

## Appendix 1: Guidance notes to support the completion of the New Medicine Formulary Application Form

### General guidance

The New Medicine Formulary Application Form should be used to document all requests to the Kent and Medway Integrated Medicines Optimisation and Prescribing (IMaP) Group for new medicines to be recommended to the Integrated Medicines Optimisation Committee (IMOC) for inclusion in the Kent and Medway Joint Formulary with the exception of medicines with a positive NICE TA, for which the NICE TA Governance form should be completed.

- Please complete **all** details – incomplete forms will be returned.
- Applications should be completed by the requesting clinician with support from the specialist or formulary pharmacist. The application must have the support of the relevant Clinical Director. For primary care, applications may be pharmacist led, with support from a GP clinical advisor or GPwSI.
- Applications must consist of critically appraised evidence-based data outlining the efficacy, therapeutic advantage, safety and cost relevant to the products already used.
- Applicants should see the notes in Appendix on conducting a literature search and critical appraisal of the evidence.
- An application for a drug that has been rejected within the last twelve months will normally be refused, unless it is for a different indication, is based on new evidence/new national guidance or in circumstances deemed exceptional by the Group.
- The manufacturer/supplier (drug company) may provide information supporting the application – (this must be referenced appropriately), but the application **MUST** come from an appropriate applicant working within the local NHS (see above).
- Where possible electronic versions of any references and other supporting documents should be attached to the application (do not embed documents in the application, please send as separate attachments)
- Applications and any supporting guidelines/pathways etc should be in the final version or near to final version to allow for efficient discussion and decision making during the meeting. Do not submit documents containing comments or watermarks.
- All engagement with stakeholders should occur prior to submission of the application.
- Applications should be submitted at least 4 weeks in advance of the IMaP meeting to allow for review and any critical amendments to be undertaken.
- The form should be submitted electronically as a **Word document** by e-mail to your Trust Formulary Pharmacist or for Primary care colleagues to [kmicb.medicinesoptimisation@nhs.net](mailto:kmicb.medicinesoptimisation@nhs.net)
- Please ensure that the name of the medicine is included in the file name e.g. “Medicine” - KM Joint Formulary New Medicine Application Form
- The applicant is expected to present the application at the IMaP meeting. They should present a maximum 5 minute summary of the evidence and be prepared to answer questions from the group members for a maximum 10 minutes.

- A decision will then be made by the IMaP to either recommend / not recommend the application to the IMOC. If recommended, this application will then be submitted to the IMOC for final approval.
- Any changes to papers requested by IMaP, prior to IMOC approval, are the responsibility of the applicant. Updated papers should be shared with the IMOC meeting organiser in accordance with meeting deadlines for papers.
- Information on the IMOC decision will be included in the minutes from the meeting and on a summary report which will be sent to the lead Healthcare Professional/Applicant within 2 weeks of the IMOC meeting.
- Each organisation is responsible for implementing the IMOC decision within their own organisation.

## The following guidance explains how to complete each section of the New Medicine Formulary Application Form

### **PART A**

Part A is to be completed by the health care professional, requesting the addition of the medicine to the formulary.

#### **1. Requestor Details**

**Name / Designation:** Provide your full name and job title. For secondary care applications, the request must be consultant-led. Applicants must work within an NHS organisation or an organisation commissioned to provide NHS services.

**Organisation:** Must be a Kent & Medway NHS provider or commissioned provider of NHS services. Applications from industry representatives are not accepted.

**Support of Clinical Director:** State the name and title of the senior clinician confirming support for the application

**Declaration of interests:** All applicants must provide a full and accurate Declaration of Interests to support transparent and unbiased decision-making. Please disclose any financial, professional, or personal interests that could reasonably be perceived to influence your application. This includes relationships with pharmaceutical companies, consultancy roles, sponsorships, research funding, gifts, or any other relevant affiliations. If no such interests exist, please tick to confirm that there are no conflicts of interest in relation to your application. Incomplete or omitted declarations may delay the assessment process.

