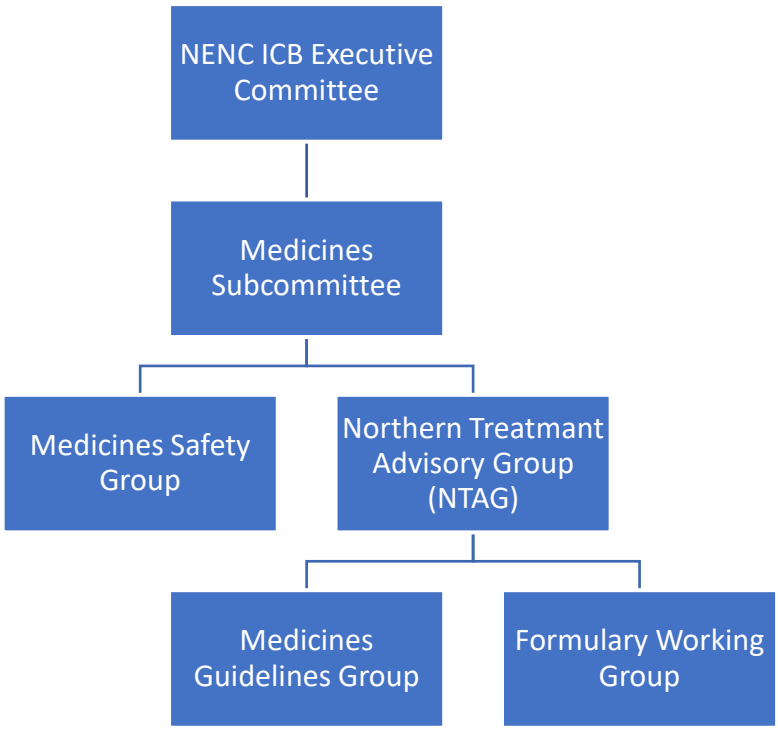
NHS
North East and North Cumbria

NENC ICB Medicines Governance Process

NENC ICB Medicines Governance Structure



Standard Governance Process for Formulary Applications and Amendments

1. Request submitted or identified using the completion of the formulary application from below request. If this has not been completed an application form should be provided to requester(s) NICE Technology Appraisals are routinely considered for addition in line with the ICB's statutory requirements to implement within the period defined by NICE (typically 90 days) and do not require a formulary application.
2. Formulary request is submitted to the formulary working group (FWG) professional secretary (nuth.nyrdtc.rxsupp@nhs.net) who will support any necessary development and approval.
3. Declarations of interest should be submitted by requester(s) to the subgroup (Chair and professional secretary as a minimum) who will discuss and decide if any mitigation is required and provide authorisation to proceed.
4. Application/amendment document is considered and approved by the FWG for a public consultation via NTAG website detailing the proposed addition/amendment to the formulary. This is for a standard duration of 4 weeks. The availability of consultations will be communicated via email to the stakeholders within the ICS.
5. Consultation comments are collated by the professional secretariat and if appropriate shared with requester(s) for review and action. The professional secretariat may highlight areas of the application(s) which require attention based on the comments received. If there are deemed to be significant issues to resolve the subgroup may wish to review the application before submitting to NTAG.

6. A recommendation is provided to be considered by NTAG who will then consider making a recommendation to the Medicines Subcommittee. This should include the intended outcomes of addition/amendment to the formulary and detail where there is likely to be a commissioning and financial impact.
7. Medicines Subcommittee consider the application and the recommendations from NTAG and agree to approve the addition/amendment. Where the financial impact exceeds the threshold that Medicines Subcommittee is authorised to approve (£250k) or there are significant commissioning or other issues, a further submission to the ICB Executive committee is required.
8. The ICB Director of Medicines and Pharmacy will support the submission to the ICB Executive Committee, the executive sponsor for which will be the ICB Medical Director.
9. Following approval by the Medicines Subcommittee and/or ICB Executive Committee the decision summary will be uploaded to the NTAG website and its availability communicated to stakeholders

