East Kent Joint Formulary – Product Inclusion Request

Before completing this form, please email ACCG.eastkentprescribing@nhs.net for the application reference number. Please include your contact details and the name of the medicine.

This form must be used to document all requests for new medicines to be included in the East Kent Joint Formulary.

Any requests for new medicines must be completed by a Healthcare Professional (HCP) employed by one of the local healthcare organisations (e.g. East Kent Hospitals University Trust, Kent and Medway Partnership Trust or Kent Community Health Foundation Trust, Hospice), be sponsored by a pharmacist from the organisation and one of the East Kent CCG Prescribing Advisors (Ashford CCG, Canterbury & Coastal CCG, South Kent Coast CCG or Thanet CCG) or by one of the Senior Pharmacists (for internal EKHUFT and KMPT submissions).

Single patient use requests: An abbreviated submission for these items may be possible, please discuss with your organisation's pharmacy support team. Appendix I (available on page 22) must be completed for these requests.

Requests will be reviewed at the East Kent Joint Formulary Management Group.

A confirmation email (containing a copy of the request details) will be sent within two working days of submission. Information on the group decision will be sent to the lead HCP within 2 weeks of the joint formulary meeting.

0	**Summary of application**
Approved name:	
Brand name:	
Date of application:	
Reference number: *(issued by the CCG)*	
Status requested	☐ Preferred ● ☐ On Formulary ● ☐ Specialist Initiation ● *(See section 6 for details)* ☐ Shared Care ● ☐ Hospital Only ● *(Detail restrictions, if any, in Section 6 e.g. consultant only)*
Summary of application: *(max 250 words)*	

1a	**Details of requesting Healthcare Professional (HCP)** *(if multiple HCPs involved, copy & complete this section for each HCP)*	
Name		
Professional group *(e.g. Doctor/Nurse/ Pharmacist/etc.)*		
Organisation		
Department/team *(if applicable)*		
Head of Department *(if applicable)*		
Service line *(if applicable)*		
Specialty *(if applicable)*		
Contact number		
Email address		

1b	**Declaration of interests for requesting HCP**	
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 medicine 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:		

2a	**Details of the organisation's supporting pharmacist**	
Name		
Organisation		
Department/team *(if applicable)*		
Head of Department *(if applicable)*		
Service line *(if applicable)*		
Specialty *(if applicable)*		
Contact number		
Email address		

2b	**Declaration of interests for the organisation's senior pharmacist**	
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 medicine 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	Details of East Kent CCG Prescribing Advisor		
Name			
Organisation			
Contact number			
Email address			
Does the CCG receive any sponsorship from this manufacturer?		☐ Yes	☐ No
Is there a conflict of interest for the prescribing advisor with this application?		☐ Yes	☐ No
If yes to either of the above sections, please provide details:			

4	Item details
Is treatment proposed as:	☐ First line ☐ Second line ☐ Other (please specify)

5	Medication details
Approved name	
Brand name	
Form *(tablet/cream/IM/etc.)*	
Proposed indication(s)	
Normal dose	
Expected duration of treatment	
Manufacturer(s)	
License status	☐ Licensed ☐ Unlicensed ☐ Off-license
Proposed formulary status	☐ Preferred ● ☐ On Formulary ● ☐ Specialist Initiation ● ☐ Shared Care ● ☐ Hospital Only ● *(Detail restrictions, if any, in Section 6 e.g. consultant only)* ☐ Other, please specify below (e.g. 6 month trial, research, etc.):
Details:	

6	Restrictions			
Where can this medication be prescribed *(select all that apply)*?	**Initiation**		**Continuation**	
Tier 3 (i.e. Acute)	☐		☐	
Tier 2	☐		☐	
Tier 1 (i.e. primary care)	☐		☐	
Are there any restrictions on who can initiate and continue prescribing of this item (if yes, give details below)?	☐ Yes	☐ No	☐ Yes	☐ No
If there are restrictions, please indicate who can initiate/continue this medication *(select all that apply)*	**Initiation**		**Continuation**	
Named consultant *(provide details below)*	☐		☐	
Consultant	☐		☐	
Specialist *(please provide details below)*:	☐		☐	
Primary care but requires shared care/transfer of care	☐		☐	
Other *(please specify below, listing restrictions and associated research)*	☐		☐	
Details:				
Are any restrictions to the licensed indication proposed? If so, please specify below:				
Details:				

