

Approval for Drug use either pre SMC review or not recommended by SMC

Section 1: (to be completed by prescriber and clinical pharmacist)

1. Consultant details

Name of consultant:

Date of request:

1.2 Patient identifier:

Hospital No:

Initials:

DOB:

Patient Details: Diagnosis/clinical indicators:

1.3 Drug Details

Drug Name:

Generic:

Formulation

oral

Trade:

parenteral

other

Is the drug licensed

Yes

No

Is the drug licensed for the clinical indication above

Yes

No

Has the drug been considered by SMC

Yes

No

If yes what was the outcome:

Recommended for restricted use in NHS Scotland

Not recommended for restricted use in NHS Scotland

SMC decision pending

Not submitted to SMC - Reason

Details of restrictions if applicable.....

If no is there a planned date for SMC review.....

1.4 Treatment/Evidence Base details

What other treatment options are available

Why are other options not suitable for this patient

When is treatment required to start.

Is the patient receiving alternative treatment while awaiting the outcome of this submission

What regimen is planned with this agent for this patient

Details of Course/ Treatment Duration

Dose

Duration

Repeat course/cycle/frequency -

No of years continuation of treatment expected -

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Section 1 (Continued)

What is the evidence base (Include - Quality of trial / Outcomes (efficacy/clinical/population etc.)

1.5 Outcomes

What will be measured:

How will this be measured:

1.6 Cost details

Cost / Course :	£	/ month
Cost / Annum :	£	/ average length of treatment
Other non drug cost* :	£	/ annum
Total cost (eg. 5 yrs) :	£	/ (annual x yrs)

* Please state additional non drug cost implications e.g. blood tests/monitoring etc.

1.7 Anticipated use within Forth Valley

How many patients per annum are likely to be eligible for treatment in Forth Valley:

Total cost expectation (no of pts x cost/pt/year):

Section 2 : Declaration of interest (to be completed by prescriber and clinical pharmacist)

Declaration of interest

The following paragraph applies to all the sections listed below.

The consultant / pharmacist are asked to declare any relevant personal interest (direct or indirect) that they have had with the pharmaceutical industry and must intimate where there is a conflict of interest. This applies to amounts greater than £500 in the last 2 years. The interests may be direct (eg , lecture, consultancy fees, and sponsorship) or indirect (departmental donations, research contracts). Any other factors that will result the submission should also be declared.

2.1 It is my opinion that for the aforementioned patient the listed treatment would be the preferred clinical option and I agree to report actions quarterly to DTC via Chief Pharmacist.

Consultant / requestor signature :

Date:

2.2 Having received the patient details I can confirm that all required criteria for treatment have been met>

Clinical Pharmacist Date

Principal Pharmacist Date

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Section 3 : Decision process (to be completed by ADTC sub group)

3.1 Date of meeting when discussed:

3.2 Members present at meeting:

3.3 Details of discussion at meeting:

3.4 Decision

- Approved for use by named patient**
- Approved for use for Forth Valley patient group**
- Decision pending awaiting further information**
- Not approved for use**

Copy 1 -Central File

Copy 2- Medicines Information, master file of requests

Copy 3 - Patients notes