Medicines Formulary Policy

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| --- | --- |
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|  |  |
| --- | --- |
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| Mental Health and LD |  |
| Community Health Services |  |

Version Control Summary

|  |  |  |  |  |
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| 1.0 | December 2007 |  |  |  |
| 2.0 | December 2009 |  |  |  |
| 3.0 | March 2011 |  |  | Drug status clarified in relation to PCT prescribing. Updated with drugs reviewed by Medicines Committee. |
| 4.0 | August 2018 |  |  | Removal of formulary from policy and directing to eBNF. Acknowledgment of CCG formularies and hyperlinks. |
| 5.0 | March 2020 | Deputy chief pharmacist |  | Added section 5.3 – Prescribing a non-formulary medicine in EPMA |
| 6.0 | May 2023 | CAMHS/ MI pharmacist |  | Updated processes to reflect joint working with NELFT/ NEL/BLMK ICB |

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**1.0 Executive Summary**

The medicine formulary policy sets out the process for reviewing requests for formulary inclusion of newly marketed medicines, non-formulary medicines, new presentations of formulary medicines, and unlicensed medicines or off-label indications. For guidance on the use of unlicensed medicines or the use of licensed medicines for unlicensed indication refer to the ‘Unlicensed Medicines Policy’. All medication formulary reviews will be presented to the Trust Medicines Committee (MC), which reports to the Executive Board through the Quality Committee with respect to decision making on the introduction of new medicines. This includes existing medicines with new indications/formulations or updates based upon new clinical evidence, guidelines or appraisals.

**2.0 Introduction**

ELFT works collaboratively with two integrated care systems; NEL ICS and BLMK ICB. As part of the ICB model formulary applications need to be submitted to both ICBs for medication use across the primary and secondary care interface.

Under the new ICB model and formulary process, **ALL** medication formulary applications must go to the relevant ICB **first**, before they are presented to ELFT medicine committee.

**3.0 Integrated formulary with NEFLT**

NELFT and ELFT both fall within the NEL ICS. As part of the collaborative working model, both mental health trusts will work together to agree formulary status and likely use of medication in treatment pathways. In doing so, this will address health inequalities across the ELFT/ NEFLT boundaries in terms of access to medication.

However, there will be times where there is a difference in formulary status/ use of medication, as a result of provider/ commissioner contracts and funding of services across NELFT/ ELFT.

**4.0 NEL ICS**

The NEL ICS represents Barking and Dagenham, City of London, Hackney, Havering, Newham, Redbridge, Tower Hamlets and Waltham Forest. ELFT provides services to City & Hackney, Newham and Tower Hamlets.

Formulary applications are submitted to the Formulary and Pathways Group (FPG) which triage and review all medicine applications. The FPG has representation from primary care and acute/mental health providers, including: NHS NEL, Barts Health NHS Trust, Barking, Havering and Redbridge University Hospitals NHS Trust, Homerton Healthcare NHS Foundation Trust, North East London NHS Foundation Trust, East London NHS Foundation Trust, primary care prescribing leads and non-medical prescribing.

For further information on the NEL Integrated Care System, please follow the link below:

<https://www.northeastlondonhcp.nhs.uk/aboutus/north-east-london-integrated-care-system.htm>

**5.0 BLMK ICB**

The BLMK ICB represents Bedford borough, Central Bedfordshire, Milton Keynes and Luton. ELFT provide services to Bedfordshire and Luton. The healthcare service providers within BLMK are; ELFT, CNWL, Cambridgeshire community NHS services, Bedfordshire Hospitals NHS, Milton Keynes University Hospital NHS.

Formulary applications are submitted to the sub group within the Area Prescribing Committee (APC), known as the formulary group. The formulary group has representatives from the above group and are responsible for reviewing all applications pertaining to medication across the BLMK ICB. Once the formulary group have reviewed and made a decision with regards to a medicine application, they will send it onto the APC group for formal agreement. Once this is complete, the formulary can be updated for BLMK as well as local ELFT formulary.

