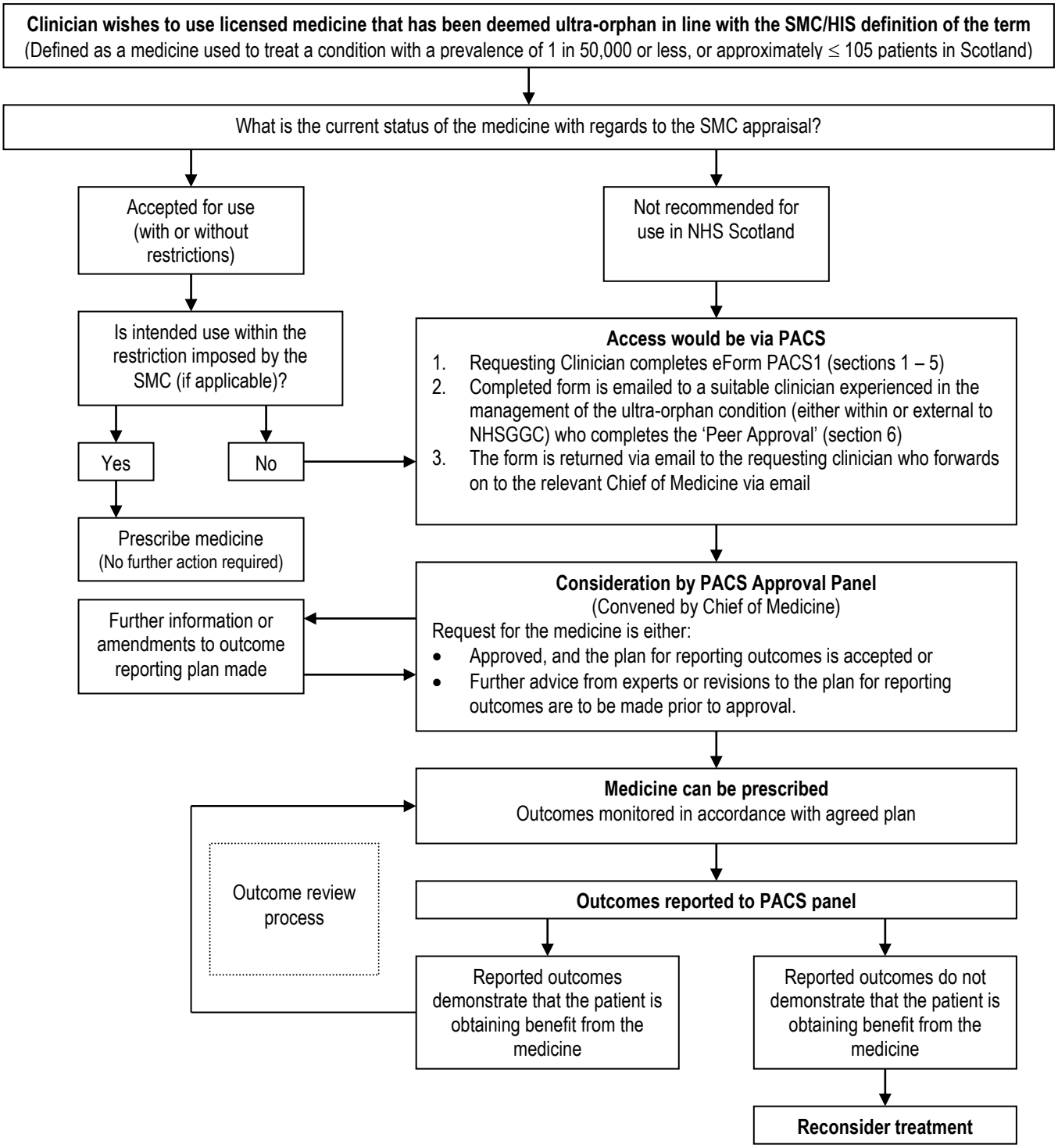
Overview of process



1. Purpose of paper

This policy outlines the NHS GG&C management process for clinicians to access medicines for ultra-orphan conditions by the Peer Approved Clinical System (PACS).

2. Background

The Peer Approved Clinical System (PACS allows clinicians to access licensed medicines used to treat ultra-orphan conditions that are not recommended for use in NHS Scotland following appraisal by the Scottish Medicines Consortium (SMC).

3. Criteria for using PACS

3.1. PACS can currently only be used to access medicines licensed for conditions meeting the HIS criteria for ultra-orphan (a condition with a prevalence of 1 in 50,000 or less) where the medicine is not routinely available in NHS Scotland.

3.2. Only consultant clinicians working within NHS GG&C can request medicines via PACS if all of the following are met:

- The medicine and indication are licensed
- Where following a submission from a pharmaceutical company the SMC, having considered the submission under their ultra-orphan framework, does not recommend the medicine for routine use in the relevant indication
- Where a clinician, having considered the advice from SMC and any other treatments recommended for use in NHS Scotland, is of the view that the prescribing of the medicine will have a measurable beneficial clinical outcome for an individual patient.

4. Principles of PACS

The principles of PACS are founded upon the Healthcare Quality Strategy for NHS Scotland and GMC's Good Medical Practice.

