-extending for patients with short life expectancy, and which are licensed for indications affecting small numbers of patients with incurable illnesses. The additional advice will apply when such treatments have an incremental cost effectiveness ratio (ICER) in excess of the upper end of the range normally approved by the Appraisal Committees, using the 'reference case' outlined in the Institute's Guide to the Methods of Technology Appraisal, and which may offer demonstrable survival benefits over current NHS practice.

1.2 The current appraisal methodology recognises that there will be circumstances in which it may be appropriate to recommend the use of treatments with high reference case incremental cost effectiveness ratios. It states (with reference to the Institute's standard appraisal criteria) that: 'Above a most plausible ICER of £30,000 per QALY gained, the Committee will need to identify an increasingly stronger case for supporting the technology as an effective use of NHS resources.' The Appraisal Committee has, in the past, made recommendations above the normal threshold range when it has explicitly identified additional benefits not readily captured in the reference case. This has occurred when the treatment involved has been life-extending, licensed or otherwise indicated for small populations with incurable illnesses.

1.3 In developing this supplementary advice, the Institute has taken account the Appraisal Committees' previous decisions, together with the relevant principles in the guide to the use of Social Value Judgements. It has also had regard to the consideration given by the Citizens Council, at its meeting in November 2008, to the circumstances in which it might be appropriate to support the use of treatments outside the Institute's cost per quality adjusted life years (QALY) threshold range. In addition, the Institute has taken account of its responsibility to recognise the potential for long term benefits to the NHS of innovation. In this context, it considers it appropriate for its Appraisal Committees to have regard to the importance of supporting the development of innovative treatments that are anticipated to be licensed for small groups of patients who have an incurable illness.

1.4 The objective of this supplementary advice is to ensure that the Appraisal Committees fully consider all the benefits which it is appropriate to take into account in appraising treatments designed to extend life, at the end of life for small populations and in particular to ensure that where benefits are not, or not adequately captured in the

reference case, that the Appraisal Committees are provided with an appropriate supplementary analysis. For this supplementary advice to be applied, a treatment will need to have been through an appraisal by NICE where the most plausible reference case point estimate for the ICER exceeds the upper end (£30,000) of the range normally considered by the Appraisal Committees to represent a cost effective use of NHS resources. Each candidate treatment will also need to meet the criteria set out in section 2.

1.5 The Institute will normally recommend to the Department of Health that it should give consideration to a data collection exercise for treatments recommended for use on the basis of the criteria set out in section 2. The purpose of this will be to assess the extent to which the anticipated survival gains are evident when the treatments involved are used in routine practice. The outcome of this exercise will be evaluated when the guidance for that treatment is reviewed.

2 Criteria for appraisal of end of life treatments

***2.1** This supplementary advice should be applied in the following circumstances and when all the criteria referred to below are satisfied:*

***2.1.1** The treatment is indicated for patients with a short life expectancy, normally less than 24 months and;*

***2.1.2** There is sufficient evidence to indicate that the treatment offers an extension to life, normally of at least an additional 3 months, compared to current NHS treatment, and;*

***2.1.3** No alternative treatment with comparable benefits is available through the NHS, and;*

***2.1.4** The treatment is licensed or otherwise indicated, for small patient populations.*

***2.2** When the conditions described in 2.1 are met, the Appraisal Committee will consider:*

***2.2.1** The impact of giving greater weight to QALYs achieved in the later stages of terminal diseases, using the assumption that the extended survival period is experienced at the full quality of life anticipated for a healthy individual of the same age, and;*

***2.2.2** The magnitude of the additional weight that would need to be assigned to the QALY benefits in this patient group for the cost-effectiveness of the technology to fall within the current threshold range.*

***2.3** In addition, the Appraisal Committees will need to be satisfied that:*

***2.3.1** The estimates of the extension to life are robust and can be shown or reasonably inferred from either progression free survival or overall survival (taking account of trials in which cross-over has occurred and been accounted for in the effectiveness review). and;*

***2.3.2** The assumptions used in the reference case economic modelling are plausible objective and robust.*

3 Review of the resulting guidance

3.1 *The guidance produced using these criteria will be subject to review in accordance with the Institute's current arrangements. The review will normally take place no later than 2 years after the guidance has been issued. The review can be either brought forward or delayed, depending on the outcome of any data collection exercise or the availability of other new evidence.*

3.2 *Treatments approved following the application of the supplementary advice will not necessarily be regarded or accepted as standard comparators for future appraisals of new treatments introduced for the same condition. Second and subsequent licences for the same product will be considered on their individual merits. The Appraisal Committee will take into account the cumulative population for each product in considering the strength of any case, for justifying decisions which employ, in whole or part, the supplementary criteria outlined above*

