This form is to be used for applications for new drugs, new formulations and extensions to previously agreed uses for drugs and other relevant pharmaceutical products including medicated dressings, prescribable nutritional products, borderline substances and pharmaceutical medical devices to be prescribed by NHS services in County Durham and Tees Valley.

**Guidance on completing the form**

* Your submission should be comprehensive and indicate which, if any, information has been supplied by a pharmaceutical company. The manufacturer/ supplier may provide information supporting the application, but the application must come from a clinician working within one of the APC stakeholder organisations.
* The application must be completed with the input from the the Lead Clinical Pharmacist for that speciality (secondary care) or Medicines Optimisation Pharmacist (primary care)
* The application must reflect consensus from your directorate, speciality or area.
* **Full clinical evidence does not to be submitted or completed for NICE TA approved drugs or those recommended in NICE Clinical Guidelines just the sections on finance and how introduction of the drug will be managed locally Sections 6,7.8).**
* Please complete **all** details – incomplete forms will be returned.
* The application MUST be supported by the relevant Clinical Director or Chief of Service (secondary care) and/or GP Prescribing Lead (primary care) before submitting. If you have done this please give details in the relevant section of the form.
* An application for a drug that has been rejected within the last 12 months will normally be refused, unless it is for a different indication, is based on new evidence/ new national guidance or in circumstances deemed exceptional by the Committee.
* The manufacturer/ supplier (drug company) may provide information supporting the application, but the application must come from an appropriate applicant (see above).
* **The form should be submitted electronically by e-mail by completing this document and sending to:**
  + **For CDDFT** [**Beverley.Walton2@nhs.net**](mailto:Beverley.Walton@cddft.nhs.net)
  + **For NTHFT** [**mohammedmajid@nhs.net**](mailto:mohammedmajid@nhs.net)
  + **For STHFT** [**andrew.lloyd3@nhs.net**](mailto:andrew.lloyd3@nhs.net)
  + **For TEWV** [**christopher.williams@nhs.net**](mailto:christopher.williams@nhs.net)
  + **For Primary Care in County Durham & Tees** [**nuth.nyrdtc.rxsupp@nhs.net**](mailto:nuth.nyrdtc.rxsupp@nhs.net)

**Submission to County Durham & Tees Valley APC**

* Applications must be submitted at least two weeks before the meeting wherever possible otherwise the submission is likely to go to the following APC meeting.
* The Formulary Lead Pharmacist/Technician will notify you of the date of the meeting when the application will be considered.
* Where possible electronic versions of any references and other supporting documents (preferably Word or PDF format) should be e mailed at the same time.
* Secondary care consultants must discuss their request with, and obtain support from, other consultants working in their speciality prior to submitting a request. When this is done please give details in the appropriate section of this form.
* For medications with a positive NICE TA a submission to Trust D&Ts is still required to allow consideration updates to pharmacy systems, clinical guidelines and local stock holding.

**The decision making process**

**County Durham & Tees Valley APC will base their decisions on the following key areas:**

* Clinical effectiveness
* Cost effectiveness / resource impact
* Strength of evidence
* Patient safety
* Place in therapy relative to available treatments
* National guidance and priorities
* Local health priorities
* Equity of access
* Stakeholder views
* Environmental sustainability

**Decision Summary**

This will be recorded by the APC. Each organisation is then responsible for cascading the decision to its clinicians and other relevant parties.

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| **1. APPLICANT’S DETAILS** | | |
| ***Name:***  Click or tap here to enter text. | ***Position / Role:***  Click or tap here to enter text. | ***NHS Organisation:***  Click or tap here to enter text. |
| ***Contact details (Address/email address):***  Click or tap here to enter text. | | ***Tel:***  Click or tap here to enter text. |
| ***Department/Unit:***  Click or tap here to enter text. | | |