For further information about the BLMK ICB structure and services please follow the link below:

<https://bedfordshirelutonandmiltonkeynes.icb.nhs.uk/about-us/> (accessed May 2023)

**6.0 Purpose**

The aim of this policy is to set out the process for the completion of a drug review and formulary application to primary care stakeholders and ELFT medicine committee, for medication which fall into any of the below categories:

Inclusion of newly marketed medicines

Non-formulary medicines

New presentations of formulary medicines

Change/ addition in license indications for formulary medicines

Unlicensed/ off-label use of medicines

Request for change in formulary state for any of the medications in the above categories

**7.0 Roles and Responsibilities**

Decisions with regards to medication formulary status must be kept **confidential** until there is an agreement with regards to medication status between NEFLT (where appropriate), ICBs and medicines committee.

7.1 Clinicians

If a clinician/ prescriber within ELFT would like a particular medication to be reviewed for addition to/ change in formulary status, they should contact their local pharmacy team.

7.2 Pharmacy

The local pharmacy team will direct the clinician/ prescriber/ service to the pharmacist who has oversight of the formulary and formulary application process.

7.3 Formulary pharmacist

The pharmacy team are responsible for having an allocated person to have oversight of:

The formulary application process to medicines committee

Submission of a drug review and recommendations for formulary status for a new medication

Submission of a formulary application for a new medication/ change in license/ formulary status to the relevant stakeholders.

Liaising with the relevant stakeholders (internal and external to ELFT) to submit the appropriate formulary applications and agree formulary status in the respective services provisions across the secondary and primary care interface

Update the ELFT BNF and reflect grading of medication

To be involved in the process of implementation and dissemination of information where a new medication/ formulary status change has been introduced.

7.4 Medicines Committee

The medicines committee is responsible for reviewing all drug reviews, considering and agreeing if a medication should be added to the formulary and how it should be graded.

7.5 NEL ICS/ BLMK ICB

Review of formulary applications and to agree status across primary and secondary care.

Where appropriate, to be involved in the process of implementation and dissemination of information where a new medication/ formulary status change has been introduced.

**8.0 Formulary grading of medication**

**Please note:** the grading of formulary is subject to change depending upon the agreement across primary and secondary care

The Trust formulary can be found on the Electronic British National Formulary (eBNF) and only applies to psychiatric medicines (see ELFT intranet desktop for link). Where appropriate, the medication will contain links to the relevant policies on the intranet medicines policies/guidelines page.

Formulary for NEL ICS can be found at: <https://primarycare.northeastlondon.icb.nhs.uk/home/meds/bhrut-formularies/>

Formulary for BLMK ICB can be found at:

<https://medicines.bedfordshirelutonandmiltonkeynes.icb.nhs.uk/categories/formulary/>

<https://www.bedsformulary.nhs.uk/default.asp>

8.1 Table: The INTERNAL formulary status for ELFT reflects the agreement across primary and secondary care:

|  |  |
| --- | --- |
| **Green** | Can be initiated by primary or secondary care. Patients started in secondary care can be moved to primary care on discharge. |
| **Yellow**  **Secondary care initiation and stabilisation (either/ all conditions apply)** | 1- Requires secondary care initiation and stabilisation  2- Stabilised patients can be transferred to GP/ primary care (without/ without shared care agreement)  3- Prescribing stays in secondary care, but does not require completion of any ELFT formulary paperwork for prescribing  4- GP can agree to take over prescribing of the medication (local agreement) |
| **Orange**  **Non-formulary (either/ all conditions apply)** | 1-Requires completion of non-formulary form and/or sign off my associate/clinical director  2-Requires completion of initiation/ continuation form  3-Requires secondary care initiation and stabilisation.  4-Stabilised prescribing can be moved to GP/ primary care (without/ without shared care agreement)Note-  5-Prescribing stays in secondary care  Those admitted on a non-formulary medication, can be continued if clinically appropriate. Transfer to primary care would be based on local agreement, otherwise prescribing would be retained within ELFT |
| **Red: Not approved for use** | 1- Not approved for use within ELFT  2- Cannot be transferred to primary care  3- Primary care do not support prescribing  Note- if patient admitted on this medication, then ELFT would continue to prescribe if clinically appropriate to do so. Transfer to primary care would be based on local agreement, otherwise prescribing would be retained within ELFT |

**9.0 Horizon scanning**

The formulary pharmacist will horizon scan with the aim of providing advanced warning to the Medicines Committee on:

New medicines likely to be available in the United Kingdom during the forthcoming 12 months.

New presentations of formulary medicines.

Medicines with newly licensed indications which may be used within ELFT services.

New evidence based research for non-formulary medicines.

