

Forth Valley Area Drugs & Therapeutics Committee

Process for the consideration of Therapeutic Advances either pre SMC Review or which were not recommended by SMC for use in NHS Scotland but where there is a local request for use by a medical specialist due to clinical need

This process has been established to provide a consistent approach to decisions relating to agents which fall outwith the standard process and which may have a significant impact on future prescribing policy.

Criteria

The criteria noted below would be used to identify agents which should be considered via this 'exception' type process :

- Product is pre-SMC or is pending SMC appeal and there is clinical urgency for use of the agent
- Where SMC has decided 'not to recommend for use in NHS Scotland' and use outwith this decision is likely to affect policy or has high cost implications.
- When request is for more than 1 patient (or where use is likely that more than more than 1 patient will require this agent) and is likely to have a significant impact on future prescribing policy
- For use by one patient where the annual cost for that patient is greater than £20 k
- Where the product is the subject of media attention and/or political/patient pressure

Process

A flow chart of this process is attached (Appendix I)

If the request is deemed to fall within the criteria listed above the requestor would be asked to complete a standard proforma (Appendix II). The sub group members would be contacted and a meeting convened as appropriate. The sub group members would be drawn from the following members:

- Medical Director NHS FV
- Chair of FV Area Drug & Therapeutics Committee
- Chair of FV Acute Services Drug & Therapeutics Committee
- Chair of FV Primary Care Prescribing Group
- Chief Pharmacist FV Acute Services
- Chief Pharmacist CHPs
- Lead Finance Manager for New Drugs with delegated authority from Director of Finance
- Key stakeholder/specialist where appropriate

There is recognition that this sub-group may be required to convene at very short notice and despite the logistical difficulties a physical meeting should be arranged where possible. If this is impossible a virtual electronic discussion may be considered. For each submission the following issues will be considered by the sub-group:-

1. Clear diagnosis
2. Standard therapy tried and failed / not tolerated
3. Availability of alternatives – evidence base, licensed product, licensed indication
4. Evidence base for proposed therapy – is it a licensed drug / licensed indication
5. Monitoring / end-points / outcomes – are they measurable / tangible
6. Duration of therapy and associated costs
7. Time period that funding will be given for – this may mean a subsequent request will be required looking at pt progress
8. Cost of treatment versus cost of not treating
9. Safety / tolerability of proposed therapy – risk / benefit analysis
10. Previous decisions made to ensure consistency

Once a decision has been reached by the sub-group, a letter will be sent to the requestor detailing the decision and the duration for which funding is agreed. It will be stressed that should a subsequent request be required that a 3 month application period should be allowed for the group to discuss. The requesting consultant will also be reminded that it is prudent for them to ensure that they have received informed consent from the patient / parent / guardian and that the patient / parent / guardian is fully aware of the risk / benefit profile of treatment. The sub-group will aim to provide a decision within 4 weeks of receipt of request / proforma.

The details of each drug considered along with summary of discussions, decision and correspondence will be held centrally on file. This would allow reflection on previous decisions as an aid to future decision making and provide a robust process demonstrating a consistent approach which could be recalled.

Appeals Process

If the decision of the sub-group was not to approve the requested agent, the requestor would have the right to appeal in writing via the ADTC to the NHS FV Board Execs group. NHS Forth Valley would aim to provide a decision within 12 weeks of appeal.