4 Implementation and evaluation

4.1 *This supplementary advice will be effective from 5 January 2009.*

4.2 *The Institute intends to ensure that this supplementary advice is robust for the long-term and that it achieves its intended purpose. It will therefore be subject to a methodological evaluation. The Institute will design and manage this evaluation, the results of which will be published and used to make modifications to the supplementary advice, if necessary."*

Appendix 4: Submitting a request to the ELMMB to review a medicine

Section A Making an initial application

Requests for funding packages for groups or populations are accepted by the MMB only from registered healthcare professionals, and should be submitted initially to the:

Lancashire Medicines Management Group (which provides recommendations to the ELMMB) or to the following individuals as outlined on the New Drugs Request Form:

Lisa.Rogan3@nhs.net
Christine.woffindin@elht.nhs.uk

The requests will then be processed via the LSCMMG or other relevant group or network prior to submission to the **East Lancashire Medicines Management Board** (ELMMB)

There are three stages for group or population requests:

1. Stage One is the ELMMB's Initial Consideration Stage (delegated to the Lancashire Medicines Management Group)
2. Stage Two is the consultation stage facilitated by the LSCMMG.
3. Stage Three is the implementation stage by the ELMMB.
4. Stage Four is the Appeal to the constituent organisations' Boards.

Healthcare professionals must complete the form 'Medicine Request Form' using the guidance supplied alongside the form which provides information to help the professional decide whether or not it is appropriate to make an application to the ELMMB, and what information to provide. A copy of the form can be accessed separately on:

http://www.elmmb.nhs.uk/request-for-a-new-medicine-overview/requesting-a-policy-decision-for-medicines/

All requests will be acknowledged, via email, fax or letter, **within seven working days** and a response as to actions taken with rationale will be provided where appropriate.

ELMMB will ensure that all parties are kept informed of progress if delays occur, and will endeavour to be frank, open and sincere at all times in their dealings with colleagues.

The request will be considered at the first available meeting of the Lancashire and South Cumbria Medicines Management Group (LSCMMG).

Section B Organisational Backing for Applications

To ensure that the organisation employing or contracting the service of a healthcare professional is supporting the request for approval and funding of an application, the form MUST be signed by the relevant individuals with organisational authority. This is essential to ensure that not only treatments are approved for use across a variety of clinicians where appropriate, but there use will be consistent and there are appropriate arrangements in place to support the secure and safe handling, prescribing and dispensing of the relevant drug-based intervention or treatment.

Section C MMB's Initial Consideration Stage (delegated to the Lancashire Medicines Management Group - LSCMMG)

The LSCMMG will assess the application to ensure that it contains the required information as outlined by the headings on the form, and that the necessary signatures have been obtained. Where additional information is required this will be requested by the LSCMMG. Where the form is incomplete this will be returned to the requester as outlined below for completion.

1. Application approved for consideration by LSCMMG – either conditionally or unconditionally
In this instance, the responsible officer(s) will;

- Advise the requester(s) advising of the decision **within ten working days** of the meeting.

2. The need for further information is identified before the application can be re-considered by the LSCMMG.
In this instance, the responsible officer(s) will;

- Advise the requester(s) of the decision **within ten working days** of the meeting
- Submit the revised application with additional information to the next available meeting of the LSCMMG or ELMMB where appropriate.

3. A definitive decision is made following the presentation of additional information.
In the event of **approval** being granted at this stage, the process at C1 above applies.
If the revised application, with additional information is still incomplete, and is not approved by the LSCMMG, the process at C2 above applies.

Section D Full Consideration of the Application

LSCMMG and/or the ELMMB will assess the application in line with the respective Terms of Reference, and following discussion will make a decision on the priority of the intervention, and subsequent 'traffic light', in line with the principles outlined in this policy and the commissioning principles. Where additional information is required this will be requested accordingly. Where the form is incomplete this will be returned to the requester as outlined below for completion.

1. Application approved by the ELMMB – either conditionally or unconditionally
In this instance, the responsible officer(s) will;

- Advise the requester(s) of the decision **within ten working days** of the meeting

2. The need for further information is identified before the application can be re-considered by the LSCMMG and/or ELMMB.
In this instance, the responsible officer(s) will;

- Advise requester(s) of the decision **within ten working days** of the meeting
- Submit the revised application with additional information to the next available meeting of the LSCMMG/ELMMB.

3. A definitive decision is made following the presentation of additional information.
In the event of **approval** being granted at this stage, the process at C1 above applies.
If the revised application, with additional information is still incomplete, and is not approved by the LSCMMG, the process at C2 above applies.