#### **2. Executive Summary**

Provide a concise, high-level overview of the application including:

- The medicine's name and proposed indication
- What the committee is being asked to approve
- Brief summary of clinical rationale
- Expected financial or pathway impact

This should be understandable without reading the full form.

#### **3. About the Medicine**

**Medicine Details:** Include the following exactly as they appear in the SPC:

- Medicine name (generic plus brand if branded generic\* or biologic)
- Strength(s)
- Formulation
- Dose and frequency
- Route of administration
- Manufacturer
- Any special administration considerations (e.g., reconstitution, infusion time)

\*NB: List prices for some 'branded generics' may be lower than the reimbursement price for equivalent generics. However, any cost savings achieved by their use may be unsustainable by the manufacturer and may not necessarily be cheaper, or in the best interests of the NHS in the longer term. There are a few circumstances when it is appropriate to prescribe a specific manufacturer's product (branded or generic). These include:

- drugs with a narrow therapeutic index
- certain modified- or controlled-release drugs
- certain administration devices
- multiple ingredient products
- biological drugs including biosimilars
- drugs with different licensed indications
- ensuring adherence to long-term medications, where differences in appearance between manufacturer's products might cause confusion and anxiety

**Proposed Indication:** Explain:

- The condition being treated
- Whether the indication is licensed, off-label or unlicensed. State whether the requested use aligns with the licensed indication.
- If your proposal differs from the SPC, describe clearly and justify with supporting evidence.
- Identify any restrictions

**Proposed Duration of Treatment:** Provide expected duration (short-term, fixed course, long-term, until disease progression).

Explain:

- Typical treatment duration
- Criteria for continuation
- Review intervals

**Proposed Place in therapy**

- Outline the current patient care pathway and where the new treatment would sit within it.
- Identify relevant alternative treatments used locally or nationally.
- State whether the medicine replaces an existing treatment or acts as an additional option.
- Consider drugs in the same class, current standard of care, and non-pharmacological options (e.g., surgery, monitoring).
- Indicate if transfer of care or shared-care arrangements are expected and whether RMO shared-care criteria are met.
- Explain why the new medicine is needed and what gap it aims to fill.

- Specify whether the medicine is intended for 1st-, 2nd-, or 3rd-line use, or restricted to specific patient groups.
- Outline briefly NICE guidance in the therapeutic area or other best practice guidance in the absence of NICE where this exists.

#### 4. Evidence base

All evidence must be provided via **hyperlinks or separate attachments**. Do **not** embed documents within the form. See **Appendix 2: Guidance to support evidence review**

**Supporting References:** These may include:

- Key Randomised Clinical Trials (RCTs)
- Meta-analyses
- NICE/TAG or SMC guidance (if available)
- Real-world studies if applicable
- SPC/MHRA information

**Effectiveness:** Provide a structured summary of:

- The principal trials supporting the indication
- Study design and patient population
- Primary and secondary outcomes
- Clinical significance of results (not only statistical significance)
- How the results apply to Kent & Medway's patient population
- Whether the medicine may improve pathway outcomes (e.g. reduced admissions, improved symptom control)

**Efficacy vs Comparators:** Discuss:

- Direct comparator studies (if available)
- Relative benefits over current formulary options
- Impact on adherence, quality of life, speed of response
- Any disadvantages (cost, more monitoring, administration route)

**Safety:** Provide relevant information on:

Safety Profile:

- Common and serious adverse effects
- Contraindications and cautions
- Drug–drug and drug–food interactions
- Special populations (pregnancy, renal/hepatic impairment)
- 

Monitoring Requirements: State:

- Required tests (e.g., LFTs, FBC, ECGs)
- Frequency of monitoring
- Whether monitoring is short-term (until stable) or required throughout treatment
- Which service will provide monitoring

Administration Risks e.g.:

- Infusion reactions
- Device training requirements
- Risk of medication error due to similar names/strengths

## 7. About the Pathway

**Initiation of Treatment:** Explain the initial supply arrangements. Specify:

- Where treatment will start (hospital clinic, specialist service, community provider)
- Which clinician/role initiates therapy
- How baseline monitoring will be arranged