**10.0 Formulary process: medicines to remain within secondary care**

Where a medicine is deemed appropriate to remain with secondary care, for e.g. reasons of cost, monitoring, requiring on-going specialist input, a formulary application **may still be required for submission** to the relevant ICB.

The ICB needs to be informed of any medication which will remain in secondary care whether it is new and/ or there is a change in status. A decision will then be made if a full formulary application is required. Any medicines to remain within secondary care only, would be reflected in the ICB **hospital only list (HOL)**. The HOL is a joint list across the ICB and includes NELFT and ELFT.

The new medicine review form (Appendix 3) needs to be completed with proposed formulary status. The formulary status should also be discussed with NELFT as part of the collaborative working and NEL ICS model.

The completed drug review should be presented as the EFLT medicines committee for review and approval.

**11.0 Formulary process: New medicines across ICB/ ICS (BLMK/NEL)**

When a new medicine has been approved for use by MHRA and a NICE appraisal has been completed, the formulary pharmacist will undertake the following

Inform the medicines formulary group for BLMK ICB/ NEL ICS that ELFT will be submitting a formulary application

Liaise with NELFT (as part of NEL ICS only) model to agree formulary status across the ICB for both mental health trusts

Complete the formulary application for NEL ICS in conjunction with NELFT

Complete a new medicine review of the product identifying clinical efficacy and effectiveness, clinical risk and cost effectiveness. Comparisons will be made with established approved treatments if appropriate.

For **NEW** medicines, formulary application and status would need to be agreed with the relevant ICB/ ICS (BLMK/NEL) **before** the new medicine review and formulary recommendations are presented to medicines committee.

**Note:** If this is a NICE TA then the expectation is that medication would be added to formulary without the need for a formal application. However, trusts would be expected to agree on how they would implement the guidance.

**12.0 Formulary process: change in status**

Change in status refers to any medication where ELFT wants to present new evidence/ change in license/ use/ cost which would require change in formulary status.

For any medication requiring a change in status, the formulary pharmacist would need to liaise with NEFLT formulary for an agreement in change and to prepare the appropriate formulary application for NEL ICB.

The formulary pharmacist would inform BLMK/ NEL ICB about the proposed change, complete the necessary formulary paperwork and then take to the medicine formulary group for consideration.

The formulary pharmacist would use the new medicine review template to provide and update on the medication. This would be presented to the medicine committee alongside representation of the ICB positions and proposed updated formulary status.

**13.0 Formulary application submissions**

Formulary applications need to be submitted to both the BLMK and NEL ICB. The formulary application for NEL ICB needs to be submitted in conjunction with NELFT. The formulary application on behalf of NELFT is to be completed by the formulary pharmacist, and can include a joint application from a clinician if required.

13.1 BLMK ICB

Formulary applications are submitted to the BLMK APC (Area Prescribing Group). Prior to submission, the formulary lead should speak to the APC formulary lead to discuss how to submit application and appropriate paperwork required.

Email: [blmkicb.contactus@nhs.net](mailto:blmkicb.contactus@nhs.net)

13.2 NEL ICB

Formulary applications are submitted to the NEL FPG. The FPG is a decision making body. The expectation is that trust should discuss the application with the FPG lead in the first instance. The FPG lead can advise which form to use and send trust the latest form.

The FPG lead should be contacted via the generic email prior to making any formulary applications for advice re: process and which forms needed to be completed.

Please note: FPG have two sub-groups: Guidelines & Pathways and Shared Care Guidelines group. Depending on the item, it would be presented at the appropriate sub-group.

Email: [nelondonicb.nelfpg@nhs.net](mailto:nelondonicb.nelfpg@nhs.net)

**14.0 Implementation**

Once a formulary status agreement has been reached by NEL/ BLMK ICB and medicines committee, the formulary pharmacist completes the following:

Update the online BNF to reflect the new status

Liaise with the pharmacy team leads to roll out any necessary training/ education needed for teams/ services

Liaise with EPMA, where appropriate, to update the e-prescribing module with the necessary prescribing information

Liaise with the medicine safety officer and the communications team to inform services/ teams of the changes which have been agreed/ new medication added to formulary

Communicate when the formulary status has been updated in ELFT to the relevant internal/ external stakeholders so they are able to update their formularies and relevant guidelines

Inform the dispensary of any new medication added to formulary/ change in formulary status which would impact authorisation/ supply of medication.

**15.0 ELFT: Use of non-formulary medicine** **(status: ORANGE)**

The below process applies to community (FP10) and inpatient services.