4. Communication of decisions to the public and the wider NHS
Decisions made by the ELMMB can be requested under the Freedom of Information Act. However, the ELMMB will endeavour to publish the recommendations it makes and where relevant the rationale for these decisions on the ELMMB website at www.elmmb.nhs.uk. This website is freely available on the internet.

East Lancashire Health Economy
Medicines Management Board

Request for New Product or Change of Regimen

What is this form for?
The form must be used for all requests

- for drugs not currently used within the trust
- new indications for established drugs
- changes in practice/ regimen

What to do next?

1. **This form MUST be completed ELECTRONICALLY to allow distribution to all members of the Medicines Management Board.**
2. **The requesting consultant must complete pages 2 and 3 in full.**
3. When completed the electronic forms must be emailed to the following recipients
   a. Lisa.Rogan3@nhs.net
   b. Christine.woffindin@elht.nhs.uk
4. A copy must also be printed out and page 2 must be signed by the requesting clinician and the clinical director. These signed copies must be sent to Medicines Information, Pharmacy at BGH.
5. ALL journal references/articles used to support this application must be supplied and sent with the signed forms above.

Please note:
ONLY FULLY COMPLETED FORMS WILL BE ACCEPTED FOR SUBMISSION AT THE MEDICINES MANAGEMENT BOARD. FORMS THAT HAVE NOT BEEN FULLY COMPLETED, OR THAT DO NOT HAVE THE SUPPORT OF THE CLINICAL DIRECTOR WILL BE RETURNED.

What happens next?
Completed forms will be circulated to relevant local clinicians to obtain their comments on this request. These clinicians will be given a deadline by which they must comment, after which all comments and the request form will be submitted to the Medicines Management Board.
Pharmacy staff will add relevant financial implication data to the submission, and the requesting consultant may be approached to comment on the accuracy of these calculations. The requesting consultant may also be approached to attend the relevant Medicines Management Board to present the request.

How long will this process take?
Following receipt of a fully completed form, the new product request will be placed on the next Medicines Management Board agenda after a six week period. This six week period is used to produce accurate financial information on the impact for a new request, and to obtain and collate comments from other clinicians.

Clinical Director
The form must be signed by the clinical director to indicate that the directorate support the request for the new drug / indication.

New Medicines Request Form

NB Please use the electronic version of this form

Available at www.elmmb.nhs.uk

NB. Please complete ALL relevant sections legibly and comprehensively. Text boxes will expand to fit as information is added. Please note that any missing or illegible information will require the form to be returned to you for amendment and so may delay the application.

Please submit completed forms to:

lisa.rogan3@nhs.net and Christine.Woffindin@elht.nhs.uk

Section 1: Medicine Details

Name of medicine (generic & brand name)**:** Click here to enter text.
Strength(s) and Form(s): Click here to enter text.
Licensed indication(s): Click here to enter text.
Proposed indication(s) for use (if different from or in addition to the above): Click here to enter text.

Section 2: Evidence to Support Proposed Use

2.1 Evidence of effectiveness in the proposed indication:
What evidence is there of effectiveness for this medicine in its intended use? Please supply information on the principal trials supporting the indication(s) described above and the overall results regarding outcomes (e.g. absolute or relative risk reduction or NNT) and efficacy? Please state what the principal outcome measures are and provide copies of **up to 3 (maximum)** relevant references. Click here to enter text.
2.2 Summary of evidence on comparative efficacy
What are the advantages of this medicine compared to other treatments? Consider

medicines already recommended in your local formulary or others in the same therapeutic class or used for the same indication as being requested. Click here to enter text.
2.3 Summary of evidence on comparative safety
How does this medicine compare to existing alternatives in terms of its safety and any associated monitoring requirements? In summarising monitoring requirements, please indicate whether they are during initial stages of treatment until the patient is stable, or are required for the full duration of therapy. Click here to enter text.
2.4 Summary of evidence on cost effectiveness and patient outcomes
Is this medicine more cost-effective than alternatives, or does it result in improved quality of life for patients? Please provide information on the cost effectiveness of this medicine in terms of absolute risk reduction and cost per QALY and/or quality of life benefits. Click here to enter text.

Section 3: Place in Therapy and Impact on Alternatives

3.1 How will using this medicine change the use of other medicines or treatments?
Please indicate whether this medicine would be used in addition to or instead of others, and where in the treatment pathway it is planned to use it, e.g. 1st/2nd /3rd line/ reserved for particular patient groups. If it will replace an existing medicine, please state which one. **N.B**. Please give reasons for your proposed place in therapy. Click here to enter text.
3.2 How will using this medicine affect how services are delivered to patients?
For example, will it require fewer or more hospital visits, enable care to be delivered closer to home, etc? Click here to enter text.
3.3 Are there other any non-medicine costs or savings related to using this medicine?
For example, will it require additional clinics to be set up, avoid a surgical procedure, or result in reduced length of stay in hospital? Click here to enter text.

