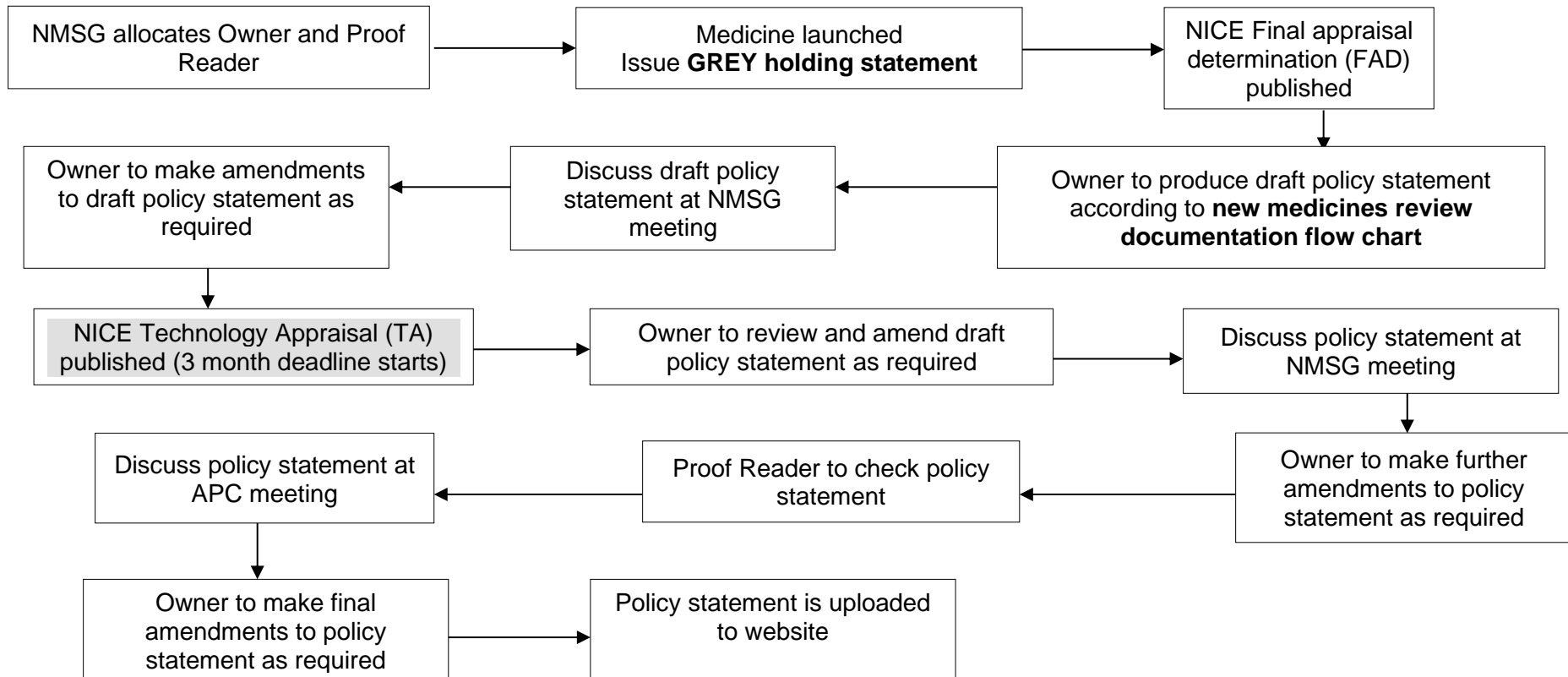


**New Medicines Sub Group Review Process for NICE TA reviews**





## **Application and Case for Introduction of New Medicine Service Developments**

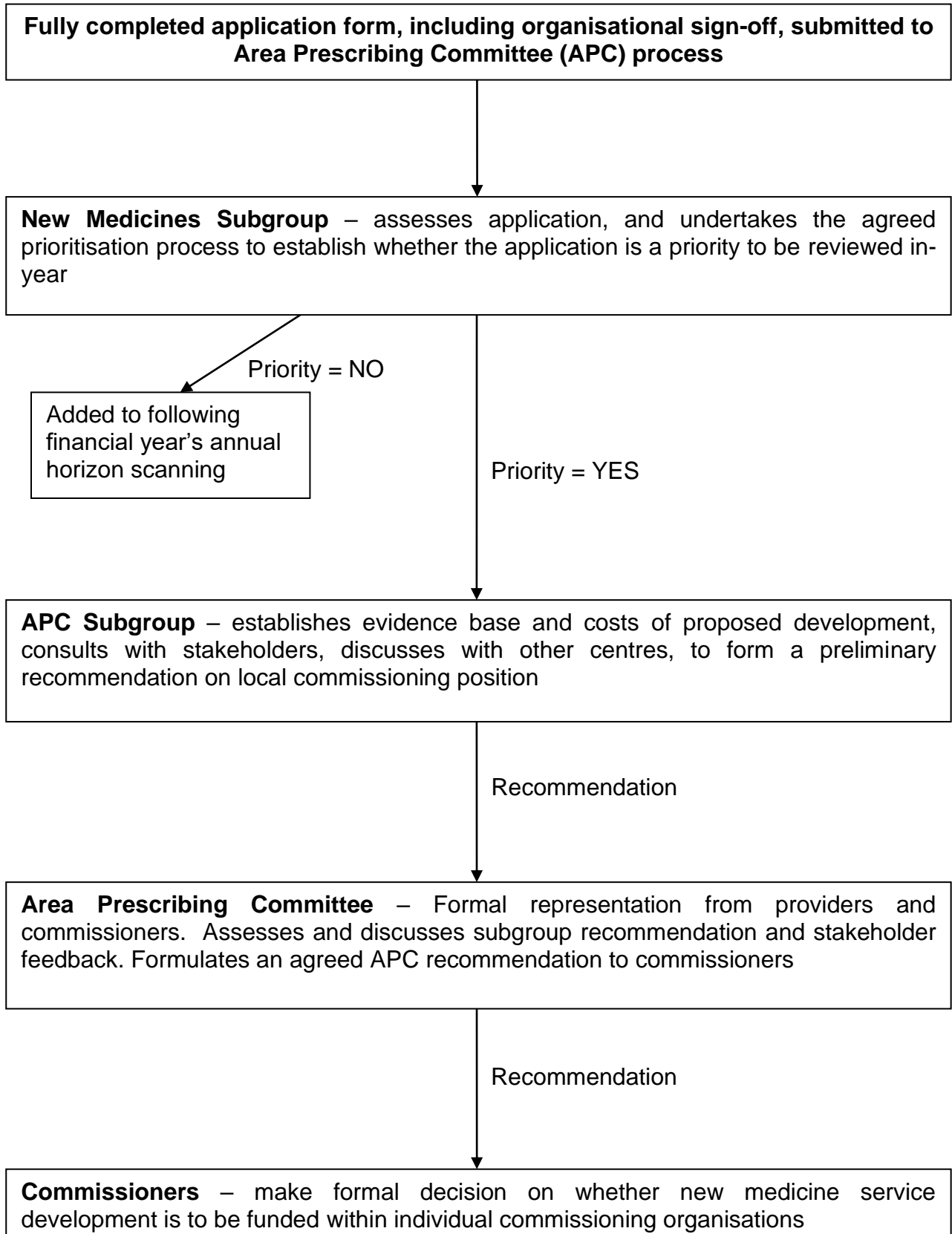
**Application for:** \_\_\_\_\_  
(please add drug name & indication)

**Purpose of this form:** for providers to apply to commissioners for in-year funding of any new drug or extended use of an existing drug (e.g. new indication, new patient group) that will impact on prescribing costs to the commissioner. This includes where the prescribing will be passed on to primary care prescribers or where the drug is prescribed in hospital but generates additional PBR costs or is excluded from the Payment by Results Tariff and drug costs are passed on to commissioners. The annual horizon scanning process should be used as the preferred route to identify the majority of new developments, and any in-year funding applications will be subject to a prioritisation process to establish whether it is a local priority to review within the current financial year. Applicants are advised that prioritisation for review does not guarantee a positive commissioning recommendation outcome.

For minor formulary changes please use the [Request for amendment to existing formulary choice or a medicine](#) switch form.