7	**If supply to be continued by GP, what is the method of providing initial supply if item is recommended by a specialist?**	
Is proposed method of initial supply to request from patients' GP *(see below)*?	☐ Yes *(provide details below)*	☐ No
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 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 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:		
Details:		

8	Place in therapy
Is this medicine a:	☐ close equivalent to existing preparations ☐ minor therapeutic advance ☐ major therapeutic advance
Is treatment proposed as:	☐ First line ☐ Second line ☐ Other (please specify)
Would this medicine replace any existing treatments?	
If yes to above - list any current items this medicine would replace	
Please list any key differences from the originator- e.g. if licensed for use in different ages, etc.	

9	**Evidence base**		
Describe context of the condition needing treatment and current treatment options:			
Has the medicine 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 NICE Technical Appraisal:			
If a NICE TA, please confirm the NICE requirement on implementation	☐ 30 days	☐ 90 days	☐ Other *(please specify below)*
Please provide a brief summary of the evidence base and /or medicine benefits *(max 500 words).* **Any submission which does not include this summary will be rejected.**			

Please provide hyperlinks and/or attach any supporting files *(e.g. NICE guidance/trial results/SPC/etc.)*:	Hierarchy rank for each item *(see below)*

If this medicine is a generic equivalent, please provide links to bioequivalence data held on the 'Heads of Medicines Agencies' (HMA) site http://mri.cts-mrp.eu/Human/

Evidence hierarchy	
Type of evidence	**Rank**
Guidance produced by national bodies (e.g. NICE, SIGN, SMC, Cochrane)	1
Evidence based disease/treatment reviews	2
Published literature, level 1 (e.g. systematic reviews or meta-analyses of randomised controlled trials (RCTs), high quality individual RCTs)	3
Published literature, level 2 (e.g. cohort studies, case control studies)	4
Published literature, level 3 (e.g. other evidence such as case series, opinions, consensus guidelines)	5

10	Local health economy
Describe the potential use of this medicine in the context of the current **local health economy agreements**	
Criteria for use	
Expected patient outcome	
Criteria to discontinue	
How will activity, prescribing, effectiveness and cost be monitored and/or evaluated against plan or applicable guidance; who will collect and present data and where will it be presented? *(max 500 words)*	

Please confirm whether initiation forms will be completed on Blueteq	
Please confirm at what intervals continuation forms will be completed	
How will on-going need of this medicine be reviewed?	
Agreed intervals for review	
Who will undertake review?	

11	Patient safety	
Are there any significant safety concerns?	☐ Yes	☐ No
State any monitoring required, relevant safety requirements (e.g. National Patient Safety Agency alerts and guidance) and how these will be met *(max 500 words)*:		

12	Ordering and prescribing process
Describe how the drug will be prescribed, dispensed and supplied to the patient and if this satisfies relevant legislation. Note any additional requirements for controlled drugs and/or if there is waste to be disposed of. Ensure adequate control mechanisms within the supply process to ensure appropriate use *(max 500 words)*:	

13	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	☐	☐
Compassionate use scheme	☐	☐
Early Access to Medicines Scheme (EAMS)	☐	☐
Free of Charge Medicines Schemes (FOC)	☐	☐
Other (please specify below)	☐	☐

14	Cost impact

Cost of 1 month's therapy *(or standard course if < 1 month)* **To be redacted if commercially sensitive**					
Impact on Trust: Expected number of patients per annum					
Impact on Trust: Estimated cost per annum *(therapy x patients)*					
Impact on CCG High Cost drug budget: Estimated cost per annum *(therapy x patients)* *Full details of, cost per unit and/or loading dose are provided separately to those with authorisation to receive commercially sensitive data*	Current financial year	Next financial year			
Estimated cost from horizon scanning					
Impact on Primary Care: Expected number of patients per annum per 100k population					
Impact on Primary Care: Estimated cost per annum *(therapy x patients)*	Year 1	Year 2	Year 3	Year 4	Year 5