Section 4 Financial Implications

4.1 What is the cost per patient of the medicine each year?
If a full course of treatment last less than one year, please indicate this and give the cost of the course**.** Click here to enter text.
4.2 If this medicine replaces an alternative medicine or treatment, what is the current annual cost per patient of this alternative?
Please include the name of the alternative medicine or treatment and the cost of one full course or one year's therapy per patient. Click here to enter text.
4.3 How many patients would receive this medicine each year?
If possible, please indicate what proportion of patients with the condition to be treated would be prescribed this medicine OR indicate whether your estimate relates only to patients to be treated by your own organisation or the total across all of Lancashire. Click here to enter text.
4.4 Where would prescribing take place? Click in the box to tick the option you propose.
Hospital/specialist services only ☐ Initiated in hospital/specialist service and continued in primary care ☐ Initiated and continued in primary care ☐
4.5 If prescribing in primary care is envisaged, do you think shared care guidance would be required? Please give the reason for your answer. Click here to enter text.

Section 5: Declaration of Potential Conflicts of Interest

5.1 Personal interests over the last 12 months

This involves payments* (or other support) from any one company to an individual clinician or their spouse/partner/or close relative. The main examples are consultancies, fee-paid work, travel grants or pharmaceutical company shares. (The amount of money involved does not have to be declared).

Company	Nature or purpose of support from the company	Period of support	
		From	To
Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.
Name of Clinician: Click here to enter text. **Date:**Click here to enter text.			

5.2 Organisational interests over the last 12 months

This implies support* from any one company for your unit or place of work. It may be financial or in kind, e.g. funding of a nurse, colleague, building or piece of equipment. (The amount of money involved does not have to be declared).

Company	Nature or purpose of support from the company	Period of support	
		From	To
Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.
Name of Clinician: Click here to enter text. **Date:** Click here to enter text.			

* for practical purposes, payments and/or support to a value in excess of £100 annually should be declared. (Threshold of £100 chosen locally to exclude amounts for trivial items such as pens, post-its, books, etc)

Section 6: Background Information

6.1 Application Completed by:
GP/Consultant - Name, specialty, full postal address and email address: Click here to enter text.
Clinical Pharmacist - Name, full postal address and email address: Click here to enter text.

6.2 Organisational support for submission given by:
Clinical Director – Name, date: Click here to enter text.
Chief Pharmacist – Name, date Click here to enter text.

N.B. Individuals submitting request are responsible for ensuring their own organisation supports the application before submitting it for consideration.

Appendix 5: Funding for treatments after private referral

The responsibility for prescribing rests with the doctor who has clinical responsibility for the patient's care. Where an NHS doctor refers a patient privately to a consultant for advice he/she should issue the necessary prescriptions at NHS expense only where this is in line with CCG policy regarding those medicines.
People who opt to be referred privately (i.e. outside the NHS) are expected to pay the full cost of any treatment they receive including all drugs and appliances.

Where the consultant has clinical responsibility for the care of a patient it is the consultants responsibility to prescribe and/or administer any specialist treatments at the patient's expense, i.e. GPs should not be asked to prescribe under these circumstances.

Following a private consultation, there is no obligation for the GP to prescribe the recommended treatment if it is contrary to his/her normal clinical practice or the usual treatments endorsed/offered by the CCG under the NHS.

Patients have a right to revert to NHS funding at any point during their care. However, if they wish to exercise this right, their care will be transferred to local agreed NHS pathways and guidelines.

Appendix 6: Appraising orphan and ultra-orphan medicines

Consideration for the funding of orphan and ultra-orphan drugs should initially be based on the same criteria of clinical and cost-effectiveness as those applied for other drugs. Where the guidance on appraising medicines at the end of life does not apply for a particular orphan or ultra- orphan drug, the following guidance will be used by the ELMMB when taking the decision whether to fund a medicine.

The rarity of the disease is not, in itself, a reason why an economic assessment cannot be made. However, orphan and ultra-orphan drugs are invariably expensive and for this reason, incremental cost-effectiveness ratios almost always exceed conventional thresholds of cost-effectiveness, making most ultra-orphan drugs not cost-effective.