15.1 Initiation of a non-formulary medicine

If there is no suitable formulary alternative and an individual Consultant wishes to initiate treatment with a non-formulary medicine, then, the Team Leader Pharmacist at the respective site should be contacted to discuss the request.

If it is considered necessary to initiate treatment with a non-formulary medicine, then a “Request To Use a Non-Formulary Medicine Form – section A” (Appendix 1) should be completed by the consultant. The form will also need to be signed by the locality clinical director and locality lead pharmacist.

For inpatient services, the Non-formulary form, must be completed and uploaded into the patient RIO notes before the medication is ordered and supplied.

15.2 Continuation of treatment with a non-formulary medicines

If a patient is admitted on a non-formulary medicine, and there is no clinically appropriate alternative available on the formulary, the site based mental health pharmacist should be contacted to discuss continuation of treatment with the non-formulary medicine.

The consultant should complete the ‘Request to use a non-formulary medication- section B: continuation’ (Appendix 2). This should be signed by the locality clinical director and locality lead pharmacist. For inpatient services, the Non-formulary form, must be completed and uploaded into the patient RIO notes before the medication is ordered and supplied.

Where appropriate the patients’ own drugs should be used to avoid a delay in treatment whilst obtaining the non-formulary medicine. Refer to ‘Policy for the handling of medicines which patients bring into hospital’. Intranet: Policies and Procedures / Pharmacy / Policy for the handling of medicines which patients bring into hospital.

**16.0 ELFT: Prescribing a non-formulary medicine in EPMA**

Once a non-formulary medication has been approved, the prescriber will be able to prescribe the medication in EPMA. If the non-formulary medication is not available for selection, the site based pharmacist should contact the EPMA Team who will build the drug into the system.

At the point of prescribing, the prescriber will be alerted that the medication is non-formulary. A reason for prescribing will need to be selected in order to continue. A list of formulary alternatives will also appear should the prescriber wish to select an alternative medication.

**17.0 Medication information from pharmaceutical industries**

Where services/ teams/ staff are contacted by a pharmaceutical representative, they should re-direct the person to their local pharmacy team.

The local pharmacy team will inform the formulary pharmacist who can arrange to meet with the pharmaceutical representative with regards to information pertaining to new medication/ change in license and/ or any other promotional information.

Pharmaceutical representatives must only provide educational sessions to hospital teams for approved use of medicines across the Trust. Meetings must be booked following Trust policy, ensuring the pharmacy are informed of all meetings in advance.

Pharmaceutical representatives must not provide educational sessions about a new medicine that has not been approved or is subject to compliance with an approved protocol or guideline. In such cases where clinicians have accepted educational sessions/ information, the locality pharmacy team must be informed, who in turn will inform the formulary pharmacist.

Information about new medicines that have not been approved or have restricted use must only be provided by request from a healthcare professional and should follow the ‘***Standards of Business Conduct Policy’***.

Please ensure declarations are upto date with regards to using industry represented resources.

**18.0 Further advice/ information**

If clinicians/ staff require further advice with regards to the formulary process or grading of medication for formulary, please contact your locality pharmacy teams below:

|  |  |
| --- | --- |
| Newham pharmacy service (mental health/ CHS/ community services/ CAMHS London areas ONLY) | elft.pharmacynewham@nhs.net |
| Tower Hamlets pharmacy service (mental health/ CHS/ community services) | elft.pharmacytowerhamlets@nhs.net |
| City and Hackney (mental health/ community services/ forensic services) | elft.pharmacycityandhackney@nhs.net |
| Luton and Bedfordshire (mental health/ CHS/ community services/ CAMHS) | elft.pharmacyluton@nhs.net |
| BLMK ICB formulary/ medicine advice | blmkicb.contactus@nhs.net |
| NEL ICB formulary/ medicine advice | nelondonicb.nelfpg@nhs.net |

**Appendix A**

**Request to Use a Non-Formulary Medicine Form: INITIATION**

**Section A.** Initiation of treatment with a non-formulary medicine.

**Patient Details**

|  |  |
| --- | --- |
| **First Name** | **Surname** |
| **Date of Birth**  **Unit Number** | **Site/Location** |
| **Sex** | **Diagnosis** |

