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| **Formulary Application Form 3 (FAF3)**  **Unlicensed / Off-Label Medicines** |

*Please read the supporting guidance that is available on the* [*formulary website*](https://formulary.nhs.scot/east/help-and-support/formulary-governance/formulary-application-process/) *before completing.*

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| **Medicine Information** *(medicine details can be checked on the* [*dm+d browser*](https://dmd-browser.nhsbsa.nhs.uk/)*)* |

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| Generic name of medicine | What is the generic name of the medicine? |
|  |  |
| Brand name of medicine | What is the brand name of the medicine? |
|  |  |
| Manufacturer | What is the name of the manufacturer? |
|  |  |
| Formulation | Which formulation(s) of this medicine should be added? |
|  |  |
| Route of administration | What is the route of administration? |
|  |  |
| Therapeutic area | Choose an area of the formulary. If not listed please type here. |
|  |  |
| Proposed indication | What is the proposed indication? |
|  |  |
| Dosing information | Enter the dosing information here (if NCMAG advice, please enter the full advice statement here). |
|  |  |
| NCMAG advice ID | For NCMAG advice, please enter the ID number for the advice document. If not, please enter N/A. |
|  |  |
| Proposed prescriber | Enter the proposed prescriber. |
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| UK licence status | Enter the UK licence status in terms of the proposed clinical use. |
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| Medicine availability | Enter details of the medicine’s availability here. |

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| **Place on Formulary** |

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| **a) Please estimate for ALL NHS Borders, NHS Fife and NHS Lothian use:** | | | | |  |
| * Prevalence (number of patients with condition): | | | | | Prevalence. |
| * Incidence (number of new patients per annum): | | | | | Incidence. |
| * Number of patients to be treated with the new medicine per annum: | | | | | Patients treated. |
|  | | | | |  |
| **b) Has a local treatment protocol been developed?**  *(If yes, please attach a copy of the protocol with this application)* | | | | | Choose an item. |
|  | | | | |  |
| **c) Has a local clinical management guideline been developed/updated?**  *(If yes, please attach a copy of the guideline with this application)* | | | | | Choose an item. |
|  | | | | |  |
| **d) Has an implementation plan been produced?**  *(If yes, please attach a copy of the plan with this application)* | | | | | Choose an item. |
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| **e) How is it proposed that the medicine will be used:**  *(If shared care is proposed, please refer to board guidance)* | | | | | Choose an item. |
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| **f) What is the criteria for patient selection?**  Criteria for patient selection (if for restricted use, please provide details. | | | | | |
| **g) Proposed place of medicine in the East Region Formulary:**  Choose an item.  ([*Contact us*](mailto:eos.prescribing@nhs.scot) for support on amending or creating pathways) | | | | | |
| **h) Does this medicine replace a current East Region Formulary choice?** | | | | | Choose an item. |
| If yes, which medicine will it replace? | | | | |  |
|  | | | | | |
| **i) What is the place in therapy in relation to other remaining formulary medicines?** | | | | | |
| Please describe the place in therapy in relation to other medicines that will appear in the formulary pathway(s) for this indication, or contact us for support. | | | | | |
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| **j) Proposed delivery route for medicine:** | | | | Choose an item. | |
|  | | | | |  |
| **k) Required formulary flags:** | | | | |  |
|  |  | - | None | | |
|  |  |  | Specialist Initiation | | |
|  |  |  | Specialist Use Only | | |
|  |  |  | Unlicensed Medicine | | |
|  |  |  | Unlicensed Indication | | |
| * What is the rationale for this choice of flags? | | | | |  |
| Please enter the rationale here. | | | | | |
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| **Clinical Effectiveness, Safety and Cost Effectiveness** |

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| **a) Summary of evidence on clinical effectiveness issues** |
| Enter here details of the principal trials supporting the indication(s) described above and the overall results regarding outcomes (e.g. absolute or relative risk reduction or NNT) and efficacy. Please summarise the principal outcome measures and provide web links to the appropriate references (up to 3 maximum). |
| **b) Summary of evidence on comparative efficacy** |
| Enter here the advantages of this medicine compared to other treatments. Consider medicines already recommended in the East Region Formulary or others in the same therapeutic class. |
| **c) Summary of evidence on comparative safety** |
| Describe any safety issues regarding this medicine in comparison to existing medicines. |
| **d) Summary of evidence on cost effectiveness** |
| Please provide information on the cost effectiveness of this medicine in terms of absolute risk reduction and cost per QALY. |
| **e) Guidelines** |
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| Please summarise the appropriate sections from any relevant local or national guidelines (e.g. SIGN, NICE). |
| **f) Information on similar use elsewhere (peer support)** |
| Please provide details of similar use of this medicine elsewhere. |
| **g) Additional information** |
| Please add any additional information or comments to support the application here. |

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| **Financial Details** |

*Tip – for NCMAG advice contact local board formulary team for budget impact assessment.*

*Guide estimates as a proportion of the Scottish population: Borders 2.1%; Fife 6.8%; Lothian 17%.*

*For cancer medicines please also include Dumfries & Galloway where appropriate.*

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| **For proposed therapy** | | **Number of eligible patients per annum** | **Annual cost per patient (£)** | **Cost per annum for all patients (£)** |
| Secondary Care | Borders | Enter here. | Enter here. | Enter here. |
| Fife | Enter here. | Enter here. | Enter here. |
| Lothian | Enter here. | Enter here. | Enter here. |
| D&G | Enter here. | Enter here. | Enter here. |
| Primary Care | Borders | Enter here. | Enter here. | Enter here. |
| Fife | Enter here. | Enter here. | Enter here. |
| Lothian | Enter here. | Enter here. | Enter here. |
| D&G | Enter here. | Enter here. | Enter here. |
| **Sub-total:** | | **Enter here.** | **Enter here.** | **Enter here.** |