**This form is not to be used for Individual Funding Requests (IFR).** These are considered where the individual or treatment is exceptional; i.e. where the treatment can be described as exceptional by virtue of the rarity of the condition or the difference of the individual from the generality of similar patients. Separate IFR documentation is available. Sometimes new, innovative treatment options are presented as exceptional: in this case every effort is made to direct the clinical team to the commissioning decision route, via this service development application, although the first few requests via the exceptional treatment route may be considered so as to offer benefit to patients where this is likely.

**Process:**



**Please complete this form as fully as possible.** Please complete all relevant sections legibly and include full references. Any missing or illegible information will delay the application. You must discuss this application with the relevant Pharmacy Dept. / Medicines Management team within your organisation and obtain organisational support and sign-off for the application before it is submitted. Applications completed by pharmaceutical companies are not acceptable.

**Please submit completed form to your organisations representative on the Subgroup in your Pharmacy Dept / Medicines Management Team**

| <b>Section 1 Clinical information</b>   |  |
|---|--|
| Name of medicine<br>(generic and brand name):   |  |
| Strength(s) and form(s) of preparation:<br>Dose and schedule of administration:   |  |
| Licensed indication(s):   |  |
| Proposed Indication (if different from or in addition to the above):  |  |
| Is this treatment instead of or in addition to any current treatment?<br>Please give details:   |  |
| Reason for proposed change.<br>If replacing current treatment please state how it compares regarding efficacy and safety / tolerability |  |
| Proposed place in therapy relative to other therapies (include protocol for use if available)   |  |

| <b>Section 1 Clinical information</b>  |  |
|--|--|
| <p>Predicted clinical impact on Primary Care<br/>e.g. will it be initiated in hospital only but then prescribed in primary care, or may it be initiated in primary care? Will it require shared care?<br/>Please describe:</p>   |  |
| <p>Monitoring requirements (e.g. for efficacy, side-effects) – if any?<br/>Do these differ from current situation?</p>   |  |
| <p>Brief summary of evidence in support of requested medicine / additional use.<br/>Meta-analyses, systematic reviews, double-blind randomised controlled trials in peer-reviewed journals.<br/>Ensure that evidence to support advantages / benefits of the new medicine over existing treatments is included where appropriate, including criteria for treatment success.<br/>Include any relevant morbidity, mortality, health economic and quality of life benefits.</p> |  |
| <p>References<br/>Please list and include copies or internet links with the application</p>  |  |

| <b>Section 2 Financial information</b>   |  |
|--|--|
| <p>Costs: (excluding VAT)<br/>           Cost per patient per year of medicine:</p> <p>Number of patients per year to be treated for the whole organisation: <i>Where possible / applicable, include assessment of patient numbers across Pan Mersey area.</i></p> <p>Additional costs e.g. day case tariff, tests per patient per year:</p> <p>Any impact on PBR activity?<br/>           Please give details:</p> <p>Overall financial impact:</p> |  |
| <p>Current treatment(s) usually used (if any):</p> <p>Cost per patient per year currently treated (excluding VAT):</p> <p>Number of patients per year currently treated:</p> <p>Current additional costs e.g. day case tariff, tests per patient per year:</p>   |  |
| <p>Predicted financial impact on Primary Care.<br/>           e.g. Is the medicine hospital only but PBR excluded, will it be initiated in hospital only but then prescribed in primary care, or may it be initiated in primary care? Please describe:</p>   |  |

### Section 3 Conflicts of Interest

Please state any potential conflicts of interest e.g. funding of research, equipment, consulting or speaking fees, other personal or non-personal or family interest etc. in relation to this request:

.....  
Name of Applicant

.....  
Role

.....  
Organisation name

**I confirm I have sent a copy of this form to my organisations Drug & Therapeutics Committee / Medicines Management Committee or equivalent, and it has been approved following the appropriate procedure within my organisation.**

.....  
Signature of Applicant

.....  
Name of Clinical Director / CCG Prescribing Lead

.....  
Signature Clinical Director / Prescribing Lead

.....  
Name of Chief Pharmacist / Head of Medicines Management

.....  
Signature of Chief Pharmacist / Head of Medicines Management

**Please note that the application will not be considered unless the Chief Pharmacist / Clinical Director / Prescribing Lead / Head of Medicines Management in your organisation has signed this form.**