

Cheshire and Merseyside Area Prescribing Group

New drug or new use of a current drug (form C)

This form should only be used for adding new drugs or new uses for existing formulary drugs. Use form A for minor formulary amendments and form B for RAG designation changes.

All forms should be completed electronically. Incomplete forms will be returned. Please list and include copies or hyperlinks to the references used in this application.

Please return completed forms to apg@cheshireandmerseyside.nhs.uk.

In case of query please contact apg@cheshireandmerseyside.nhs.uk.

Cheshire and Merseyside Area Prescribing Group (CMAPG) will only consider applications submitted through local approval processes. Applications must be signed by appropriate sponsors from a relevant advisory or decision making group. For drugs initiated in secondary care the sponsor must either be the Chair of the drugs and therapeutics committee or a medical director. For drugs initiated in primary care the sponsor must either be the Place medicines lead or medicines management group lead.

Forms completed by drug company representatives will not be accepted. It is important that applications represent the view of the sponsoring organisation rather than those of the manufacturer. The relevant directorate pharmacist or Place medicines lead will be able to provide information such as financial implications and formulation information.

**Medicines that have a positive NICE TA do not require an application. Organisations may still have to follow their own internal process.**

The final decision may take at least 12 weeks and will be communicated back to you directly.

### Application submission process

1. Primary care applications must first be approved locally by the medicines management group or lead at Place.
2. Secondary care applications must first be approved by a relevant advisory or decision making committee, for example, a Drugs and Therapeutics Committee (DTC). For drugs with a red RAG status where prescribing is retained within the trust the trust’s formulary committee decision should be submitted to the CMAPG for information only.
3. Submit fully completed applications to the CMAPG secretariat by email to apg@cheshireandmerseyside.nhs.uk for pre-screening and accuracy checking. The secretariat will submit the application to the appropriate CMAPG subgroup for review.
4. The CMAPG subgroup will review the application using a decision support summary and consultation feedback before making recommendations to the CMAPG for onward approval by the NHS Cheshire and Merseyside Medicines Optimisation and Pharmacy group.

**Primary care**: application must go through local approval process via Place medicines management group or lead.

**Secondary care**: application must go through local approval process via relevant advisory or decision making committee, e.g., Drugs and Therapeutic Committee (DTC).

**RAG status**: red - prescribing to be retained within trusts.
Hospital Formulary Committee decision sent to CMAPG for information only.

**Area Prescribing Group** - the CMAPG subgroup reviews the application using a decision support summary and consultation feedback before making recommendations to the CMAPG for onward approval by the NHS Cheshire and Merseyside Medicines Optimisation and Pharmacy group.

Fully completed applications submitted to the secretariat via email address - apg@cheshireandmerseyside.nhs.uk for pre‑screening and accuracy checking. Secretariat then submits to the appropriate subgroup for review.

## Application

### What is the purpose of this application?

Please summarise what change is required and why. What is the reason for this application?

|  |
| --- |
| Click or tap here to enter text. |

### Does the proposed medicinal product have a positive NICE technology appraisal (NICE TA) or Commissioning Policy to support its use for the proposed indication?

IF YES, state which NICE TA or Commissioning Policy.

|  |
| --- |
| Click or tap here to enter text. |

**Medicines that have a positive NICE TA do not require an application. Organisations may still have to follow their own internal process.**

IF NO, please continue to complete the remainder of this form.

### Type of application

For example, the addition of a new drug or new use for an existing drug.

|  |
| --- |
| Click or tap here to enter text. |

**If the application is for a branded version of a drug that is already on the formulary, please use the Minor Formulary Amendment form.**

## Medicine

### Generic name, brand name and manufacturer

|  |
| --- |
| Click or tap here to enter text. |

### Formulation, strength and presentation

|  |
| --- |
| Click or tap here to enter text. |

### Dose, frequency, course length and administration route

|  |
| --- |
| Click or tap here to enter text. |

### Licensed indication and proposed indication

|  |
| --- |
| Click or tap here to enter text. |

## Appropriateness

### Is there a potential alignment with a local or national strategic commissioning goal?

If so, please state the details.

|  |
| --- |
| Click or tap here to enter text. |

### Evidence for safety of the product

Summarise the evidence with references. Include evidence versus placebo and versus current therapies where possible. Include any relevant morbidity, mortality, health economic and quality of life benefits. Are there any monitoring requirements?

|  |
| --- |
| Click or tap here to enter text. |

### Will the proposed drug replace an existing drug on the formulary?

If YES, please say which drug it is replacing and describe why this new product should be used in preference. Consider patent expiry dates of the products being replaced by this proposed medicinal product.

|  |
| --- |
| Click or tap here to enter text. |

### Will the proposed drug be an additional option to an existing drug on the formulary?

If YES, please say which drug it is in addition to and describe why this new product should also be available as an option.

|  |
| --- |
| Click or tap here to enter text. |

### Is this drug routinely used as an add-on therapy (at an additional cost) to an existing treatment?

If YES, what are the other treatment options? Please indicate clearly, where within the current drug pathway the product should be used.

