NHS
Kent and Medway
Clinical Commissioning Group

Kent and Medway Joint Formulary Group
Terms of Reference

Controller:	Kent & Medway CCG Medicines Optimisation Team	**Circulation:**	
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Document history:

Versions	Created by	Date	Main Changes/Comments
1	KM MOT	October 2020	First version to be submitted to the committee for approval and comments.
2	KM JFG	November 2020	Comments received from Joint Formulary Group actioned
3	KM JFG	December 2020	Comments received from Joint Formulary Group actioned
4	KM JFG	March 2021	Inclusion of 3.15-3.16
5	KM JFG	March 2021	Comments received from Joint Formulary Group actioned
6	KM JFG	April 2021	Inclusion of Appendices

1. Mission Statement

1.1. To aid the Joint Prescribing Committee in undertaking its role and responsibilities; to facilitate system-wide, rational, consistent clinical decision making with regard to approval of new medicines/ new uses of medicines, and development of standardised pathways and guidelines for the use of medicines, following a proper consideration of the evidence, and taking into account patient experience, safety, cost-effectiveness, and place in treatment pathway.

2. Purpose

2.1. The Joint Formulary Group (JFG) is the main working group for the Joint Prescribing Committee (JPC) to advise the committee on the entry of new medicines into the local health economy, in line with principles outlined in the JPC Terms of Reference. It aims

to achieve consistency of robust decision-making across the area and oversee the development of robust care pathways within Kent and Medway.

2.2. The Group will review licensed medicines (including those being used for an off-label indication) and unlicensed medicines. The scope of the JFG does not include the review of medicines that have received a positive NICE Technology Appraisal (TA) as there is a legal obligation for these medicines to be made available, however, it will oversee the development of robust care pathways and funding decisions related to the medicine. Where multiple medicines have NICE TAs for the same indication, JFG may review the evidence underpinning each NICE TA to support safe and effective prescribing by recommending to the JPC a preference hierarchy.

2.3. The JFG may review applications for medicines that have received a negative TA, although there would need to be a strong level of clinical support for doing so. The JFG will review a decision for a medicine that is currently on the formulary, but subsequently receives a negative opinion by NICE.

2.4. The JFG prioritises applications for new medicines where there is an impact for CCG commissioners, or where it is planned that prescribing will be transferred to primary care.

2.5. To develop, manage and maintain a Kent and Medway Joint Formulary which is evidence-based, considers clinical and cost-effectiveness and reflects the needs of the local population and local affordability.

2.6. To maintain a 'Do Not Prescribe' list which is evidence based, and takes into consideration decisions made by Joint Prescribing Committee and the Policy Recommendation and Guidance Group.

2.7. Ensure correct processes and procedures are followed for submission to the JPC. The JFG makes medicines related recommendations to the JPC. The process for applications is outlined in Appendix 1. Applications to the Joint Formulary Group to appraise a medicine must be submitted by the requesting clinician using the form in Appendix 2. The application will be reviewed by the JFG and an evaluation of the literature will form the basis of the discussion at the JFG meeting. Each recommendation made by the JFG will be clearly documented as below:

- Decision – Recommended/Not Recommended /Recommended under evaluation/Deferred
- Prescribing – Hospital only/GP initiation/ Secondary Care initiation with continuation by GP
- Tariff status: Included/Excluded
- Funding: Hospital budget/Hospital and GP budget/CCG/NHS-E (If funded by NHS-E then no requirement to take to KMMOC)
- Shared care required: Yes/No. If Yes- clarify duration of initiation
- Other notes: Include any relevant information i.e. dose if off-label, monitoring requirements

Decision on recommendation will be made by consensus discussion or if necessary by a majority vote. **This recommendation will then be submitted using the "Formulary Application SBAR template in Appendix 3" to the JPC for approval prior to ratification by Kent and Medway Medicines Optimisation Committee (KMMOC) and Clinical Cabinet (CC)**.

2.8. Support clinical leads in the CCG in seeking approval from JPC on work streams.

3. Remit

3.1 The group will:

- Review and recommend new and existing formulary medicines for ratification recommendation at the JPC.
- Identify where a guideline, care pathway or shared care protocol is required to ensure the safe and effective use of formulary medicines and to ensure that these are developed and implemented in a timely manner.
- Review and agree guidelines, care pathways and shared care protocols for the effective use of formulary medicines identified.