NB: Using a supply route which requires the patients' GP to generate a prescription for the initial supply when an item has been recommended by a specialist is not the preferred route for the following reasons:

- Impact on patient; the patient now must access another healthcare professional to obtain the item
- Use of healthcare resources; additional resources (to the initial consultation) are required to supply the item

**Continuation of Treatment:** State:

- Where ongoing prescribing will occur (specialist/primary care)
- Whether a shared care protocol or prescribing guidance is required. Where possible any such documents should be submitted with the application.
- Any restrictions for primary care (e.g., only after stabilisation)

**Deprescribing:** All applications should include consideration of the deprescribing process to support safe and appropriate use of medicines throughout the treatment cycle. Within this section outline any considerations for stopping or tapering this medicine when it is no longer appropriate.

- When should this medicine be discontinued? Outline clinical situations or timepoints when stopping the medicine is appropriate.
- Responsible clinician: State which clinician is responsible for deprescribing e.g. primary care prescriber/specialist etc
- Suggested tapering or withdrawal protocols: Include any dose reduction strategies or step-down guidance, where applicable.
- Risks of discontinuation: Highlight potential risks such as withdrawal effects, relapse or rebound symptoms and whether any monitoring is needed during and after cessation (e.g. symptom review, biochemical tests).
- Support tools, resources or guidance: List any guidelines, algorithms, or patient-facing materials that support safe deprescribing.

## 6. Resource Implications & Financial Impact

### Cost of Medicine

Provide:

- [Drug tariff](#) cost (primary care)
- Trust acquisition cost (secondary care)
- Cost per pack, per course, and per patient per year
- Include VAT status where relevant

### Estimated Number of Patients

Estimate:

- Eligible population in Kent & Medway per year
- Provide justification (e.g., incidence/prevalence data)

## Cost Impact

Explain:

- Net financial change (saving, pressure, cost-neutral)
- Offsetting cost reductions (e.g. discontinued treatments, reduced admissions)
- Whether cost pressures have been included in service budgets
- Consider the impact on Other Services e.g.:
  - Clinic capacity
  - Diagnostic testing
  - Nurse time / infusion capacity
  - Reduced or increased hospital attendances
  - Changes to surgical or procedural demand
  - Impact on community services and primary care







## 7. Formulary Classification

### Therapeutic Section

- Identify where the medicine will sit within the [Kent and Medway Joint Medicines Formulary](#) structure. Add a link to the webpage if it already exists. If a new page is required (e.g. new medicine class) state name for the new page and the parent section of the website.

### Proposed Formulary Classification

Select the proposed status from the drop down.



















 On Formulary Preferred	 On Formulary Second Line	 On Formulary Third Line
 Specialist Initiation	 Secondary Care Only	 Not Approved for Formulary

Guidance on the definitions can be found here: [Kent and Medway Formulary](#)

### Formulary Annotations

Include:

- Which icons should accompany the formulary entry. Available icons are:

	Link to EMC website		Unlicensed Drug
	Link to NICE website		Brand Specific Prescribing Required
	Preparations to be initiated by Ophthalmology specialists only		Preparations classified as 'Controlled Drugs'
	Carbon footprint indicator		Blueteq required. Click icon to redirect to website to complete.
	High-Cost Drug		Available for purchase over the counter without a prescription.
	Cytotoxic Drug		Maidstone and Tunbridge Wells NHS Trust ONLY
	Drug subject to a shared care agreement		East Kent Hospital University Foundation Trust ONLY
	Unlicensed use		Dartford and Gravesham NHS Trust ONLY
	Supply/Restriction warning		Medway Foundation Trust ONLY

- The wording for any annotations to the formulary to support appropriate and safe prescribing e.g. warnings, prescribing restrictions (e.g., consultant-only, microbiology-only)

### Impact on Other Medicines

Explain whether any:

- Existing medicines on the formulary need reclassification and what these changes are
- Medicines are replaced or removed
- Changes to existing formulary pages are required

Include all actions and information for the formulary team to make the necessary amendments.

