**REQUEST TO PRESCRIBE A NON-FORMULARY MEDICINE**

**GUIDANCE NOTES**

**Requests to prescribe a non-formulary medicine (Categories 1, 2 and 4) should be considered by the relevant group as follows:**

* Secondary Care – relevant Clinical Group
* Oncology and Haematology requests – Oncology & Haematology Medicines Management Group (OHMMG)
* Mental health, Care of the Elderly, General practice requests – relevant Clinical Group

The Clinical Group/OHMMG must consider whether there are overriding factors that make the decision not to prescribe unreasonable in the particular circumstances.

**Please Note:**

* Secondary care clinicians who wish a patient to receive a medicine that is unlicensed or has not been submitted to SMC advice should make a case to their Clinical Group, as well as complete the proforma in Appendix 3 of the Policy. Prescribing approved by the Clinical Group and/or non-formulary panel remains the clinical and financial responsibility of secondary care i.e. such medicines should normally be supplied from hospital. Primary care should only be asked to continue prescribing if: This is the best care delivery method for the patient AND an adequate secondary care trial of medication has established tolerability and benefit of treatment AND a shared care agreement/ Individual Patient Treatment Plan is in place where appropriate AND the arrangement has been agreed by the patient’s GP.
* A separate form should be completed for each case, this process is not to be utilised for treatment of groups of patients where it is known at the time a group exists. For groups of patients a submission should be made to the Medicines Advisory Group after approval of the appropriate clinical group if in secondary care.
* Following discussion by the Clinical Group/OHMMG, completed forms should be forwarded to the relevant Principal or IJB Lead Pharmacist . The non-formulary database should also be completed.
* Appeals should be submitted as outlined in section 7 of the policy, seek early advice from the appropriate Principal/Lead Pharmacist if required.

**Guidance on specific questions:**

Requested medicine (Q.5)

The approved (generic) and brand name should be entered

Anticipated duration of treatment (Q.8)

Length of treatment should the unlicensed/new medicine be approved for use in this patient e.g. one course of 7 days; life-long; or duration of trial period, if that is what is intended.

Cost (Q.9)

The NHS cost for a relevant treatment period e.g. per course or per 28 day treatment period.

Reason for request (Q.11)

If the medicine is continued from another health board then details of that approval would be helpful to the application but NHS Tayside will make an independent decision.

Treatment continuation (Q.12)

If secondary care wishes to transfer the liability of prescribing to primary care on the basis that this is necessary for the patients optimal care, the appropriate approval of primary care must be sought, confirming to Primary Care that a PACS is in place, see notes above.

Previous treatment options and alternatives (Q.13 & 14)

Provide details of previous treatment options the patient has received. State any alternative medicines also licensed for the indication and reasons why they are not being used in this case.

Clinical evidence (Q.15)

Provide details of clinical outcomes associated with this unlicensed/new medicine in this patient group e.g. increase in disease free survival, overall survival and quality of life. Indicate the quality of evidence to support use, attach relevant references. For Category 1, unlicensed medicines, evidence of safety is vital to construct a risk: benefit argument supporting use. If the medicine represents a financial liability then evidence of cost effectiveness will usually be required, such as alterative costs saved, hospital admissions reduced etc.

Treatment outcomes and timescales (Q.16)

In order to ensure financial governance clear timescales for treatment trial, duration and exit strategies will need described. Objective measures of treatment success and failure resulting in treatment stopping will usually need to be described, it is also desirable for this to explained to the patient if clinically appropriate.

Service Implications (Q.17)

Describe any service pressure that will result, such as additional expensive tests/monitoring. Describe any service savings if not previously described.

Exceptionality (Q.18)

In this section you must explain why this patient’s clinical circumstances and potential response to treatment with this medicine would be significantly different from the patient group/population considered by SMC/NHS QIS or NHS Tayside. The significant benefit you expect this patient to gain must be clearly explained and how you expect to measure/demonstrate this.

Timelines (Q. 21)

Please describe the timescale within which a decision is needed. It is very difficult to hold frequent panels, NHS Tayside will endeavour to hold in-person panels for these requests. Should an urgent decision be clinically necessary please indicate this and why. A decision will be taken via the most appropriate communication means to meet the clinical deadline.

Declaration (Q.22)

It is important to describe this process to the patient/carer, and to explain that the request may be rejected so as not to raise false hope/expectation if this is clinically appropriate. Ensure also you provide the patient/carer with the described leaflet, the hyperlink to which is on the electronic form (see *Appendices 4 & 5*).

**REQUEST TO PRESCRIBE A NON-FORMULARY MEDICINE**

This form (guidance on completing this form is available in Appendix 2) should be completed by the clinician**\*** who wishes the patient to receive a non-formulary medicine in any of the following circumstances:

|  |
| --- |
| **Unlicensed** |
| Category 1 | Unlicensed medicines requests, including special formulations |
| **Licensed** |
| Category 2 | ‘Off-label’ medicines requests, i.e. use out with their licensed indications |
| Category 3 | PACS requests use separate National form at *Appendix 4* |
| Category 4 | Non-formulary requests out with NHS Tayside Drug and Therapeutics Committee advice. This includes medicines that are accepted by SMC but are not listed in the formulary/specialist list or local protocols. |

**\*** Note that a Specialist recommending treatment should complete this form and submit to the relevant Clinical Pharmacist.

