

Guidance on Completing a New Medicines Application Form

Please discuss the application and completed form (including countersignatory OR corresponding nhs.net email addresses) with appropriate members of your Pharmacy team prior to submission. This will then be sent via your Pharmacy Team to the Herefordshire & Worcestershire Medicines and Prescribing Committee (H&W MPC). This is to ensure that the application has sufficient evidence to progress it through the H&W MPC. Please note that incomplete application forms will be returned to the applicant for completion.

An application to the H&W MPC should not be made for any medicine and treatments commissioned by NHS England

Medicine Details and Use

- Medicines include prescribable (FP10) appliances.
- Please specify the main indications for which you or others are applying for. Consider how this product will be used in relation to existing products. For example, those not tolerating/contraindicated to 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 General Practitioners/Primary Care prescribers of a secondary care 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 H&W 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. References are requested 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 H&W population (~803,500).
- 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 28day packs.

Applicant Details and Declaration

- Applications will only be accepted from consultants, General Practitioners or lead prescribing practitioners.
- It is essential that the extent of interest in prescribing the product is understood. Please obtain Directorate support in HWHCT, WAHT or WVT, 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 the application form has all required signatories (or corresponding nhs.net email addresses as an alternative to signatory, for purposes of ease in virtual collation and submission).
- It is important that any conflicts of interest are declared on the form.

Contacts:

Herefordshire & Worcestershire Health and Care NHS Trust (HWHCT)

HWHCT Pharmacy: whcnhs.medicines@nhs.net

Worcestershire Acute Hospitals NHS Trust (WAHT)

WAHT Medicines Information: wah-tr.druginfo@nhs.net

Wye Valley NHS Trust (WVT)

WVT Medicines Information: meds.infowvt@nhs.net

Primary Care

HWCCG Medicines Commissioning Team - hw.medicines@nhs.net

H&W Medicines and Prescribing Committee

Liz Yarnold-Smith - hw.medicines@nhs.net

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