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| **2. COMPUSLORY SUPPORT FROM DEPARTMENT OR PRACTICE, SPECIALITY LEAD, PRESCRIBING LEAD, ORGANISATION AND BUSINESS/FINANCE OFFICER**  Does this application have support from all relevant stakeholders in County Durham and Tees Valley?  Does this application have speciality wide support and not just that of individual clinicians?  Does the application have support from Trust Finance if appropriate e.g. High cost drug? | | | |
| **Name of supporting individual or group** | **Organisation** | **Comment** | **Date of Review** |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap to enter a date. |
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| **3. DETAILS OF DRUG** | |  |  | |  |
| ***Non-proprietary (generic) name:*** | Click or tap here to enter text. | | | ***Brand name:*** | Click or tap here to enter text. |
| ***Dosage form and strength (e.g. tablets 50mg)*** | Click or tap here to enter text. | | | | Tick if applies  Unlicensed Drug  Unlicensed Indication  Unlicensed Route of Administration |
| ***Manufacturer:*** | Click or tap here to enter text. | | | | Manufacturer signed up to All Trials  Petition?  <https://www.alltrials.net/supporters/organisations/>  YES  or NO |
| ***Commissioning – ICS or NHSE? Tariff included or tariff excluded?*** | Click or tap here to enter text. | | | |  |

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| **4. INDICATIONS** | |
| ***Licensed indication for this drug*** *(see SPC)*:  <https://www.medicines.org.uk/emc> | Click or tap here to enter text. |
| ***Indication for which Product is requested*** | Click or tap here to enter text. |
| ***Dose / strength / frequency of administration*** | Click or tap here to enter text. |
| ***Route of administration*** | Click or tap here to enter text. |
| ***Duration of treatment: one off / fixed period / long term / other*** | Click or tap here to enter text. |

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| **5. REASON(S) FOR REQUEST** | | |
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| ***Please classify Reason(s****)* – Tick box(es) | Therapeutic advantage over existing treatment  More cost effective than alternative treatment  Improved Compliance  Greater environmental sustainability than current options | No alternative  New formulation  Other (please specify) |
| ***If there are advantages over existing drugs/ treatments for same indication(s) please state here.*** | Click or tap here to enter text. | |
| Details of evidence for these advantages in terms of **EFFICACY, SAFETY, CONVENIENCE** or **COST EFFECTIVENESS.** Copies of the key papers referred to should be submitted with the application as full text not abstracts (continue on separate sheet if necessary). | | |
| Click or tap here to enter text. | | |

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| **6. ANTICIPATED PLACE IN THERAPY** |
| Please give a clear guideline including algorithms or flowcharts as necessary, indicating which group(s) of patients should and should notbe eligible to receive this drug, including details of whether the drug is 1st line or not and the suggested criteria for selecting or not selecting the drug. (either explain below or attach a pathway). |
| Click or tap here to enter text. |

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| **7. EXISTING DRUGS** | |  |  |
| ***Existing products(s) for the same indication(s):*** | Click or tap here to enter text. | | |
| ***Would the product requested be:*** | 1. An addition to what is already existing *OR* | | **YES  NO** |
|  | 2. A replacement for what is already existing | | **YES  NO** |
| ***If a replacement, which product(s) can be deleted:*** | Click or tap here to enter text. | | |
| ***Does this product offer any opportunities for deprescribing of other products currently on the formulary or in the clinical pathway for this condition? If so, which ones?*** | Click or tap here to enter text. | | |
| ***Potential disadvantages e.g. side-effects, cost, extra monitoring)*** | Click or tap here to enter text. | | |

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| **8. PRESCRIBING AND MONITORING** | |  | |  |
| ***Dosage regimen proposed for this application****:* | **Dose and Frequency:**  Click or tap here to enter text. | | **Likely duration of treatment:**  Click or tap here to enter text. | |
| ***Monitoring requirements (including criteria for stopping treatment, implications for continued care and who does the monitoring)****:* | What monitoring is required? | | Click or tap here to enter text. | |
| Who is responsible for what monitoring? | | Click or tap here to enter text. | |
| Criteria for stopping treatment | | Click or tap here to enter text. | |
| Who assesses for stopping treatment? | | Click or tap here to enter text. | |
| ***Proposed formulary classification and any restrictions*** | Classification:  Red  Amber shared care  Amber specialist initiation  Amber specialist recommended  Green | | Prescriber restrictions  (e.g. Consultant only, etc)  Click or tap here to enter text. | |
| ***Is the application for:*** | Single consultant ☐ Speciality ☐  Single Site ☐ Whole Trust ☐  Outpatients ☐ Inpatients ☐ Both ☐  Primary care use ☐ Secondary care use ☐ Both ☐ | | | |