Minimum Timescales for Approval of Formulary Requests

Process Stage	Minimum timescale
Application discussed at FWG	Week 0
FWG provides approval for consultation	Week 1
Consultation closes	Week 5
Comments collated, shared with requester(s) and a recommendation is submitted to NTAG for approval	Week 8
Medicines Subcommittee considers NTAG recommendation for approval	Week 12
ICB Executive Committee considers recommendation from Medicines Subcommittee (where applicable)	Week 14
Publication to NTAG website and communication to stakeholders	Week 12 (16 if exec decision required)

Consultation Process

Consultations are hosted on the NTAG website and run for 4 weeks as standard. A shorter 2-week consultation is run for NICE TAs which have a 30 day implementation period. Consultations are open to all ICS stakeholders as well as the general public and pharmaceutical industry, and provide an opportunity for the identification of barriers to implementation.

Application for an addition or amendment to the North East and North Cumbria ICB Formulary

This form is to be used for applications for new drugs, new formulations and extensions to previously agreed uses for drugs and other relevant pharmaceutical products including medicated dressings, prescribable nutritional products, borderline substances and pharmaceutical medical devices to be prescribed by NHS services in North East and North Cumbria (NENC) ICB.

Guidance on completing the form

- Please complete **all** details – incomplete forms will be returned.
- Your submission should be comprehensive and indicate which, if any, information has been supplied by a pharmaceutical company. The manufacturer/ supplier may provide information supporting the application, but the application must come from a clinician working within one of the NENC ICB stakeholder organisations.
- The application must be completed with the input from the Lead Clinical Pharmacist for that speciality (secondary care) or Medicines Optimisation Pharmacist (primary care)
- The application must reflect consensus from your directorate, speciality or area.
- Applications are **not** required for NICE TAs / NICE Clinical Guidelines / NHSE commissioning policies. For NICE TAs / Clinical guidelines information around patient numbers and how implementation will be managed locally should be submitted via the monthly RDTC formulary amendment consultation. A submission to your Trust D&T **may be** required - please seek advice from your local Formulary Lead Pharmacist/Technician.
- The application **must** be supported by the relevant Clinical Director or Chief of Service (secondary care) and/or GP Prescribing Lead (primary care) before submitting. If you have done this please give details in the relevant section of the form.
- An application for a drug that has been rejected within the last 12 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 Committee.
- The manufacturer/ supplier (drug company) may provide information supporting the application, but the application must come from an appropriate applicant (see above).
- **The form should be submitted electronically by e-mail by completing this document and sending to:**
    - **For CDDFT Beverley.Walton2@nhs.net**
    - **For NTHFT mohammedmajid@nhs.net**
    - **For STHFT andrew.lloyd3@nhs.net**
    - **For TEWV Richard.morris2@nhs.net**
    - **For NUTH nuth.Medicines.Management@nhs.net**
    - **For CNTW Medinfo@cntw.nhs.uk**
    - **For NCIC Fiona.McKean@ncic.nhs.uk**
    - **For ST&S Robert.lapham@nhs.net**
    - **For NHCFT Alastair.Green@northumbria-healthcare.nhs.uk**
    - **For QEH v.echanique@nhs.net**
    - **Primary care nencicb-sun.mo@nhs.net**

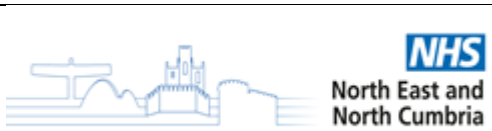
Submission to NENC ICB Formulary Working Group (FWG)

- Applications must be submitted electronically to **nuth.nyrdtc.rxsupp@nhs.net** at least 6 weeks before the meeting otherwise the submission is likely to go to the following FWG meeting. You will be notified of the date of the meeting when the application will be considered.
- Where possible electronic versions of any references and other supporting documents (preferably Word or PDF format) should be e mailed at the same time.
- Secondary care consultants must discuss their request with, and obtain support from, other consultants working in their speciality prior to submitting a request. When this is done please give details in the appropriate section of this form.