|  |
| --- |
| Click or tap here to enter text. |

### What is your proposed position RAG status in the formulary?

Refer to the [RAG definitions and criteria](https://www.cheshireandmerseyside.nhs.uk/media/5yzo3tzp/definitions-and-criteria-for-categorisation-of-medicines-in-the-cheshire-and-merseyside-formulary.pdf). Please note that RAG status refers to the drug not the condition being treated.

|  |
| --- |
| Click or tap here to enter text. |

### What setting is this drug proposed to be prescribed?

Consider initiation and continuation prescribing. For example, out-patient clinics, primary care, general practice.

|  |
| --- |
| Click or tap here to enter text. |

### Is this medicine excluded from the NHS Payment Scheme?

Previously known as the Payment by Results tariff (PbR)?

|  |
| --- |
| Click or tap here to enter text. |

### Have prescribing guidelines been produced?

If YES, please attach or provide a hyperlink.

|  |
| --- |
| Click or tap here to enter text. |

### Will this medication have any prescribing or commissioning restrictions?

For example, microbiological advice or consultant use only, requires completion of a Blueteq form.
If YES, what are the restrictions?

|  |
| --- |
| Click or tap here to enter text. |

### Which local groups, networks and provider trusts has this application been discussed with and supported by?

Applications should not be made by an individual or organisation in isolation without involving other groups, networks and local provider trusts as appropriate. Please state the details of the discussion and the outcome.

|  |
| --- |
| Click or tap here to enter text. |

### What impacts will this treatment have on the environment?

For example, does it help optimise prescribing by reducing the demand for other medicines? Is this a lower carbon alternative to an existing medicine, for example, dry powder inhaler? Would approving this application help the ICS to deliver on its NHS Green agenda objectives? Does this medicine have a positive impact on global warming potential?

|  |
| --- |
| Click or tap here to enter text. |

## Clinical effectiveness

### Summarise the evidence for efficacy of the product, with references.

Summary points should include clinical outcomes; numbers needed to treat (NNT’s); quality-of-life measures; how the outcomes might extrapolate on the system population level. Discuss evidence versus placebo and versus current therapies where possible.

|  |
| --- |
| Click or tap here to enter text. |

### Could the product improve overall effectiveness of the pathway?

|  |
| --- |
| Click or tap here to enter text. |

## Cost-effectiveness

### Could the product improve overall cost-effectiveness of the pathway?

|  |
| --- |
| Click or tap here to enter text. |

### Do related clinical trials demonstrate resource benefit?

If so, please state top level details: name of trial and the resource benefit.

|  |
| --- |
| Click or tap here to enter text. |

## Affordability

### Cost of the product (excluding VAT)

Include primary care cost and secondary care costs. Specify if listed prices are branded or generic. Specify pack sizes.

|  |
| --- |
| Click or tap here to enter text. |

### Comparative cost of existing alternative treatments

Please state comparative costs for each existing treatment option. Use most cost-effective comparator which may be branded or generic. Include primary care cost and secondary care costs. Specify if listed prices are branded or generic. Specify pack sizes

|  |
| --- |
| Click or tap here to enter text. |

### Estimated number of patients to be treated per annum

Based on Cheshire and Merseyside population of approx. 2.7M

|  |
| --- |
| Click or tap here to enter text. |

### What is the financial cost or saving resulting from the introduction of the product?

|  |
| --- |
| Click or tap here to enter text. |

### If there is a cost pressure, can this be offset by a reduction in expenditure on anything else?

Please specify, for example, could the use of this medicine improve secondary care capacity?

|  |
| --- |
| Click or tap here to enter text. |

### Any other costs and considerations?

|  |
| --- |
| Click or tap here to enter text. |

### Are the cost implications supported by your finance lead?

Include the details and outcome of any discussions and the name of your finance lead.

|  |
| --- |
| Click or tap here to enter text. |

## Ethics

### Could the treatment improve productivity in the population?

For example, through employment or reduction in social welfare.

|  |
| --- |
| Click or tap here to enter text. |

### Could the product help maintain independence?

Is there an impact on the need for carer or social care (home or residential) support?

|  |
| --- |
| Click or tap here to enter text. |

## Supplementary information

### Any additional background information relevant to application (optional)

|  |
| --- |
| Click or tap here to enter text. |

## Declarations of interest

### Applicant

|  |
| --- |
| Click or tap here to enter text. |

### Sponsor

|  |
| --- |
| Click or tap here to enter text. |

## Signatories

Applications must be signed by appropriate sponsors from a relevant advisory or decision making groups. For drugs initiated in secondary care the sponsor must either be the Chair of the drugs and therapeutics committee or a medical director. For drugs initiated in primary care the sponsor must either be the Place medicines lead or medicines management group lead.

Completed forms should be returned to apg@cheshireandmerseyside.nhs.uk.

Applicant’s name: Click or tap here to enter text. Date: Click or tap here to enter text.

Applicant’s job title, department or specialty: Click or tap here to enter text.

Sponsor’s name: Click or tap here to enter text. Date: Click or tap here to enter text.

Sponsor’s job title, department or specialty: Click or tap here to enter text.