3.2 Liaise with JPC, relevant secondary care trust Drug and Therapeutics committees and other relevant bodies to ensure that any new drug with wider health economy implications is passed on to the formulary group for wide recommendation.

3.1. To respond to important new information on drug safety e.g. MHRA safety updates and new evidence of efficacy by amending the formulary and related guidelines, care pathways or shared care protocols.

3.2. To maintain a list of medicines recommended by NICE and indicate the place of approved medicines in the K&M Formulary.

3.3. To maintain a separate 'Do Not Prescribe' list and a "Not Suitable for Routine Prescribing" (or Grey List) which is evidence based and takes into consideration decisions made by the JPC. The JFG may review applications to decommission medicines where medicines are considered by the applicant, or NHS England, to be of low clinical value.

3.4. To highlight and support the development of specific treatment pathways, system wide policies to complement the joint formulary.

3.5. To support clinical workstream leads and their work stream groups to prepare recommendations for the JPC ensuring all necessary information is included to allow robust decision-making across the area.

3.6. The committee will continually review its decision making processes based on the DH guiding principles and best practice as defined by the National Institute for Health and Care Excellence (NICE) and the NHS Constitution. It will also ensure appropriate liaison with commissioning processes.

3.7. To liaise with the K&M system wide clinical reference groups and relevant committees in matters affecting medicines and the JPC.

3.8. To seek ratification of formulary applications at JPC, Kent and Medway Medicines Optimisation Committee (KMMOC) and Clinical Cabinet (CC). These Committees in turn hold overall accountability of decisions made within their respective organisations.

3.9. Collate and track the uptake of recommendations and decisions made by JPC and regularly report activities to JPC.

3.10. Engage ICP Medicines Optimisation Groups (MOG) and Medicines Networks by seeking input into recommendations and communicating JPC recommendations across Kent and Medway

3.11. JFG will ensure that all K&M formularies are kept up to date and all relevant links are included within an agreed period of time. The formularies will be reviewed on a regular basis

to consider new evidence or guidance issued i.e. to include NICE and the MHRA in particular.

3.12. Ensure continued governance procedures e.g. compliance with NICE Good Practice Guidance for formulary development and may request and review audit reports in order to monitor the impact of specific decisions.

3.13. Recommendations on standardization of medicines optimisation systems and polices across K&M including standardized document formatting, standardized shared care and standardized guidelines.

3.14. Undertake an annual horizon scanning exercise of and a working plan for the introduction of new medicines, National Institute for Health and Clinical Excellence (NICE) guidelines, revised use of existing medications, and unlicensed and or off label use of medication. This activity log identifies which medicines will be allocated for review by NHSE or NICE, and therefore which should be prioritised for the JPC. Any reviews allocated to the JFG should be applicable to the Kent and Medway ICS services and will be identified in the JFG work plan.

3.15. New formulary applications for the addition of different strengths/formulations of an existing drug on formulary will not be required. A SBAR report can be completed to present to the group for information. However, if the different strengths/formulation of an existing formulary drug present safety issues/ cost pressures/ present a new licensed indication, then a formal application would be required to ensure inclusion is evidence-based, considers clinical and cost-effectiveness and reflects the needs of the local population and local affordability.

3.16. The Joint Formulary Group will report and is accountable to the Kent and Medway Joint Prescribing Committee. The Joint Formulary Group minutes and other supporting documents will be presented to the Joint Prescribing Committee.

4. Out of scope:

4.1. Medicines that are exclusively used in the secondary care /tertiary setting **and** where there is no impact on primary care services, processes, or costs outside the secondary care /tertiary organization. Medicines that are solely to be used in secondary care/tertiary setting will be directly ratified at the relevant secondary care trust Drug and Therapeutics committees.

4.2. Non-prescribable devices and appliances (devices that are prescribable may be considered by the Committee if a more appropriate decision- making forum is not identified)

4.3. Procedures and other non-drug interventions

4.4. Medicines, indications, or services commissioned by NHSE Specialised Commissioning, and excluded from CCG commissioning, unless there is an impact on locally commissioned medicines or services that needs to be considered. This includes cancer medicines.