## 8. Sustainability

Provide environmental considerations, including:

- Carbon footprint relative to alternatives
- Impact of packaging (e.g., plastics, gases, inhaler propellants)
- Storage and transport requirements
- Waste disposal impact
- Whether switching from an existing therapy improves environmental sustainability

## 9. Ethics

Consider:

- Patient autonomy, equity and access
- Whether the medicine reduces reliance on carers/social care
- Potential productivity benefits (ability to work or remain independent)
- Whether the treatment addresses unmet need or reduces inequalities

## 10. Engagement

### Kent & Medway Stakeholder Engagement

Effective engagement is essential to ensure that formulary decisions reflect clinical practice, service models and patient needs across all Kent & Medway organisations. Applications that do not demonstrate comprehensive engagement will not be accepted.

#### 1. Identify Relevant Stakeholders

Engagement must include all organisations and clinical areas where the medicine could be used. As the Kent & Medway Joint Medicine Formulary is system-wide, you must consult beyond your own organisation.

Stakeholders may include:

- **Acute Trusts:** EKHUFT, DVH, MTW, MFT
- **Primary care:** via the ICB medicine optimisation team
- **Community / specialist providers:** e.g. KCHFT, KMMH or other relevant commissioned services e.g. community dermatology
- **Relevant networks or MDTs:** e.g. condition-specific specialist groups, pathway oversight groups

- Any other service likely to be affected by implementation or change in practice

Where commissioned services differ between organisations, this should be highlighted and reflected in the engagement approach.

## **2. Invite stakeholders to participate in development of the application**

Stakeholders should be engaged as early as possible in the development of the application to ensure that the proposal reflects practice and impact across all relevant Kent & Medway services. Early engagement enables stakeholders to provide informed input on:

- Current practice across their service
- Clinical views on the proposed medicine
- Anticipated patient numbers
- Expected impact on patients and outcomes
- Operational considerations including capacity, workforce, training requirements and resource implications
- System implications such as equalities issues, variation in commissioned services, pathway differences and cross-boundary working
- Any concerns, risks or recommendations related to the proposal

The method of engagement should be appropriate to the complexity of the topic and may include:

- Direct email contact with relevant specialists, service leads and pharmacy teams
- Discussion via existing working groups, MDTs or networks
- Establishing task and finish groups for more complex proposals requiring detailed clinical or operational input
- Engagement with primary care is via the Kent and Medway Medicines Optimisation Group (KMMOG). Submissions requiring primary care input must be sent to the following mailboxes, which will arrange review and scheduling on the KMMOG agenda:
  - [kmicb.eastkentprescribing@nhs.net](mailto:kmicb.eastkentprescribing@nhs.net)
  - [kmicb.dgscg.medman@nhs.net](mailto:kmicb.dgscg.medman@nhs.net)
  - [kmicb.wkmedman@nhs.net](mailto:kmicb.wkmedman@nhs.net)
  - [kmicb.medwayswale.meds@nhs.net](mailto:kmicb.medwayswale.meds@nhs.net)

## **3. The formulary application must include:**

- Name, job role, and organisation of those consulted
- Summary of feedback received, capturing key themes, points of agreement or disagreement, concerns, and any variation between organisations
- Level of support or outstanding concerns
- Evidence that feedback has been considered or incorporated, demonstrating that changes have been made based on feedback, or the rationale for not adopting certain suggestions.

Applications must show that the engagement process has produced a Kent & Medway system-wide perspective, not an individual-organisation viewpoint, unless differences are due to commissioning arrangements.

**Applications lacking full engagement will not be accepted.**

## **External Organisations**

Summarise:

- Pan-London guidance (if any)
- Neighbouring ICS positions
- NICE, SMC or AWMSG stance (if relevant)

## **11. Supplementary Information (Optional)**

Use this section for any additional background information relevant to the application not already covered within the application (optional) e.g.:

- Additional clinical context
- Unique patient needs
- Local service issues
- Further unpublished or emerging data

## **12. Implementation**

### **Implementation Plan**

Describe:

- What actions are required for safe roll-out
- Responsible individuals/teams
- Expected timelines
- Whether ScriptSwitch messages (primary care point-of-prescribing decision support tool) or clinical communications are needed
- Required staff training or SOP updates

### **Secondary Care Considerations**

- ePMA implications: are there any expected implications when adding this medicines or its administration instructions to the ePMA system?
- Any updates required to infusion pump/driver drug libraries?