The decision making process

NENC ICB FWG base their recommendations on the following key areas:

- Clinical effectiveness
- Cost effectiveness / resource impact
- Strength of evidence
- Patient safety
- Stakeholder views
- Environmental sustainability
- Place in therapy relative to available treatments
- National guidance and priorities
- Local health priorities
- Equity of access

Application for an addition or amendment to the North East and North Cumbria ICB Formulary	

1. APPLICANT'S DETAILS		
Name: Click or tap here to enter text.	***Position / Role:*** Click or tap here to enter text.	***NHS Organisation:*** Click or tap here to enter text.
Contact details (Address/email address): Click or tap here to enter text.		***Tel:*** Click or tap here to enter text.
Department/Unit: Click or tap here to enter text.		

2. COMPUSLORY SUPPORT FROM DEPARTMENT OR PRACTICE, SPECIALITY LEAD, PRESCRIBING LEAD, ORGANISATION AND BUSINESS/FINANCE OFFICER

Does this application have support from all relevant stakeholders in NENC ICB?
Does this application have speciality wide support and not just that of individual clinicians?
Does the application have support from Trust Finance if appropriate e.g. High cost drug?

Name of supporting individual or group	**Organisation**	**Comment**	**Date of Review**
Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.	Click or tap to enter a date.
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3. DETAILS OF DRUG

Non-proprietary (generic) name:	Click or tap here to enter text.	***Brand name:***	Click or tap here to enter text.
Dosage form and strength (e.g. tablets 50mg)	Click or tap here to enter text.		Tick if applies Unlicensed Drug ☐ Unlicensed Indication ☐ Unlicensed Route of Administration ☐
Manufacturer:	Click or tap here to enter text.		Manufacturer signed up to All Trials Petition? https://www.alltrials.net/supporters/organisations/ YES ☐ or NO ☐
Commissioning - Tariff included or tariff excluded?	Click or tap here to enter text.		

4. INDICATIONS

Licensed indication for this drug *(see SPC)*: https://www.medicines.org.uk/emc	Click or tap here to enter text.
Indication for which Product is requested	Click or tap here to enter text.
Dose / strength / frequency of administration	Click or tap here to enter text.
Route of administration	Click or tap here to enter text.
Duration of treatment: one off / fixed period / long term / other	Click or tap here to enter text.

5. REASON(S) FOR REQUEST

Please classify Reason(s) – Tick box(es)	Therapeutic advantage over existing treatment ☐ More cost effective than alternative treatment ☐ Improved Compliance ☐ Greater environmental sustainability than current options ☐	No alternative ☐ New formulation ☐ Other (please specify) ☐
If there are advantages over existing drugs/ treatments for same indication(s) please state here.	Click or tap here to enter text.	

Details of evidence for these advantages in terms of **EFFICACY, SAFETY, CONVENIENCE** or **COST EFFECTIVENESS.** Copies of the key papers referred to should be submitted with the application as full text not abstracts (continue on separate sheet if necessary).

Click or tap here to enter text.

6. ANTICIPATED PLACE IN THERAPY

Please give a clear guideline including algorithms or flowcharts as necessary, indicating which group(s) of patients should and should not be eligible to receive this drug, including details of whether the drug is 1st line or not and the suggested criteria for selecting or not selecting the drug (either explain below or attach a pathway).

Click or tap here to enter text.

7. EXISTING DRUGS

Existing products(s) for the same indication(s):	Click or tap here to enter text.	
Would the product requested be:	1. An addition to what is already existing *OR* 2. A replacement for what is already existing	**YES ☐ NO ☐** **YES ☐ NO ☐**
If a replacement, which product(s) can be deleted:	Click or tap here to enter text.	

Does this product offer any opportunities for de-prescribing of other products currently on the formulary or in the clinical pathway for this condition? If so, which ones?	Click or tap here to enter text.
Potential disadvantages e.g. side-effects, cost, extra monitoring)	Click or tap here to enter text.