5. Membership, delegation and responsibilities

Members: Organisation represented	
Kent & Medway CCG	Lead Pharmacist - Formulary and Governance

Dartford, Gravesham & Swanley	Formulary Pharmacist or representative from Darent Valley Hospital DGS CCG Lead Pharmacist and/or Lead Technician
East Kent	Formulary Pharmacist or representative from East Kent Hospitals University NHS Foundation Trust East Kent CCG Lead Pharmacist and/or Lead Technician
Medway & Swale	Formulary Pharmacist or representative from Medway Foundation Trust Medway and Swale CCG Lead Pharmacist and/or Technician
West Kent	Formulary Pharmacist or representative from Maidstone and Tunbridge Wells Trust West Kent CCG Lead Pharmacist and/or Technician
Administrative support	Administration officer
Provider	KCHFT (to invite but not mandatory)
Provider	KMPT (to invite but not mandatory)

- The group will be chaired by the CCG Associate Director. In their absence, the individual's chosen respective deputies will chair the meeting. The membership will take account of professional and organisational representation as well as involving other stakeholders.

Members

- Input into the JFG work programme.
- Ensure all formulary applications for new drugs are discussed at JFG.
- Promote two-way communication between the committee and relevant NHS colleagues / organisations and local ICP MOGs.
- Disseminate papers to relevant clinicians for comment in a timely manner
- Feed any comments regarding papers back to the author for inclusion and discussion
- Take specific views from the committee back to your own organisation for comment
- Feed any responses regarding items back to the Committee, as appropriate
- Commit to regular attendance of meetings
- Disseminate decisions within their organisation and MOG meetings.

Quoracy

The JFG meeting will be considered quorate if the Chair (or Deputy), plus two CCG members and two different acute trust pharmacists are present.

6. Frequency of meetings

6.1. The Group will meet on a monthly basis and on request of the JPC.

7. Papers to Joint Prescribing Committee

7.1. Papers to JPC must be ready two weeks before the JPC meeting.

7.2 Where JPC has previously made a recommendation/decision, resubmission of applications will not be considered, unless additional information or evidence that may influence the decision was not considered when discussing the original decision, is provided. If provided, this group will prepare the additional information to be taken to the Committee along with the original paper and previous minutes where this was discussed. All formulary applications will be required to be submitted in the form of "Formulary Application SBAR in Appendix 3".

8. Timescales

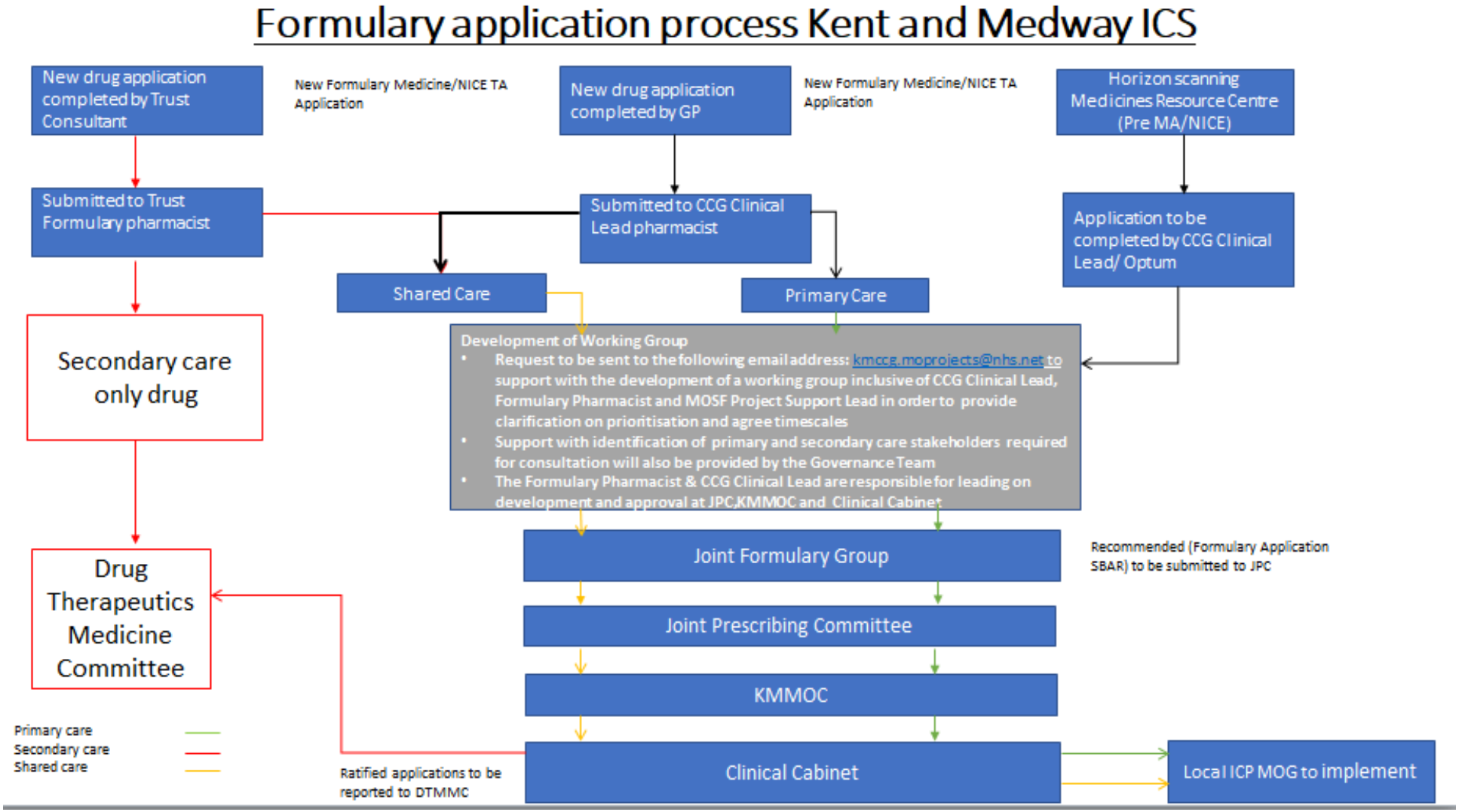
8.1. The JFG will send papers requiring consultation and engagement out to members for review and dissemination within their organisations to allow at least 7 working days before the JFG meeting.