## **PART B – To Be Completed by a Pharmacist**

### **13. Sponsor Details**

Confirm:

- Name
- Designation
- Organisation
- Whether any declarations of interest exist in relation to the application

Sponsor must be a senior formulary pharmacist or therapeutic area lead.

### **14. Independent Pharmacist Review**

**Reviewing Pharmacists Comments:** Provide:

- Critical appraisal of evidence
- Assessment of safety, cost-effectiveness and governance
- Suitability for GP prescribing (if requested)
- Risks, mitigations and practical implementation issues

**Recommendation to committee:** Final recommendation (support / do not support / support with conditions)

## **Appendix 2: Guidance to support evidence review**

### **1. Conducting a Literature Search**

A robust literature search is essential to demonstrate the clinical and cost-effectiveness of the proposed medicine. Follow these steps:

- **Define the Research Question:** Use the PICO (Population, Intervention, Comparator, Outcome) framework to guide your search.
- **Identify Reliable Sources:** Prioritise high-quality, peer-reviewed sources such as:
  - PubMed/MEDLINE
  - Cochrane Library
  - Embase
  - NICE Evidence Search
- **Use Appropriate Search Terms:** Include the drug name, therapeutic area, and relevant clinical outcomes. Use synonyms and medical subject headings (MeSH) to capture all relevant studies.
- **Filter for High-Quality Evidence:** Focus on systematic reviews, meta-analyses, and randomised controlled trials where possible.
- **Document Your Search Strategy:** Record the databases searched, date of search, keywords used, and any filters applied.
- Search <https://clinicaltrials.gov/ct2/search/advanced> for studies which are planned however have not reported. Knowledge of forthcoming trials will support the Committee in understanding the degree of uncertainty surrounding the risk/benefit and may support the Committee in delaying a decision until the evidence base has matured.
- Use the above link to identify the NCT number then enter the number into <https://scholar.google.co.uk/> to establish whether the study results are in the public domain.

### **2. Summarising the evidence:**

Outline and summarise the clinical literature reviewed. Include a brief explanation of the trials included and the rationale for focusing on specific studies (for example, active comparator RCTs only may be considered, or a recent meta-analysis). For included studies summarise key characteristics; for RCTs, for example:

- The trial design including the population and any important inclusion/exclusion criteria
- The number of subjects and the allocation process
- The primary efficacy endpoint
- The key results and their statistical / clinical significance

Consider, for example, how internal and external validity of the trials might affect use in actual clinical practice; and what the absolute advantages of the drug are in comparison to a natural comparator – are there any direct comparisons, meta-analyses, Cochrane reviews etc, or can data from other registrational studies be used as a loose comparison.

How does this compare with current therapy? What are the limitations in comparing older studies with newer ones – study design, duration, patient populations, endpoints etc.

### 3. Critical Appraisal of Evidence

When evaluating the quality of the identified studies, consider the following:

- **Study Design and Methodology:** Assess whether the studies are well-designed (e.g., RCTs, cohort studies) and appropriately powered.
- **Risk of Bias:** Use standard tools like the Cochrane Risk of Bias tool or CASP checklists to assess for potential bias. See [CASP Checklists - Critical Appraisal Skills Programme](#)
- **Outcome Relevance:** Ensure the reported outcomes are clinically meaningful and aligned with the proposed indication.
- **Applicability to Local Population:** Consider whether the patient population in the studies reflects those likely to use the medicine within the Kent and Medway area.
- **Consistency of Findings:** Review whether the evidence consistently supports the proposed benefits of the medicine.
- **Transparency and Data Integrity:** Check for conflicts of interest and ensure the data is accurately reported without selective outcome reporting.