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| **9. FINANCIAL ASPECTS** | | | |
| Please complete the following to allow likely usage and costs to be calculated. | | | |
| ***No of patients likely to be treated per year in North Yorkshire & York wide*** | ***Average daily dose*** | ***Likely duration of treatment*** | ***Duration of treatment likely to be supplied by hospital***  *(i.e. duration of treatment course supplied by hospital)* |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |
| If you already have an estimate of the likely cost (to your directorate) of using this product please give details below: | | | |
| ***Has a robust cost effectiveness analysis been completed for this medicine? Include details and link e.g. NICE, SMC, AWMSG*** | Click or tap here to enter text. | | |
| ***Estimated cost:***  ***If a business case has been prepared involving the use of this product please enclose details with this form****.* | In next 12 months £ Click or tap here to enter text.  Subsequent Years £ Click or tap here to enter text. | | |
| ***Details of how estimated costs have been calculated / obtained*** | Click or tap here to enter text. | | |
| ***Details of compensatory saving resulting from use of new product (please include details of possible savings in areas other than drugs expenditure)*** | Click or tap here to enter text. | | |
| ***Other costs and considerations e.g. drug monitoring, clinic attendance, staff time*** | Click or tap here to enter text. | | |
| ***What is the likely impact of this product on primary care prescribing?*** | Click or tap here to enter text. | | |
| ***What, if any, are there additional cost or service implications for primary care as a result of this formulary application?*** | **Additional cost (e.g. monitoring, workload) associated with a transfer of prescribing from the acute sector to primary care.** If so, please provide additional detail, for example the cost per patient per year and the estimated number of patients:  **Additional monitoring requirements for Primary Care.** If so, please provide detail including whether agreement has been made to reimburse GP Practices for this monitoring via the Local Enhanced Service (LES): | | |
| ***What, if any, are there additional cost or service implications for secondary care as a result of this formulary application?*** | **Additional cost (e.g. workload) associated with a transfer of prescribing from the primary care to acute sector.** If so, please provide additional detail, for example the cost per patient per year and the estimated number of patients:  **Additional monitoring requirements for Secondary Care.** If so, please provide detail including whether agreement has been made to provide funding to secondary care for this monitoring  **Need to** **establish a repeat dispensing system** | | |

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| **11. ENVIRONMENTAL SUSTAINABILITY** | |
| ***Does this product have a reduced carbon footprint compared to comparators? (If known)***  *If yes why/how/evidence?* | Click or tap here to enter text. |
| ***Does this product have any advantages in terms of packaging?***  *If yes – why/how?* | Click or tap here to enter text. |
| ***Does this product have any advantages in terms of shelf life?***  *If yes – why/how?* | Click or tap here to enter text. |
| ***Does this product have result in less waste compared to comparators?***  *If yes – why/how?* | Click or tap here to enter text. |

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| **12. SUPPLEMENTARY DETAILS** |
| Please give a concise outline of any additional information you would like to be considered along with this Formulary Request. This can include links to trial data, SIGN documents, NICE guidance, SMC guidance, or any other relevant information. Plus Other local commissioning positions where known.  Please provide any relevant information on Side effect profile, Safety / Pharmacovigilance and Significant drug interactions |
| Click or tap here to enter text. |

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| **13. DECLARATION OF INTEREST** | | | |
| *It is mandatory that Members of the Formulary Subcommittee and Area Prescribing Committee declare interests prior to discussing items relating to individual products. All applicants must do the same.* | | | |
| Details of any support or sponsorship (for staff, clinical trials, other research etc.) received or likely to be received from the manufacturer of this product within the last/next 12 months. If none state NONE | | | |
| ***Personal***  Click or tap here to enter text. | | ***Departmental***  Click or tap here to enter text. | |
| ***Applicant’s Signature\**** | Click or tap here to enter text. | ***Date:*** | Click or tap to enter a date. |
| \* If the form is only being submitted electronically print name and email. The authenticity of the emailed document will be verified when the application is processed | | | |