8.2. JPC Agenda with papers will be sent out 7 working days before the Committee meeting.

8.3. Draft minutes of the meeting will be forwarded to attendees within 5 working days of the meeting for comment. Attendees will be given 5 working days to comment/suggest amendments. Any comments or suggested amendments should be shared with all attendees. After this point, the minutes will be considered as final. Decisions will then be forwarded to respective boards of the member organisations for information and ratification (where required).

8.4. Decisions will also be communicated to providers through the stakeholder organisation's pharmacy teams or relevant drug & therapeutics committees as appropriate.

Appendix 1: Formulary Application Process



Appendix 2: Formulary Application Form

Drug Name:	

This form must be used to document all requests to the Kent and Medway Joint Formulary Group (JFG) for new products to be recommended to the Joint Prescribing Committee (JPC) for inclusion in the Kent and Medway Joint Formulary. Any requests for new medicines must be completed by the requesting clinician employed by one of the local healthcare organisations.

Applications must consist of evidence-based data outlining the efficacy, therapeutic advantage, safety, or cost relative to the products already used. Ideally, supporting data should be from randomised controlled studies from peer review journals.

- Please complete **all** details – incomplete forms will be returned.
- The form should be submitted electronically by e-mail to your Trust Formulary Pharmacist or for Primary care colleagues to kmccg.moprojects@nhs.net
- The application should ideally be completed by the requesting clinician and should be supported by the relevant Clinical Director (Provider Trust).
- 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, but the application **MUST** come from an appropriate applicant (see above).
- Where possible electronic versions of any references and other supporting documents should be emailed at the same time.
- The applicant is expected to submit the application for consideration at the Joint Formulary Group (JFG) meeting. A decision will then be made by the JFG to either recommend / not recommend the application to the JPC. If recommended, this application will then be presented at the JPC for approval where the applicant will be expected to present the case in person.

Information on the JPC decision will be included in the minutes from the meeting and sent to the lead Healthcare Professional (HCP)/Applicant within 2 weeks of the JPC meeting. Please note the JPC will recommend the application for approval but final ratification will be sought from the Clinical Cabinet. It can take up to 8-10 weeks from point of application to final ratification decision at Clinical Cabinet.

