**Formulary application**

This form should be used to propose an addition or amendment to the Humber and North Yorkshire Formulary. Please complete ALL relevant sections fully and comprehensively. Any missing or illegible information will delay the application. See supporting guidance available at <https://humberandnorthyorkshire.org.uk/area-prescribing-committee-apc-documents-page/> for further information.

# APPLICANT

|  |  |
| --- | --- |
| Name |  |
| **Role and position** |  |
| Organisation |  |
| Department or specialty |  |
| Email address |  |

# MEDICINE DETAILS:

|  |  |
| --- | --- |
| Name of medicine(generic & proprietary name) |  |
| **Strength(s) and form(s)** |  |
| **Route of administration** |  |
| **Frequency of administration** |  |
| **Course length** |  |
| **Status** | Select a licensing status.  Other (please specify): |
| Licensed indication(s) |  |
| Intended indication(s) for use if different from the above |  |
| Is this medicine novel?Select all that apply | First in class  “Me too” medicine  Generic  Branded generic  New formulation  New indication for existing medicine |
| Reason for application | Therapeutic advantage  Cost saving  Improved compliance  Unmet need  Other (please specify): |

# EVIDENCE TO SUPPORT APPLICATION

|  |
| --- |
| **Summary of evidence in support of application**  Summarise evidence from high quality sources, e.g. meta-analyses, systematic reviews, double-blind randomised controlled trials in peer reviewed journals etc. Ensure that evidence to support the reason for application indicated above is included. |
| **References** enter references for any evidence discussed above |
| **Provide any relevant morbidity, mortality, health economic and quality of life benefits that support of this application** |

1. **MONITORING**

|  |  |
| --- | --- |
| Does this medicine have any monitoring requirements | No  go to next section  Yes |
| Purpose of monitoring e.g. adverse effects, efficacy |  |
| Frequency of monitoring |  |
| Where will monitoring be conducted e.g. primary care, secondary care |  |

# FORMULARY IMPLICATIONS:

|  |  |
| --- | --- |
| Reason for application | New addition to formulary  Amend an existing formulary entry  If amending an existing entry, what is the current status? Please specify: |
| Intended formulary position | First line  Second line  Third line  Other (please specify): |
| Should the medicine be reserved for exceptional use in a defined population? | No  Yes (please specify): |
| Will this replace an existing medicine | No  Yes (please specify):. |
| **Additional information**  Please give additional information as appropriate. E.g., how the medicine compares with the existing formulary options with regard to efficacy, safety, acceptability; guidelines for the use of the new medicine; place in the therapy in relation to other formulary medicines  Click here to enter text. | |

# FINANCIAL AND OTHER IMPLICATIONS:

|  |  |  |  |
| --- | --- | --- | --- |
| **Cost of new medicine** | Specify pack size and cost. If price is expected to differ in primary and secondary care, please supply both | | |
| **Cost of existing formulary options**  If applicable | Please specify as above | | |
| **Expected number of patients per year** | Please provide a primary / secondary care breakdown, if appropriate | | |
| **Specify annual CHANGE to medicines expenditure:** | | | |
| **In Secondary Care** | | In Primary Care |
| Specify any other costs incurred by change in treatment:  e.g. extra monitoring requirements, staff or patient training |  | | |

# Proposed red / amber / green (RAG) status:

|  |  |  |
| --- | --- | --- |
| **Red** | Specialist prescribing only  The specialist\* initiates, continues and completes all ongoing monitoring. |  |
| **Amber shared care (Amber SCP)** | Specialist initiation with ongoing monitoring  Medicines that must be initiated by a specialist\*, and which require significant monitoring on an ongoing basis.  Full agreement to share the care of each specific patient must be reached under the shared care protocol (SCP) which must be provided to the primary care provider.  If a commissioned SCP is not available these must be treated as red. |  |
| **Amber specialist initiation**  **(Amber SI)**  Formerly known as Amber 2 in Humber | Must be started by a specialist\* and remain with specialist until the patient is stable on the new medicine but can then be transferred to primary care (general practice) to continue prescribing without ongoing arrangements between specialist and general practice. General practice can refer back to specialist at any time in relation to medication query, if required. |  |
| **Amber specialist recommendation (Amber SR)**  Formerly known as Amber 1 in Humber | Does not need to be initiated by a specialist but can be recommended by a specialist to general practice.  No ongoing arrangements between specialist and general practice. General practice can refer back to specialist at any time in relation to medication query, if required. |  |
| **Green (with pathway/guideline)**  Formerly known as Amber 1 in Humber | Can be prescribed in primary care in line with a recommended approved pathway/guideline. |  |
| **Green (no pathway/guideline)** | Medicines suitable for routine use within primary care and secondary care.  Can be prescribed in primary care, as per the wording on the formulary and considering both the drug SPC and BNF. |  |
| **Black (NRC)** | Not routinely commissioned. These drugs have been formally considered by the APC and are not recommended for prescribing due to, e.g. safety/cost |  |
| \* Specialists can be e.g. secondary care consultants or specialist independent prescriber. The specialist must be defined for each drug and indication. | | |
| **Rationale for proposed RAG status**: please comment on safety and required monitoring | | |

# CONFLICTS OF INTEREST

Please declare any relevant or associated interests that may conflict with your request

e.g. funding of research, equipment, visits to conferences

|  |  |
| --- | --- |
| **Declaration of conflict of interest** |  |

For consideration by the group, this form must be signed below by the applicant and supported by a clinical or medical director, medicines optimisation lead, or other person with a similar position.

Applications must be returned to the professional secretary of the subgroup no later than two weeks (14 days) prior to the meeting. Note that even if this deadline is met the group cannot guarantee that your submission will be considered at the next meeting due to existing work plans. Meetings take place on the third Wednesday of each month.

Please enclose as applicable:

* Application Form
* Supporting Evidence
* Guidelines for Use

# APPLICANT SIGNATURE AND SUPPORT

|  |  |
| --- | --- |
| Applicant signature |  |
| Date | Click or tap to enter a date. |
| **Application supported by**  All applications must be supported by a clinical or medical director, medicines optimisation lead, or other person with a similar position | |
| **Name** |  |
| **Role and position** |  |
| Organisation |  |
| Department or specialty |  |
| Email address |  |
| Signature of supporting person |  |
| Date | Click or tap to enter a date. |

Please send completed forms to: [hnyicb.mfg@nhs.net](mailto:hnyicb.mfg@nhs.net)