PACS should:

4.1. Empower those clinicians with the most expertise in a particular area to take decisions in the best interests of their individual patients;

4.2. Be outcome driven and focus on the overall benefit to the patient based on their particular clinical circumstances;

4.3. Be subject to peer review and monitoring of whether the treatment is delivering the anticipated benefit;

4.4. Be timely in line with urgency of clinical circumstances;

4.5. Provide an opportunity to collect data for patients in Scotland outside of the clinical trial environment and for these to be shared throughout NHS Scotland;

4.6. Operate on an individual patient basis.

5. Declaration of interests

Relevant declarations of interest of all persons involved in the request (and the consideration of the request) should be captured as part of this system. The designated request form has specific fields to be completed on this matter.

6. Process for submitting PACS

6.1. Where the criteria for PACS outlined above are met, the clinician should make the case for the prescribing the medicine, focussing on the measurable benefit that the medicine would deliver for the patient.

6.2. A designated request form (eForm PACS 1) should be used by the clinician to make the case for prescribing and to propose a schedule for measuring benefit and reporting it back to the PACS Approval Panel.

6.3. The requesting clinician should ensure that there is open and honest discussion with the patient (or their carer) about treatment options and likely benefits, together with the associated risks. In addition, the clinician should inform the patient (or carer) about the PACS process.

6.4. There should be agreement with the patient around monitoring of outcomes and the sharing of these for the wider benefit of NHS Scotland. The discussion should include decisions that may need to be taken should the treatment not demonstrate the expected outcome. In line with usual best clinical practice, if a treatment is not delivering the anticipated clinical benefit then clinicians will consider whether that particular treatment should end.

7. Peer support

7.1. The prescribing clinician should seek the views from at least one clinical colleague experienced in the treatment of the condition. This clinical colleague can be drawn from anywhere in Scotland, or should there not be a suitably experienced clinician in Scotland, elsewhere in the UK.

7.2. In the event that a clinical colleague experienced in the treatment of the condition is not available, the prescribing clinician should seek the views of their Clinical Director.

7.3. Where there is support from clinical colleague(s) for the prescribing clinician's proposal, the prescribing clinician will provide their case to a panel of clinicians nominated by the Health Board.

7.4. The designated form contains a section on Peer Support for Proposed Treatment. However, if access to the form by the clinical colleague is not possible, the requesting clinician may submit the form with separate attachments detailing the peer support (e.g. email communications).

8. Process for approving ultra-orphan medicines via PACS

A designated PACS panel will review the request, supporting evidence and proposed schedule of monitoring benefit and take one of the following courses of action:

- Confirm that they agree with the proposal for prescribing in the circumstances put forward and to the proposal for monitoring and sharing outcomes, including adverse effects

OR

- Request revision of the proposal to seek further expert input or draw out further evidence

9. PACS panel membership

The panel for reviewing a request for a treatment via PACS will typically consist of:

- The relevant Chief of Medicine (or nominated deputy)
- Senior pharmacist
- Senior medical representative, ideally with specialist knowledge of the condition, though this is not a requirement.

In some circumstances it may be appropriate for panel discussion and decision-making to be conducted remotely without the need to meet.

The roles of the panel members will differ in relation to their position.

- The Chief of Medicine will act as chair and will consider the view of the other panel members before seeking (typically) a consensual decision or (rarely) a majority decision on the request.
- The role of the senior medical representative is to inform the panel of his/her perspective of the case being considered and the proposed outcome monitoring and schedule.
- The senior pharmacist will facilitate with interpretation of the clinical evidence and ensure alignment with process

10. Nature of evidence

This case should focus on the clinical evidence, including drawing on any experience in clinical practice. The prescribing clinician should also set out proposals for monitoring of clinical outcomes and how these will be able to be shared with the individual patient and the panel including frequency of reporting

11. timescale for decision

Timescales for the decision-making process will be established in accordance with the patient's clinical needs and by communicated to the patient by the clinician responsible for the patient's care, following

discussion with those involved in dealing with the request. Upon receipt of a request for use of an ultra-orphan medicine, in establishing a PACS Approval Panel, due consideration should be given to the urgency of the request given the patient's clinical condition. A date should be set to review the request and the requesting clinician advised so that they can advise the patient accordingly. The aim is for the timescale between the receipt of the PACS request and a decision not to exceed 20 working days.

12. Documentation and communication of decision

The decision of the PACS Approval Panel will be recorded in full by the chair of the panel in the relevant section of the designed PACS request form. Should further revision of the proposal be required (such as amendment of the outcome reporting plan, or further information/evidence from the supporting peer), this should be clearly documented, along with further guidance on timescales for reconsideration.

The chair of the PACS Approval Panel will then inform the requesting clinician of the decision in writing by providing a copy of the fully completed designated PACS form.

13. Revision of original proposal

If, following the initial review by the PACS panel, further information is required prior to approval, then the requesting clinician will be responsible for taking forward any required action. Amendments or further information can be made to the PACS form before resubmitting to the chair of the PACS Panel.

14. Communication with the patient

The patient (or carer) is supported and guided through PACS primarily by his/her consultant, who will outline the principles of the PACS process and basis for the case, including agreement around monitoring and reporting outcomes. The consultant will also support the patient by answering any specific questions they may have, seeking support from elsewhere if required and inform the patient of progress and eventual decisions relating to the request.

15. Outcome reporting to PACS panel

As part of the approval process, the requesting clinician will be expected to provide agreed updates on outcome monitoring to the chair of the PACS panel as outlined in the approved request form.

A specific PACS Reporting Form has been developed to allow subsequent outcome reporting. This document should be retained by the requesting consultant, with copies provided to the PACS panel as agreed.