1	**Applicant's Details** ***(If multiple HCPs involved, copy & complete section 1 and 2 for each HCP. Please include clinical director declaration of support in this section and ensure that all relevant HCPs within your organisation have been consulted)***
Name	
Job Title	
Organisation	
Department/team *(if applicable)*	
Specialty *(if applicable)*	
Direct contact number	

Email address	

2	Declaration of interests for requesting HCPs		
In line with governance policies (with which the applicant is expected to be familiar) any interest the applicant or their service have in the manufacturer of the requested product must be declared – this includes sponsorship for study leave or lectures. Applications with major undeclared conflicts of interest will be rejected (including inappropriate lobbying by industry).			
Have you or your department/team/Trust received any sponsorship from the manufacturers?		☐ Yes	☐ No
Do you have any financial interest in the manufacturing company?		☐ Yes	☐ No
Were you involved in any sponsored clinical trials of the drug?		☐ Yes	☐ No
If yes to any of the above sections, please provide details:			

3	New product details
Approved name	
Brand name	
Form *(tablet/cream/IM/etc.)*	
Licensed Indication(s)	
Proposed indication(s)	
Intended Dose and Route	
Expected duration of treatment	
Manufacturer(s)	
License status	☐ Licensed product ☐ Unlicensed product ☐ Off-license use
Proposed formulary status (tick all that apply)	☐ GP initiation ☐ Specialist Initiation ☐ Hospital only ☐ Shared Care required

4	**Clinical responsibility**		
Is shared care / transfer of care anticipated for GP prescribing/ monitoring?	☐ Shared care	☐ Transfer of care	☐ No
If Shared Care or Transfer of Care anticipated, are there shared care guidelines already available?	☐Yes	☐No	
If Yes applies, please attach existing guideline If No applies, please note a shared care guideline must be drafted and presented to the Joint Prescribing Committee on application.			

5	**Initial supply** **If supply to be continued by GP, what is the method of providing <u>initial</u> supply if item is recommended by a specialist?**	
Is proposed method of supply to request from patients' GP *(see below)*?	☐ Yes	☐ No
Duration of treatment to be supplied by specialist		

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 <u>not</u> the preferred route for the following reasons:

- Impact on patient; the patient now has to access another healthcare professional to obtain the item
- Use of healthcare resources; additional resources (to the initial consultation) are required to supply the item
- Governance; prescribers should be aware of the risks and benefits of items they prescribe and it may not be possible to provide sufficient training across primary care for a specialist product when patient numbers per medicine are low

If the answer to the above question is 'yes ', please describe why this route is the preferred option, which alternative routes were investigated and reasons why they are not suitable:

6	Place in therapy
Is this product a:	☐ close equivalent to existing preparations ☐ minor therapeutic advance ☐ major therapeutic advance
Would this product replace any existing treatments?	
If yes to above - list any current items this item would replace. Please confirm whether items being replaced can be removed from the formulary as a result.	
Please indicate where in the treatment pathway it is planned to use it, e.g. 1st/2nd /3rd line/ reserved for particular patient groups. Please give reasons for your proposed place in therapy.	
Are there any restrictions to the licensed indication proposed? If so, please specify:	

7	Evidence base	
Has the product been reviewed under the NICE guidance?	☐ Yes	☐ No
Has the product been reviewed under the NICE Technical Appraisal (TA) process?	☐ Yes	☐ No
If yes, was the recommendation positive or negative?	☐ Positive	☐ Negative
Reference number and date of recommendation:		
Has the product been recommended by national organisations e.g. SMC/AWSMG/DoH? (please provide references)		
Please provide a brief summary of the evidence base and /or medicine benefits under the three categories below: **Any submission which does not include this summary will be rejected (If a NICE TA is available please summarise key conclusions below)**		
Effectiveness 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 and efficacy? **Efficacy in comparison to other treatments** 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.		

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
Please provide hyperlinks and/or attach any supporting files *(e.g. NICE guidance/trial results/etc.)*: Please provide copies of **a minimum of 2** relevant references.
1. 2.

8	**Local health economy**
Describe the potential use of this drug/appliance in the context of the current **local health economy agreements**	
Expected patient outcome	
How would the addition of this drug benefit patient care?	
Expected impact on wider health outcomes for patients	
Are there any other non-medicine costs or savings related to using this drug? For example, will it require additional clinics to be set up, avoid a surgical procedure, or result in reduced length of stay in hospital? Will it result in fewer or more hospital visits, enable care to be delivered closer to home etc.?	
Criteria for discontinuation	

9	Funding stream		
Select all that apply		**Initiation**	**Continuation**
Within contract price/tariff		☐	☐
National Tariff Excluded (NTe) NHSE funded		☐	☐
National Tariff Excluded (NTe) CCG funded		☐	☐
National Tariff Excluded (NTe) Cancer Drug funded		☐	☐
Individual Funding Request (IFR) funding		☐	☐
Primary care budget		☐	☐
Consultant only		☐	☐
Other (please specify)		☐	☐