8. PRESCRIBING AND MONITORING		
***Dosage regimen proposed for this application**:*	**Dose and Frequency:** Click or tap here to enter text.	**Likely duration of treatment:** Click or tap here to enter text.
***Monitoring requirements (including criteria for stopping treatment, implications for continued care and who does the monitoring)**:*	What monitoring is required?	Click or tap here to enter text.
	Who is responsible for what monitoring?	Click or tap here to enter text.
	Criteria for stopping treatment	Click or tap here to enter text.
	Who assesses for stopping treatment?	Click or tap here to enter text.
Proposed formulary classification and any restrictions	Classification: Red ☐ Amber ☐ Green Plus ☐ Green ☐	Prescriber restrictions (e.g. Consultant only, etc) Click or tap here to enter text.
Is the application for:	Single consultant ☐ Speciality ☐ Single Site ☐ Whole Trust ☐ Outpatients ☐ Inpatients ☐ Both ☐ Primary care use ☐ Secondary care use ☐ Both ☐	

9. FINANCIAL ASPECTS			
Please complete the following to allow likely usage and costs to be calculated.			
No of patients likely to be treated per year for ICB / Local Trust (please specify)	***Average daily dose***	***Likely duration of treatment***	***Duration of treatment likely to be supplied by hospital*** *(i.e. duration of treatment course supplied by hospital)*
Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.
If you already have an estimate of the likely cost (to your directorate) of using this product please give details below:			

Has a robust cost effectiveness analysis been completed for this medicine? Include details and link e.g. NICE, SMC, AWMSG	Click or tap here to enter text.
Estimated cost: ***If a business case has been prepared involving the use of this product please enclose details with this form.***	In next 12 months £ Click or tap here to enter text. Subsequent Years £ Click or tap here to enter text.
Details of how estimated costs have been calculated / obtained	Click or tap here to enter text.
Details of compensatory saving resulting from use of new product (please include details of possible savings in areas other than drugs expenditure)	Click or tap here to enter text.
Other costs and considerations e.g. drug monitoring, clinic attendance, staff time	Click or tap here to enter text.
What is the likely impact of this product on primary care prescribing?	Click or tap here to enter text.
What, if any, are there additional cost or service implications for primary care as a result of this formulary application?	☐ **Additional cost (e.g. monitoring, workload) associated with a transfer of prescribing from the acute sector to primary care.** If so, please provide additional detail, for example the cost per patient per year and the estimated number of patients: ☐ **Additional monitoring requirements for Primary Care.** If so, please provide detail including whether agreement has been made to reimburse GP Practices for this monitoring via the Local Enhanced Service (LES):
What, if any, are there additional cost or service implications for secondary care as a result of this formulary application?	☐ **Additional cost (e.g. workload) associated with a transfer of prescribing from the primary care to acute sector.** If so, please provide additional detail, for example the cost per patient per year and the estimated number of patients: ☐ **Additional monitoring requirements for Secondary Care.** If so, please provide detail including whether agreement has been made to provide funding to secondary care for this monitoring ☐ **Need to establish a repeat dispensing system**

11. ENVIRONMENTAL SUSTAINABILITY	
Does this product have a reduced carbon footprint compared to comparators? (If known) *If yes why/how/evidence?*	Click or tap here to enter text.
Does this product have any advantages in terms of packaging? *If yes – why/how?*	Click or tap here to enter text.
Does this product have any advantages in terms of shelf life? *If yes – why/how?*	Click or tap here to enter text.
Does this product have result in less waste compared to comparators? *If yes – why/how?*	Click or tap here to enter text.
Has the manufacturer of this product published a carbon reduction plan?	Click or tap here to enter text.

12. SUPPLEMENTARY DETAILS
Please give a concise outline of any additional information you would like to be considered along with this Formulary Request. This can include links to trial data, SIGN documents, NICE guidance, SMC guidance, or any other relevant information. Plus other local commissioning positions where known. Please provide any relevant information on Side effect profile, Safety / Pharmacovigilance and Significant drug interactions
Click or tap here to enter text.

13. DECLARATION OF INTEREST			
It is mandatory that members of the Formulary Working Group declare interests prior to discussing items relating to individual products. All applicants must do the same.			
Details of any support or sponsorship (for staff, clinical trials, other research etc.) received or likely to be received from the manufacturer of this product within the last/next 12 months. If none state NONE			
Personal Click or tap here to enter text.		***Departmental*** Click or tap here to enter text.	
Applicant's Signature*	Click or tap here to enter text.	***Date:***	Click or tap to enter a date.
* If the form is only being submitted electronically print name and email. The authenticity of the emailed document will be verified when the application is processed			