**Medicine Details**

|  |
| --- |
| **Drug and preparation requested (including strength, and formulation) and dosage (including strength and frequency)** |
| **Clinical indication for use** |
| **What formulary options have been tried?** |
| **What is the reason for preferred use of the named product?** |

|  |
| --- |
| Consultant …………………………………………………………………………………………….  Signature………………………………………………………Date………………………………………..  Directorate………………………………………………. |

|  |
| --- |
| Clinical Director …………………………………………………………………………...………………….  Signature.……………………………………………………Date.……………………..………………….. |

|  |
| --- |
| Site Lead Pharmacist …………………………………………………………………….………………….  Signature:………………………………………………………Date……………………….……………….. |

**Please upload form into patient RIO record once complete**

**Appendix B Request to Use a Non-Formulary Medicine Form: CONTINUATION**

**Section B.** Continuation of treatment with a non-formulary medicine.

**Patient Details**

|  |  |
| --- | --- |
| **First Name** | **Surname** |
| **Date of Birth**  **Unit Number** | **Site/Location** |
| **Sex** | **Diagnosis** |

**Medicine Details**

|  |
| --- |
| **Drug and preparation requested (including strength, and formulation) and dosage (including strength and frequency)** |
| **Clinical indication for use** |
| **Are there any clinically appropriate formulary options available for this patient?** |

|  |
| --- |
| Consultant Name:…………………………………………………………………………………………….  Signature:………………………………………………………Date:……………………….………………..  Directorate:……………………………………………………………………………………………………. |

|  |
| --- |
| Site Lead Pharmacist:……………………………………………………….………………….  Signature:………………………………………………………Date:………………………..…………….. |

**Please upload form into patient RIO record once complete**

|  |  |  |
| --- | --- | --- |
| **Appendix 3: East London Foundation Trust Foundation (ELFT):**  **Medicines Review/ Formulary status form** | | |
| NAME OF DRUG  LAUNCHED BY  APPROVED | | |
| **Content of review**   1. Summary 2. Product overview 3. Clinical Efficacy 4. Evidence Synopsis 5. Safety 6. Alternative pharmacological interventions 7. Budget impact 8. Funding 9. Recommendations for use and FORMULARY status 10. Decision from the Medicine Committee | | |
|  | | |
| 1. **Summary** | | |
|  | | |
| 1. **Product Overview (1)**   *Background*  *Licenced indication*  *Dose schedule*  *Interactions*  *Monitoring* | | |
|  | | |
| 1. **Clinical Efficacy**   POPULATION SAMPLE  LICENSED INDICATION  CLINICAL/ RESEARCH EVIDENCE | | |
|  | | |
| 1. **Evidence Synopsis**  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | Author | Summary | Primary outcome | Secondary outcome | Main findings | Limitations/ Side effects | |  |  |  |  |  |  | |  |  |  |  |  |  | |  |  |  |  |  |  | |  |  |  |  |  |  | | | |
|  | | |
| 1. **Safety**   ADVERSE EFFECTS> MOST COMMON TO MORE SERIOUS  EVIDENCE BASE TO SUPPORT E.G. SPC, RESEARCH, OTHER REVIEWS | | |
|  | | |
| 1. **Alternative pharmacological interventions**   Licensed options:  Off label/ unlicensed treatments: | | |
|  | | |
| 1. **Budget impact**   COST INFORMATION FROM E.G. NHS EVIDENCE SUMMARY, DRUG TARIFF  PRICES FOR DIFFERENT PACK SIZES  PROJECTED COST> 28 DAY AND ANNUAL  COST COMPARISON IF APPROPRIATE TO EQUIVALENT PRODUCTS  COST PROJECTION FOR THE DRUG AND/ OR IN COMPARISON TO EQUIVALENT PRODUCTS    **Estimated cost projection for ELFT**  COST FROM ELFT | | |
|  | | |
| 1. **Funding**   Cost of initiation and maintenance  CCG  Transfer of care and cost would need to be agreed with CCG and GPs | | |
|  | | |
| 1. **Recommendations for use and FORMULARY status**   SUMMARISE IN A FEW BULLETINS | | |
|  | | |
| 1. **Decision from Medicine Management Committee**  * TO BE ADDED AFTER MEDS COMM * SUMMARISE IN A FEW BULLET POINTS | | |
|  | | |
|  | | |
|  | | |
| **Complied by** | **NAME OF PERSON WHO WROTE REVIEW** | **DATE** |
| **Reviewed by** | **BODIES E.G. MEDS COMM** | **DATE** |