10	Cost impact		
		Primary care	**Secondary care**
Cost of 1 month's therapy *(or standard course if < 1 month)per patient*			
Expected number of patients per annum per 100k population (estimate)			
Estimated cost per annum *(therapy x patients)*			
Will this product have implications for other services *(E.g. blood tests, diagnostic tests or imaging required before or after treatment, input from community services, waste disposal)*? Please provide an estimate of costs or savings per annum			
How will on-going supply of this medication be provided?		☐ Acute Trust 'in house' prescribing ☐ Acute Trust via Homecare ☐ GP via FP10 prescription ☐ KMPT 'in house' prescribing ☐ Specialist service via FP10 ☐ Specialist service via 'off' prescription' route ☐ Other (please specify):	
Is the NICE recommendation based on a Patient Access Scheme?		☐ Yes	☐ No
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 cost and/or quality of life benefits	

11	**Consultation with colleagues (The submission will not be accepted if this section has not been completed)**	
Trust	**Please Tick**	**Names of Individuals consulted and summary of comments received**
EKHUFT	☐	
DGT	☐	
MTW	☐	
MFT	☐	
Primary Care	**Please Tick**	**Names of Individuals consulted and summary of comments received**
EK	☐	
DGS	☐	
WK	☐	
M&S	☐	

12	**Declaration**
This submission form has been completed by a clinician(s) and not by a pharmaceutical industry representative: ☐ **This submission has been discussed with and is agreed by the Prescribing Lead:** ☐	

Final Checklist:

- Application form **fully** completed ☐
- Supporting documents to append:
  References ☐
- Treatment Protocol/Guideline ☐

Signature of requesting Consultant/GP.....Print Name..... Date.....

Appendix 3: Formulary Application SBAR

Formulary Application SBAR

This form must be used to document all requests to the Kent and Medway Joint Prescribing Committee (JPC) for inclusion in the Kent and Medway Joint Formulary. Any requests for new medicines must be completed by a healthcare professional employed by one of the local healthcare organisations.

Drug Name:	

JFG recommendation:
✓ *Recommended use* ✓ *Any recommendation exclusions*

Situation:

Background:

Assessment:

Recommendation:

Supporting Paper/Appendices:

This document has been formulated to provide evidence-based advice about drug therapy. The information contained herein is believed to be true and accurate. It is issued on the understanding that it is the best available from recognized published information sources at the time of issue.

Checklist on what to include in the Formulary Application SBAR

Background information

- ✓ *Product description/Brief pharmacology*
- ✓ *Indication*
- ✓ *Information on product licence*
- ✓ *Administration*
- ✓ *Fixed dose treatment/ titration*
- ✓ *Dose frequency*
- ✓ *Any prescribing restrictions*

Clinical responsibility i.e. shared care/ transfer of care anticipated?

- ✓ *Describe/summarise as per application form*

Place in therapy

- ✓ *Describe/summarise as per application form*

Clinical effectiveness

- ✓ *Describe/summarise as per application form*

Patient safety

- ✓ *Main adverse events*
  - *NNH (main adverse events)*
- ✓ *Safety alerts*
- ✓ *Safety concerns (similar names, dose reduction in renal impairment etc.)*
- ✓ *Study Limitations*

Cost of treatment and cost effectiveness

- ✓ *Cost compared to existing treatment (from application form + JAC/BNF)*
- ✓ *Indirect cost saving or increase in cost (e.g. monitoring etc.)*
- ✓ *Include details of source of funding (with tariff or HVD (PBR excluded)*

Local health priorities and Stakeholder views

- ✓ *any information on PRGC/CCG views*
- ✓ *Are local primary care guidelines available for the indication that refers to the use of product?*
- ✓ *Local formulary status inclusion*

Benefits for the patient

- ✓ Include any information from application form on benefits such as reduced frequency of monitoring or pill burden etc.
- ✓ Information about improved patient outcomes

Policy Drivers

- ✓ *NICE/SMC/AWMSG/DoH recommendations for use*

Equity of access

- ✓ *Any impact expected*

Any impact expected on one or more equality groups differently to others Age; Disability; Gender reassignment; Marriage & Civil Partnership; Pregnancy & Maternity; Race; Religion & Belief; Sexual Orientation