For drugs that have been shown not to be cost-effective, additional considerations should be made of the following (in descending order of priority):

- The degree of severity of the untreated disease, in terms of quality of life and survival
- Whether the drug can reverse, rather than stabilise the condition
- Overall budget impact
- Whether the drug may bridge a gap to a "definitive" therapy (e.g. gene therapy), and that this "definitive" therapy is currently in development
- The innovative nature of the drug

Orphan and ultra-orphan drugs should be appraised on a case-by-case basis, and all patients receiving approved drugs should be entered into registries for recording prospective measures of clinical outcome. An advice review date may be set to ensure that additional clinical trial evidence or clinical audit data is reviewed, and this may require an additional submission.

Appendix 7: Evidence for relative treatment effects

Introduction

The treatment effect of a medicine can be summarised as the difference between the duration and state of health or Health Related Quality of Life (HRQL) (including the impact of any adverse effects of treatment) that would be experienced on average by patients receiving the medicine and that experienced by the same group were they to receive alternative care.

The primary research methods and designs that are used to measure the treatment effect can be categorised into experimental or observational studies. The most reliable evidence about the relative treatment effects of a medicine is obtained from experimental studies with high internal and external validity. For an assessment of internal validity, the different types of study design can be ranked according to design features that affect their validity for estimating relative treatment effect, ranging from RCTs to uncontrolled observational studies.

The potential for bias, including performance, measurement and attrition bias, is greater in studies lower in the ranking. However, it is important to recognise that, even for the analysis of relative treatment effects, RCT data are often limited to selected populations and may include comparator treatments and short time spans that do not reflect routine or best NHS practice. Therefore, good-quality non-randomised studies may be needed to supplement RCT data. In addition, the value of evidence from anywhere in the ranking will depend on its quality and relevance to the appraisal.

If relevant, up-to-date and well-conducted systematic reviews that include studies least open to bias are available, these should be considered.

Randomised controlled trials (RCTs)

RCTs are designed to minimise potential external influences so that the effects of one or more interventions in a precisely defined patient group are isolated. Randomisation aims to prevent selection bias in the allocation of interventions to participants and ensure balance between the intervention groups in known and unknown factors. The outcome of the trial should, in principle, be a minimally biased estimate of the magnitude of any benefits or risks associated with the medicine relative to those that are associated with the control. RCTs are therefore considered to be most appropriate for measures of relative treatment effect.

ELMMB has a strong preference for evidence from ‘head-to-head’ RCTs that directly compare the medicine with the appropriate comparator in the relevant patient groups. When such evidence is available and includes relevant outcome evidence, this is preferred over other study designs.

The relevance of RCT evidence to the appraisal depends on both the external and internal validity of each trial. Internal validity is assessed according to the features of the design and conduct of a trial that are important for eliminating bias. These features include blinding (when appropriate), the method of randomisation and concealment of allocation, and the completeness of follow-up. Other important considerations are the size of the trial, the selection and measurement of outcomes, and analysis by intention to treat. External validity is assessed according to the generalisability of the trial evidence; that is, the applicability of the results to wider patient groups over a longer follow-up than is reported in the trials and to routine clinical practice, including appropriate comparator technologies.

Non-RCT evidence

Non-RCT, both experimental and observational, evidence will be required, not just for those situations in which RCTs are unavailable, but also to supplement information from RCTs when they are available. The problems of confounding, lack of blinding, incomplete follow-up and lack of a clear denominator and endpoint will usually be much worse in non-randomised studies than in RCTs. But in some circumstances, evidence from these studies will be needed in addition to RCT data, in particular to estimate relative treatment effect over longer time horizons or to measure particular outcomes that have not been included in the RCTs. In the absence of valid RCT evidence, evidence from studies least open to bias will be considered preferentially with reference to the inherent limitations of the specific design.

Inferences about relative treatment effects drawn from non-RCT evidence will necessarily be more circumspect than those from RCTs with properly controlled evidence. The bias that may be present in non-randomised data means the results should be interpreted cautiously. When possible, the use of more than one independent source of such evidence needs to be examined to gain some assurance of the validity of any conclusions drawn.

Adapted from: NICE. : June 2008. Guide to the methods of technology appraisal. Available online at: http://www.nice.org.uk/media/B52/A7/TAMethodsGuideUpdatedJune2008.pdf

NHS East Lancashire Clinical Commissioning Group
NHS Blackburn with Darwen Clinical Commissioning Group
East Lancashire Hospitals NHS Trust

East Lancashire Health Economy Medicine Management Board
www.elmmb.nhs.uk NHS

Appendix 8: ELMMB Decision Map *[Version 6.1 Review date April 2023]*

East Lancashire Health Economy Medicines Management Decision Map – March 2020