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| --- | --- | --- | --- | --- |
| **For replaced therapy** | | **Number of eligible patients per annum** | **Annual cost per patient (£)** | **Cost per annum for all patients (£)** |
| Secondary Care | Borders | Enter here. | Enter here. | Enter here. |
| Fife | Enter here. | Enter here. | Enter here. |
| Lothian | Enter here. | Enter here. | Enter here. |
| D&G | Enter here. | Enter here. | Enter here. |
| Primary Care | Borders | Enter here. | Enter here. | Enter here. |
| Fife | Enter here. | Enter here. | Enter here. |
| Lothian | Enter here. | Enter here. | Enter here. |
| D&G | Enter here. | Enter here. | Enter here. |
| **Sub-total:** | | **Enter here.** | **Enter here.** | **Enter here.** |

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| **Total net cost:**  *(proposed minus replaced)* | **Enter here.** | **Enter here.** | **Enter here.** |

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| * How were these costs calculated?   Please describe how the annual cost per patient for proposed therapy and replaced therapy have been calculated, including any other key information to explain how the costs were arrived at. |

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| * Are there any other associated costs? | Choose an item. |
| If yes, please detail (e.g. Additional Medicine Therapy, X-rays, Lab Tests, etc.) | |
| * Have other service implications been discussed with appropriate services? | Choose an item. |
| If yes, please provide details. | |
| * Will a homecare service be used for the delivery/procurement of this medicine? | Choose an item. |
| If yes, please provide details for each board. | |
| * Is any hospital discount available for the proposed medicine? | Choose an item. |
| If yes, please provide details. | |
| * Will prescribing be continued in General Practice? | Choose an item. |

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| **Applicant Details & Declaration of Interests (last 3 years)** |

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| First name | Click or tap here to enter text. |
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| Surname | Click or tap here to enter text. |
|  |  |
| Health Board | Choose an item. If not listed please type here. |
|  |  |
| Position held | Click or tap here to enter text. |
|  |  |
| Email address | Click or tap here to enter text. |

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| Do you have a **personal specific** interest to declare? Select.  If yes, enter the nature of the interest being declared here. |
| Do you have a **personal non-specific** interest to declare? Select.  If yes, enter the nature of the interest being declared here. |
| Do you have a **non-personal specific** interest to declare? Select.  If yes, enter the nature of the interest being declared here. |
| Do you have a **non-personal non-specific** interest to declare? Select.  If yes, enter the nature of the interest being declared here. |

* **I declare** that the information I have given is correct and complete.
* **I understand** that if I knowingly provide false information this may result in disciplinary action and I may be liable for prosecution and civil recovery proceedings.
* **I understand** this form is a public record, and it will be made available for audit or other inspection, or disclosure under the Freedom of Information Act.

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| Name: Enter full name. | Date: Select a date. |

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| **Supporting Pharmacist Details & Declaration of Interests (last 3 years)** |

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| First name | Click or tap here to enter text. |
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| Surname | Click or tap here to enter text. |
|  |  |
| Health Board | Choose an item. If not listed please type here. |
|  |  |
| Position held | Click or tap here to enter text. |
|  |  |
| Email address | Click or tap here to enter text. |

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| Do you have a **personal specific** interest to declare? Select.  If yes, enter the nature of the interest being declared here. |
| Do you have a **personal non-specific** interest to declare? Select.  If yes, enter the nature of the interest being declared here. |
| Do you have a **non-personal specific** interest to declare? Select.  If yes, enter the nature of the interest being declared here. |
| Do you have a **non-personal non-specific** interest to declare? Select.  If yes, enter the nature of the interest being declared here. |

* **I declare** that the information I have given is correct and complete.
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* **I understand** this form is a public record, and it will be made available for audit or other inspection, or disclosure under the Freedom of Information Act.

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| Name: Enter full name. | Date: Select a date. |

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| **Clinical Director Approval Details** |

Clinical Directors (or equivalent medical manager) should be made aware of this application, in order to aid with any implementation plans that may need to be put in place in order to safely deliver this medicine.

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| Clinical Director – NHS Borders: | Choose an item. |
| Clinical Director – NHS Fife: | Choose an item. |
| Clinical Director – NHS Lothian: | Choose an item. |

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| Additional details: | Please add additional information regarding clinical Director or equivalent medical manager approval including name, job title and board. [Tip - in the case where the service is only provided by one of the boards, this should be clearly stated in the application. Confirmation of clinical director (or equivalent medical manager) support from all three boards is required where cross board charging applies.] |

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| **Additional Information** |

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| Additional information | Please add any additional information you wish to be considered as part of this application. |

**The applicant should return the form by email to** [**eos.prescribing@nhs.scot**](mailto:eos.prescribing@nhs.scot) **copying in the supporting Pharmacist.**

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| **For internal use only** |

**Additional Information**

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| Additional information for Formulary Committee reviewer: | Additional information for formulary committee reviewer. |

**Formulary Committee Decision**

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| Formulary status: | What is the status of this application? |
|  |  |
| Rationale: | What is the rationale for this status? |
|  |  |
| Other comments/actions: | Capture any comments or actions required here. |
|  |  |
| Date: | Select a date. |
|  |  |
| Additional information: | Capture any additional information here (e.g. details provided by clinical team.) |