**Guidance on completing this form is available at *Appendix 2*.**

|  |  |
| --- | --- |
| **1. Clinical Group/IJB:** |  |
| **2. Clinical Team/Speciality:** |  |
| **3. Requesting Clinician:** |  |
| **4. Patient CHI:** |  |
| **5. Requested Medicine:** |  |
| **6. Indication the medicine is to be used for:** |
| **7. Dose** (including strength, form and frequency): |  |
| **8. Anticipated duration of treatment:** |  |
| **9. Treatment Cost:**  |  | **Annual Cost:** |  |
|  |  |  |  |
| **10. Exception Category:**(*please tick*) |  | Category 1: Unlicensed medicines requests, including special formulations **(NB: Read Policy Section 3)** |
| I have read and understood Section 3 – Signed: ……………………………………………………………………… |
|  |  |  |  |
|  |  |  | Category 2: ‘Off-label’ medicines requests, i.e. use out with their licensed indications and/or medicines not submitted to SMC |
|  |  |  |  |
|  |  |  | Category 3: Use separate form at *Appendix 4 (PACS)* |
|  |  |  |  |
|  |  |  | Category 4: Non-formulary requests out with NHS Tayside Drug and Therapeutics Committee advice. This includes medicines that are accepted by SMC but are not listed in the formulary/specialist list or local protocols. |
|  |
|  |  |
| **11.** | **Reason for Request:****Continuation of medicine initiated in primary care: Go to Section 22**(If previous authorisation not granted: supply may be refused)**Continuation of previous hospital supply: Go to Section 22**(If previous authorisation not granted: supply may be refused)**Continuation of medicine approved in other health board:** **New treatment decision:**  |
| **12.** | **Will treatment continue:****Only in hospital Hospital, then in primary care** **If to be continued in primary care:****Individual Patient Treatment Plan written\*** **\*Seek advice from Principal Pharmacist.**  |
| **13.** | **Previous treatments that the patient has received:** |
| **14.** | **Explain why available licensed and formulary medicines are not appropriate in this case:** |
| **15.** | **Summary of peer reviewed evidence for use in this indication in terms of safety, clinical and cost effectiveness if available** (attach relevant references)**:*****NB: If for Category 1 or 2 then safety evidence is necessary to enable a risk/benefit assessment.*****Evidence Quality** (*Please tick)*

|  |  |  |
| --- | --- | --- |
|  | I | RCTs |
|  | II | Case control or cohort studies |
|  | III | Non-analytic studies e.g. case reports, case series |
|  | IV | Expert opinion |

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| **16.** | **Treatment Outcomes and Timescales:**Please note that treatment will only be authorised if agreed outcomes and timescales are clear. If approved, circumstances in which treatment may cease should be explained to the patient or carer by the prescriber. Please indicate clearly circumstances in which treatment will be stopped. |
| **17.** | **Service Implications** (if any): |
| **18.** | **Approval Rationale***Example:* Explain how the patient is expected to gain significantly greater benefit from this drug than the normal treatment group considered by SMC or NHS Tayside policy for this drug. |
| **19.** | **Monitoring requirements for treatment:**If required of primary care, an individual patient treatment plan is needed (seek advice from pharmacy) |
| **20.** | **Details of all discussions relevant to this case:***Example*: Advised by national experts, second opinions, colleagues etc. |
| **21.** | **Timeliness** (Please indicate timeframe, if relevant, in which decision is needed - this must be realistic and clinically relevant): |
| **22.** | **Declaration:****I declare I have completed a conflict of interest form that I have explained this process to the patient or carer and that approval is not guaranteed.****Signed: ……………………………………… Name (BLOCK CAPITALS): …………………………………..** **E-Mail Address: …………………………………………………….…………… Page: ……………..…………** |
| **Any request needs to be supported by the relevant Clinical Lead or Associate Medical Director****By signing you are confirming that you have discussed this with the requesting Clinician and support the application.** **Clinician in support of application:****Signature:****Name (BLOCK CAPITALS): Date:****Clinician in support of application:****Signature:****Name (BLOCK CAPITALS): Date:****Pharmacist in support of application:****Signature:****Name (BLOCK CAPITALS): Date:** |

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| --- |
| **Authorisation:** **To be completed by the Principal Clinical Pharmacist/Lead Pharmacist** |
| I have reviewed the request and the evidence for safety, clinical and cost effectiveness.Yes N/ARequest Approved Clinical Service Manager notified Request referred to Clinical Group/IJB levelRequest referred to non-formulary panel Request rejectedName: Signature: Date:**NB: Ensure original is returned to medical notes and a copy forwarded to patients GP.** |
| Rationale behind decision: |
| **AUTHORISATION:** **To be completed by Chair of the decision-making panel** |
| **Decision and supporting statement:**(Including any conditions such as duration, evidence of outcomes, etc.)**NB: Ensure original is returned to medical notes and a copy forwarded to patients GP.** |
| Name: Signature: Date: |