

Guidance on completing a new medicines application form

Please discuss application and completed form with appropriate member of your pharmacy team, as indicated below, prior to submitting it to the Worcestershire Area Prescribing Committee (APC). This is to ensure that the application has sufficient evidence to progress it through the APC:

- Worcestershire Acute Hospitals Trust (WAHT): Richard Cattell, Rachael Montgomery
- Worcestershire Health and Care NHS Trust (WHACT): John Morrison, Andy Down
- Primary Care: Anne Kingham

Please note that incomplete application forms will be returned to the applicant for completion.

An application to the Worcestershire APC should not be made for any medicine and treatments commissioned by NHSE.

Medicine Details and Use

- Medicines include prescribable (FP10) appliances.
- Please specify the main indications for which you or others will be using the product. Consider how this product will be used in relation to existing products. For example, those not tolerating first line treatment.
- Please consider who will be responsible for managing the patient from initiation to on-going treatment, including any necessary monitoring requirements. In some cases a Local Prescribing Guideline may be desirable in order to facilitate continuing supply by GPs of a hospital initiated product.
- Please include a copy of the suggested treatment pathway, supporting local guidance or proposed local prescribing guidance as appropriate.
- If the application is part of a proposed service development, include a copy of the accompanying business case/service development proposal.
- Please express use relative to other medicines or in terms of clinical status if applicable. For example, 'the 10% of patients who do not respond to medicine X' or patients who meet the following criteria for disease severity.....'

Evidence for Efficacy and Safety

- This section is designed to establish the evidence base available to support acceptance of the product onto the Worcestershire Joint Medicines Formulary.
- Please list and include, if possible, no more than four references to support your application. These should be the most recent and relevant available. If there is a good systematic review you need not include the original papers. We are looking for references from reputable sources that are unbiased with good methodology. Reviews from expert groups will also be considered.
- Where evidence is equal to other agents, has only been compared with placebo, or there is no long term outcome data published, it may be useful to provide quality of life data if it is available.
- Comparative safety of the product is obviously of great interest. Many new medicines arrive on the market with as few as 1500 patients having been exposed. The Summary of Product Characteristics (SPC) or clinical trials are a good source of adverse event reports.

Level of Use and Financial Implications

- Please provide costs for different doses where applicable.
- Consider where the costs will be incurred i.e. primary or secondary care.
- Estimate the number of patients who are likely to be treated.
- Consider use in relation to the whole Worcestershire population (556,000).
- Consideration should be given to incidence, prevalence and place in therapy, in terms of estimating the likely numbers of patients.
- Where possible provide an indication of cost-benefit, cost-effectiveness (for example numbers needed to treat, NNT) or cost utility (for example cost per QALY).
- When calculating annual costs please incorporate 365 days which equates to 13 x 28 day packs.

Applicant Details and Declaration

- Applications will only be accepted from consultants, general practitioners or lead prescribing practitioners
- It is essential that we are made aware of the extent of interest in prescribing the product. Please obtain Directorate support in the WHAT or WHACT, or have MDT approval. If one product is to be replaced with another, this must be a Trust wide switch. There will be no confidence in financial predictions if all potential users have not been consulted before the application.
- Ensure that both applicant and Clinical Director have signed the application form.
- It is important that any conflicts of interest are declared on the form.

Contacts:**Area Prescribing Committee**

Acting Chair: Jane Freeguard – Head of Medicines Commissioning
via - Jane.Freeguard@worcestershire.nhs.uk

Secretary: Danielle Clark – Medicines Assurance Pharmacist
via - Danielle.clark@worcestershire.nhs.uk

[Worcestershire Acute Hospitals NHS Trust Medicines Safety Committee (MSC)

Chairman: Dr Steve Graystone stephen.graystone@nhs.net
Director of Pharmacy Mr Richard Cattell rcattell@nhs.net
– MSC *currently under restructure*

Worcestershire Health and Care NHS Trust Medicines Management Safety Sub-Committee (MMSSC)

Chairman: Dr David Lewis (*interim*) David.lewis5@nhs.net
Chief Pharmacist Mr John Morrison john.morrison6@nhs.net