Will this medicine have implications for other services *(e.g. additional medication required, 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 for the CCG/Trust per annum **and** per annum per 100k population		
Is on-going supply required?	☐ Yes	☐ No *(go to 15)*
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 below)*	
Details:		
Provide a comparison of the costs of the standard intervention and proposed treatment indicating whether overall this new medicine will be cost saving, cost neutral or a cost pressure; (*include considerations such as whether costs will be offset by a reduction in the use of other medicines or changes in clinical pathways; if costs will be incurred by screening or monitoring; monitoring of risk share or patient access schemes? Projection of any ongoing cost pressures due to cumulative increases in patient numbers.)*		
Is a rebate arrangement available to the CCG?	☐ Yes	☐ No
Is a discount available to dispensing practices?	☐ Yes	☐ No
Is a rebate price available to acute trusts?	☐ Yes	☐ No
Is the NICE recommendation based on a Patient Access Scheme?	☐ Yes	☐ No

15	Support for community pharmacies/dispensing practices
Please list the wholesalers that the manufacturer has confirmed will hold stock of the medication:	
Please include below the information the manufacturer has provided on how they will monitor stock levels to avoid an out of stock scenario (as stock holding is based on historic data):	
Please include below the information the manufacturer has provided to community pharmacies/dispensing practices:	

16	Patient experience
Describe the benefit to patients and outcome measures; what and how will information be provided to patients/carers and relevant health professionals; will patients need support to take medicines as intended; how will the patient access monitoring if applicable? *(max 500 words)*	

17	Equality of access
Are there any equality of access issues to consider? *(max 500 words)*	

18	Shared care		
Is shared care / transfer of care anticipated? ***If yes, Appendix 2 <u>must</u> be completed.***	☐ Shared care	☐ Transfer of care	☐ No

19	Decision		
This medicine is approved for inclusion onto the East Kent Joint Formulary	☐ Yes	☐ Yes, with modifications identified below	☐ No
Modifications to submission (if required)			
Reason for decision			
Chair of East Kent Joint Formulary Management Group signature			
Date			

20	EKHUFT Decision		
This medicine is approved for use within EKHUFT	☐ Yes	☐ Yes, with modifications identified below	☐ No
Modifications to submission (if required)			
Reason for decision			
Chair of D&T Committee signature			
Date			
Division/Speciality Lead signature			
Date			

Appendix I	Single patient use details
Title & name of patient	
NHS number	
Hospital number	
Reason for prescribing non-formulary drug	

Appendix II	**Shared care**
Why is shared care/transfer of care being proposed? *(e.g. patient preference, reduction in referral costs, better patient care, etc.)*	
Who has been consulted on the need for shared care / transfer of care?	
When will patients be transferred into shared care arrangements? Is it the same for all patients? If not is this clarified in the shared care/transfer of care protocol?	
Have the funding arrangements for this drug been agreed? Have patient volumes been estimated? (e.g. can funding be released from secondary care pathways into primary care ; is this a replacement for a current therapy or does new money need to be identified)	
Can this drug be safely prescribed by GPs? *(i.e are there any administration, side effect or monitoring issues that need to be considered?)*	
Does a healthcare professional need to administer the drug? If so has an increase in workload been considered / funded?	
Are monitoring and follow up required? Are responsibilities clear within the SCP? Is there any significant increase in GP workload anticipated due to blood test requirements? Is sufficient educational / financial support provided to enable GPs to undertake their responsibilities?	
Are dose changes required? Is method & timescale of communication clear?	
GP Education / information provided – is practical guidance re: managing side effects, dealing with abnormal monitoring results, general information about the drug that will improve prescriber confidence available? Is specific training required?	
Are specialist contact details available?	
Drug discontinuation – is responsibility for this clear?	
How do prescribers access specialist support and how long will it take to obtain?	
Who will be responsible for recalling patients for review?	
Who will notify the patient when treatment should be discontinued?	
Confirm the lead clinician and pharmacist who will produce the **shared care** documentation for consideration at the East Kent Prescribing Group	Lead clinician: Pharmacist: