





NHS Grampian, NHS Orkney and NHS Shetland staff policy for requesting non-formulary licensed medicines for licensed indications (including Peer Approved Clinical System (PACS) Tier One and Tier Two).

Co-ordinators: Kim Cruttenden Principal Pharmacist (Clinical), ARI	Consultation Group:	Approver: Grampian Medicines Management Group
--	----------------------------	--


Signature: 		Signature: 
--	--	---

Identifier: NHSG/Policy/NonForm_Lic/ MGPG988	Review Date: October 2021	Date Approved: October 2018
---	-------------------------------------	---------------------------------------

Uncontrolled when printed
Version 1

Executive Sign-Off

This document has been endorsed by the Directors of Pharmacy for NHS Grampian, NHS Orkney and NHS Shetland

Signature: 

Title: NHS Grampian, NHS Orkney and NHS Shetland staff policy for requesting non-formulary licensed medicines for licensed indications (including Peer Approved Clinical System (PACS) Tier One and Tier Two).

Unique Identifier: NHSG/Policy/NonForm_Lic/MGPG988

Replaces: The PACS Tier Two process will replace the Individual Patient Treatment Requests (IPTR) process. Information included in this policy regarding PACS Tier Two replaces all previous guidance on IPTRs contained in MGPG509.

Across NHS Boards	Organisation Wide	Directorate	Clinical Service	Sub Department Area
Yes				

This controlled document shall not be copied in part or whole without the express permission of the author or the author's representative.

Lead Author/Co-ordinator: (as per front cover)

Subject (as per document registration categories): Prescribing Policy

Key word(s): Policy, Peer Approved Clinical System, PACS, non-formulary, licensed medicine, IPTR

Process Document: Policy

Document application: NHS Grampian, NHS Orkney and NHS Shetland

Purpose/description: To set out the policy and good practice for staff dealing with requests to prescribe non-formulary licensed medicines for licensed indications.

Organisational: Chief Executive and Management Teams
Corporate: Senior Managers
Departmental: Heads of Service/Clinical Leads
Area: Line Managers
Hospital/Interface services: Assistant General Managers and Group Clinical Directors
Operational Management Unit: Unit Operational Managers

Policy statement: It is the responsibility of all staff to ensure that they are working to the most up to date and relevant policies, protocols procedures.

Review: This policy will be reviewed in three years or sooner if current treatment recommendations change

This document is also available in large print and other formats and languages, upon request. Please call NHS Grampian Corporate Communications on (01224) 551116 or (01224) 552245.

Responsibilities for review of this document: Principal Pharmacist (Clinical), Aberdeen Royal Infirmary (ARI)

Responsibilities for ensuring registration of this document on the NHS Grampian Information/Document Silo: Principal Pharmacist (Clinical), ARI

Physical location of the original of this document: Pharmacy Office, Aberdeen Royal Infirmary

Job/group title of those who have control over this document: Grampian Medicines Management Group

Responsibilities for disseminating document as per distribution list: Principal Pharmacist (Clinical), ARI

Revision History:

Revision Date	Previous Revision Date	Summary of Changes (Descriptive summary of the changes made)	Changes Marked* (Identify page numbers and section heading)
October 2018		The PACS Tier Two process will replace the IPTR process. The information included in this policy regarding PACS Tier Two replaces all previous guidance on IPTRs contained in MGPG509.	

* Changes marked should detail the section(s) of the document that have been amended i.e. page number and section heading.

Contents

1	Introduction.....	3
1.1	Objectives	4
1.2	Scope.....	4
1.3	Clinical situations	5
1.4	Patient groups to which this document applies	5
1.5	Situations to which this document does not apply.....	5
1.6	Submission process.....	5
1.7	Patient Involvement.....	9
1.8	Decision making process	9
1.9	Panel membership and process.....	10
1.10	Process for patients from NHS Grampian, NHS Orkney and NHS Shetland referred to another board	12
1.11	Process for patients from other boards referred to NHS Grampian, NHS Orkney and NHS Shetland	12
2	Process of national review in PACS Tier Two	12
2.1	Introduction	12
2.2	Applications to the NRP	13
2.3	Outcome of the review process.....	14
2.4	Final decision	15
3	Process of appeal excluding PACS Tier Two	15
3.1	Appeals for PACS Tier One and SMC non-submission medicines	15
3.2	Grounds for appeal	15
3.3	Appeals process.....	15
3.4	Appeal panel membership	16
3.5	Requesting clinician representation	16
3.6	Reporting	16
4	Maintaining accurate records and data capture.....	16
4.1	Maintaining accurate records	16
4.2	Data capture	16
5	References	17
6	Glossary	17
7	Distribution list	17
	Annex A: Non-formulary medicines request process	18
	Annex B: Peer Approved Clinical System (PACS) Tier One.....	19
	PACS Tier One request form and decision record	19
	Part A: PACS Tier One ultra-orphan medicines request details	20
	Part B: PACS Tier One ultra-orphan medicines case for prescribing	23

Part C: PACS Tier One peer review	24
Part D: PACS Tier One ultra-orphan decision record	25
Appendix 1: PACS Tier One outcome report form.....	27
Annex C: Peer Approved Clinical System (PACS) Tier Two.....	30
PACS Tier Two request form and decision record	30
Part A: PACS Tier Two request details.....	31
Part B: PACS Tier Two case for prescribing.....	33
Part C: PACS Tier Two peer review	36
Part D: PACS Tier Two decision record	37
Appendix 1: Application to National Review Panel	39
Appendix 2: National Review Panel advice	40
Annex D: Patient information letter for PACS Tier Two process	41
Annex E: SMC non-submission	43
SMC non-submission medicine request form and decision record.....	43
Part A: Request details (SMC non-submission requests).....	44
Part B: Case for prescribing (SMC non-submission requests)	46
Part C: Peer review (SMC non-submission requests)	50
Part D: Decision record (SMC non-submission requests)	51
Annex F: Decision making framework - PACS Tier Two.....	53
Annex G: Decision making framework - SMC non-submission requests	55



NHS Grampian, NHS Orkney and NHS Shetland staff policy for requesting non-formulary licensed medicines for licensed indications (including Peer Approved Clinical System (PACS) Tier One and Tier Two).

1 Introduction

It is NHS Scotland policy that medicines not recommended by the Scottish Medicine Consortium (SMC), including those not recommended due to a non-submission, should not routinely be made available by NHS Boards. However, Boards are required to have published policies in place to articulate their arrangements for consideration of requests for individual patient treatment with such medicines.

In October 2013 the Scottish Government announced that the previous framework of Individual Patient Treatment Requests (IPTR) outlined in CEL 17 (2010) was to be replaced by a Peer Approved Clinical System (PACS).

This policy sets out the principles and processes for handling requests in NHS Grampian, NHS Orkney and NHS Shetland (NHS G, O and S) to seek access to licensed medicines used to treat conditions that are not recommended for use in NHS Scotland following appraisal by the SMC.

This policy also describes how requests to use a licensed medicine for a licensed indication which has NOT been submitted to SMC for review will be managed locally. It should be noted that these non-submitted medicines fall outside of the national PACS guidance, i.e. PACS criteria, review arrangements and Scottish Government reporting requirements do not apply.

Requests for unlicensed medicines or medicines used in an 'off-label' way (i.e. outside of marketing authorisation) are not covered by this policy. Refer to unlicensed/off-label medicines policy.

PACS applies in the following circumstances

A request for a licensed medicine used for a licensed indication which has been:

1. considered by SMC and not recommended for use in NHS Scotland; or
2. accepted for restricted use by SMC but the intended use is outside of the SMC restrictions; or
3. submitted to and awaiting/undergoing evaluation by SMC.

N.B. All of the above require a full company submission to have been made to SMC for appraisal.

There are two parts to PACS:

- 1. PACS Tier One – applies to individual requests for ultra-orphan medicines for licensed use in the circumstances described earlier in this policy. Ultra-orphan medicine - defined as a medicine used to treat a condition with a prevalence of 1 in 50,000 or less, or a maximum of 100 people in Scotland.**
- 2. PACS Tier Two – applies to individual requests for medicines other than ultra-orphan in the circumstances described earlier in this policy.**

Guidance on the PACS Tier Two process was issued to NHS Boards on 29 March 2018. The framework is designed to enhance the consistency of approach across all NHS Boards in Scotland in relation to PACS Tier Two requests for individual patients. As part of this drive for consistency a national review process has been put in place which may be instigated by the referring clinician to enable a review of a decision to decline access to a treatment under PACS Tier Two on the basis of failure to observe due process or unreasonableness of the decision outcome.

A summary flow diagram for the non-formulary medicine request process is provided in [Annex A](#).

1.1 Objectives

The purpose of this policy is to:

- Set out the processes for handling PACS Tier One and Tier Two requests.
- Set out the processes for handling requests for medicines which have not been submitted to SMC for review.
- Ensure that process adheres to relevant legislation and national guidance.
- Ensure that public and patients have adequate provision of information.
- Set out suggested evidence on which decisions should be made.
- Ensure that panels are representative and contain relevant expertise as required.
- Specify referral criteria for requests and for national review.
- Ensure timely and appropriate communication of decisions.
- Ensure adequate record keeping and data capture and sharing with Scottish Government.

1.2 Scope

The PACS process will relate to NHS patients under the care of an NHS G, O and S clinician.

A PACS application may be made when:

- The SMC or Healthcare Improvement Scotland (HIS) have issued not recommended advice for the medicine, or

- The request relates to use of the medicine outside of an SMC restriction, for example the patient or their clinical condition does not meet the specified inclusion criteria, or
- In the immediate post marketing authorisation period, when a submission is being actively considered by SMC but before SMC advice is available. The policy position across Scotland is that the medicine should not be prescribed. However there is acceptance that clinical urgency may dictate otherwise, and so where clinical urgency can be demonstrated the PACS process may be applied.

This policy also describes the processes to be followed for a licensed medicine requested for a licensed indication which was not submitted to SMC for review.

1.3 Clinical situations

This policy applies to all patients under the care of NHS G, O and S whether within the acute service or in the primary care setting.

1.4 Patient groups to which this document applies

This policy applies to all patients under the care of NHS G, O and S who require an individual treatment covered by Section 1.2.

1.5 Situations to which this document does not apply

This policy does not apply to groups of patients who require treatment with the same medicine for the same indication. The NHS G, O and S formulary application processes should be followed where a treatment request is for a group of patients. There may be situations where clinical urgency dictates that this policy should be used for an individual/individuals from a group of patients if requests cannot wait for formulary process. The decision on this will be made by the relevant Principal/Lead Pharmacist and requesting clinician.

1.6 Submission process

There is standardised NHS Scotland paperwork for the PACS processes, [Annex B](#) – Tier One (ultra-orphan) requests and [Annex C](#) – Tier Two requests. For SMC non-submissions see [Annex E](#).

The requesting clinician should submit the completed request form to the Principal Pharmacist (Clinical) NHS Grampian, or the Principal Pharmacist for NHS Orkney or NHS Shetland, or a nominated deputy. For the vast majority of cases requests will be initiated by a specialist clinician within secondary care.

There may be rare instances where a General Practitioner wishes to initiate a request. It is important in these situations that the medicine requested is one that is suitable for initiation and maintenance in primary care by a General Practitioner. General Practitioners are advised to discuss any potential application with secondary care specialist colleagues who may be better placed to make an

application. If the request originates in the primary care setting then the same form should be completed and submitted to the Health and Social Care Partnership (HSCP) Lead Pharmacist for (Aberdeen City, Aberdeenshire or Moray) or a nominated deputy, in the island boards these should be submitted to the Principal Pharmacist. Peer review of a request from a General Practitioner must be sought from a suitable secondary care specialist clinician for all applications.

The requesting clinician will be responsible for outlining any time limiting factors the panel should be aware of in their case report documentation. Such factors would include clinical urgency or time limited window of clinical opportunity. A preliminary examination of the request will take place to ensure that consideration is given to the urgency of the request.

1.6.1 Responsibilities of the requesting clinician PACS Tier One requests

This process is used only to request access to a licensed medicine for a licensed indication that has been designated ultra-orphan by the SMC and is:

- not recommended for use in NHS Scotland by the SMC on the basis of a full submission by a pharmaceutical company; or
- outside of SMC restrictions recommended in the SMC advice statement; or
- for a medicine which is being actively considered by the SMC; i.e. a company submission has been made but no decision has been released.

See [Annex B](#) for the request form and guidance on PACS Tier One requests.

The requesting clinician should complete 'Part A' and 'Part B'.

'Part C: Peer review' should be completed prior to submitting the form and it is the responsibility of the requesting clinician to ensure that this is done (see section 1.6.4).

1.6.2 Responsibilities of the requesting clinician PACS Tier Two requests

The responsibility for initiating a request through PACS Tier Two rests with the requesting clinician who must actively support prescribing the requested medicine for the patient under their care.

The requesting clinician is required to demonstrate the clinical case for the patient to be prescribed the medicine within its licensed indication(s) where the following criteria apply:

1. The clinician can demonstrate that a reasonable attempt, or appropriate consideration, has been made to treat the patient in the first instance with medicines currently accepted by the SMC for routine use in NHS Scotland for this condition and for the patient in question that these medicines are deemed unsuitable or have been found to be ineffective.

And

2. The clinician can present an evidence-based case to demonstrate the potential that the patient will achieve a measurable clinical benefit at least

comparable to if not better than that experienced by the population considered by the SMC.

It is the responsibility of the requesting clinician to provide an evidence-based case detailing all the relevant information on the reasons why their patient would receive measurable clinical benefit from the requested medicine that is at least comparable to, if not exceeding, that which is normally expected of that medicine compared to the population considered by SMC. This includes explaining why an SMC accepted medicine would not be suitable.

Factors submitted from clinicians to evidence both criteria may include:

- An increased capacity to benefit.
 - An overriding clinical need.
 - Features which suggest a higher likelihood to benefit from treatment.
 - Expected survival rates.
 - Intolerable side effects from conventional treatment.
 - Ineligibility for a clinical trial.
 - The balance between benefit and risk (from adverse effects or contraindications).
 - Specific genetic sub-types where clinical evidence is stronger.
 - Individual characteristics are present which have been shown to have a positive influence on response.
- (This list is not exhaustive).

1.6.3 Responsibilities of the requesting clinician SMC non-submission medicine requests

The responsibility for a request rests with the requesting clinician who must support prescribing the requested medicine. The requesting clinician is required to demonstrate the clinical case for the patient to be prescribed the medicine within its licensed indication(s) where the following criteria apply:

1. The clinician can demonstrate that a reasonable attempt, or appropriate consideration, has been made to treat the patient in the first instance with medicines currently accepted by the SMC for routine use in NHS Scotland for this condition, and for the patient in question, that these medicines are deemed unsuitable or have been found to be ineffective.

And

2. The clinician can present an evidence-based case to demonstrate the potential that the patient will achieve significant clinical benefit from the requested treatment.

And

3. The clinician can demonstrate that awaiting SMC advice would lead to the patient missing an opportunity for cure, long-term remission (5 years), a significant extension of life or avoidance of permanent disability. This could include situations where the medicine requested is a bridging treatment to other treatments which would provide the benefits above or where

alternative medicine choice would be associated with significant, permanent patient harm and the risk of that harm is high enough to preclude the alternative medicine as a treatment option.

It is the responsibility of the requesting clinician to provide an evidence-based case detailing all the relevant information as to why their request meets the criteria above and why their patient would receive significant clinical benefit from the requested medicine and the measurable nature of that significant clinical benefit.

Factors submitted from clinicians to evidence both criteria may include:

- An increased capacity to benefit.
 - An overriding clinical need.
 - Features which suggest a higher likelihood to benefit from treatment.
 - Expected survival rates.
 - Intolerable side effects from conventional treatment.
 - Ineligibility for a clinical trial.
 - The balance between benefit and risk (from adverse effects or contraindications).
 - Specific genetic sub-types where clinical evidence is stronger.
 - Individual characteristics are present which have been shown to have a positive influence on response.
- (This list is not exhaustive).

1.6.4 Peer/Multidisciplinary Team (MDT) Support

Clinicians must seek peer support for their application from other clinicians for all applications made under the processes described in this document. Part C of the request forms should be completed by another clinician with suitable experience in treating the condition for which the medicine is being requested. The reviewing clinician may be from the same NHS Board, but if there are no other clinicians with suitable expertise locally, then experts within the NHS from elsewhere in Scotland or the UK can provide the peer review.

The reviewing clinician should consider whether:

- a) Any alternative accepted medicines have been considered and excluded as suitable treatment options;

And

- b) The patient characteristics detailed and the clinical evidence presented imply that the response to treatment will be at least comparable to, if not increased, compared to the population considered by the SMC (only relevant if SMC have completed a review).

Multidisciplinary Team (MDT) – where the patient is under the care of a MDT, clinicians must take the opportunity to discuss and gain the support of the team for the medicine requests and indicate their support in Part A of the paperwork.

1.7 Patient Involvement

Patient (or patient representative) involvement is through discussion with the clinician submitting the request for the medicine, the clinician will represent the patient's interests. This clinician will also act as the patient's contact for advice and support around the process.

When an application is under consideration for PACS Tier Two, the clinician requesting treatment will provide the patient or their representative with the leaflet 'Information about your doctor's treatment request' ([Annex D](#)).

The requesting clinician will present the case to the decision panel for the medicine using the standardised national paperwork ([Annex B](#), [Annex C](#)) for PACS and the local paperwork for SMC non-submissions ([Annex E](#)). In doing so, the clinician will have ensured that the patient understands the application which is being submitted on their behalf and that the patient has consented to its submission.

In line with Scottish Government guidance the patient is NOT permitted to be present when the panel meet. In addition verbal or written statements by patients should not be submitted to the panel.

Where appropriate, the clinician should provide the contact details of suitably trained personnel within NHS G, O and S who can provide further advice and support to the patient/patient representative, including any other patient information and support mechanisms available.

Appropriate language or communication support should be provided for patients, if required.

1.8 Decision making process

The responsibility to demonstrate the evidence-based case for the individual patient lies with the requesting clinician. The clinician will present the case to the panel for the medicine on behalf of the patient via the request forms ([Annex B](#) – Tier One, [Annex C](#) – Tier Two, [Annex E](#) – SMC non-submission).

PACS Tier Two - the requesting clinician will provide an evidence-based case detailing all the relevant information on the reasons why their patient would receive measurable clinical benefit from the requested medicine that is at least comparable to, if not exceeding, that which is normally expected of that medicine compared to the population considered by the SMC (if applicable). This includes explaining why an SMC accepted medicine would not be suitable as described in section 1.6.2.

Non-submissions to SMC - the requesting clinician will provide evidence as to why/how the clinical circumstances of their patient meet the criteria laid out in section 1.6.3.

The decision making panel will consider a range of information/tools including, but not limited to:

- SMC advice (if available).
- Any new evidence that has emerged since an SMC decision.
- The decision making framework (Annex F/G).
- The PACS request case report from the requesting clinician which details the evidence base for the request (Parts A - C of the paperwork) where appropriate.
- The SMC non-submission request form where appropriate.

Appropriate evidence can include published peer reviews evidence, new emerging evidence still to be published and expert opinion.

Equity of access across other parts of the UK is not one of the decision making criteria. However both the requesting clinician and the panel should consider whether availability elsewhere in the UK is driven by new evidence that has emerged since an SMC decision was published which is of relevance to the individual patient.

The decision making framework (Annex F/G) should be followed and provides structure to the meeting and forms part of the meeting note.

If the panel agrees the decision making criteria have been met and that prescribing the medicine is considered of benefit to both the patient and to the wider NHS then the request should be approved.

If the panel feels the decision making criteria have not been met and/or the medicine is not considered of benefit to the patient and to the wider NHS then the request should not be approved and the clinician should be informed of the rationale for this decision, for onward communication to the patient.

The acquisition (purchase) cost of the medicine will not be part of the decision making process.

1.9 Panel membership and process

1.9.1 Panel membership

Core membership will be multi professional and may include:

- Divisional Clinical Director or Associate Medical Director.
- Unit Clinical Director.
- Clinical Specialist.
- Senior pharmacist – team leader or highly specialised.
- General Manager/ Service manager.

In order to make a decision the panel must have a minimum of four members and should be medical clinician led. As a minimum the panel should contain two senior medical clinicians and a senior pharmacist. Panels held in the

islands will be rare and in the island Boards the panel is likely to consist of a medical clinician, a senior pharmacist and two other members.

Panel members must be aware of their responsibilities in relation to any conflicts of interest which could potentially impact on their impartiality in decision making. Conflicts of interest will be declared and recorded at the panel meeting.

1.9.2 Panel Process

- Following receipt of the request and assessment of urgency the Principal or Lead Pharmacist will arrange a panel within a suitable timeframe (within a maximum of 20 working days).
- The panel will normally meet in person to discuss the request and the requesting clinician should attend this meeting. If the requesting clinician is not available then they should arrange a suitable deputy or agreement should be made with the Principal/Lead Pharmacist that the meeting can be held in their absence.
- The panel will review all of the evidence in the request and anything added verbally during the meeting (by the requestor). The requestor should not bring additional written information to the meeting as this should have been submitted in advance for the panel to review. The panel will use the decision making framework (Annex F/G) to structure the meeting and discussion and to form a record of the meeting.

1.9.3 Communicating decisions

- On reaching a decision the record of the PACS Tier One, Tier Two or SMC non-submission decision (Part D) should be emailed to the requesting clinician on the original electronic application within 5 working days, or within the same day if possible if it is an urgent request. This will be done by the Principal/Lead Pharmacist. The record should include the rationale for the decision, including where possible a detailed breakdown of the panel's assessment of the application against the decision making framework and should be as comprehensive as possible to aid understanding of the decision.
- Decisions should be communicated to the patient/patient's representative by the requesting clinician responsible for their care within a timescale and method previously agreed with the patient/patient's representative.
- The requesting clinician should discuss the outcome of the request in detail, and clarify the options open to the patient for future treatment. Where the clinician is of the view that decision making has failed to follow due process and this situation cannot be resolved locally or where they believe there is a case to be made that the decision reached is unreasonable in light of the evidence submitted, the clinician can make an application for review. Request for review of a PACS Tier Two decision is via the National Review Panel (NRP) refer to Section 2. Request for review of a Tier One or SMC non-submission decision is via local appeal process, refer to Section 3.

- In addition if the patient is not satisfied with the way the PACS process was handled, they can progress their concerns via the NHS complaints process. The complaints process is separate to the NRP.

1.10 Process for patients from NHS Grampian, NHS Orkney and NHS Shetland referred to another board

NHS G, O and S may request the involvement of another board in a patient's care; the request can be for advice, or treatment, or both. When a patient has been referred by NHS G, O and S to another (host) board the relevant processes align with the clinician taking responsibility for the prescribing.

The following principles apply:

- Where the referral is for advice alone, then NHS G, O and S retains responsibility for the patient's treatment.
- Where the referral to another (host) board is for that board to undertake treatment then the processes of the host board apply – including their PACS process should their clinician seek to request a non-approved medicine. NHS G, O and S would request representation on the host board panel. Suggested representation – referring clinician and/or specialist pharmacist.

1.11 Process for patients from other boards referred to NHS Grampian, NHS Orkney and NHS Shetland

Where the referral was for advice alone then the referring board retain the responsibility for the patient's treatment.

Where the referral is for NHS G, O and S to undertake treatment then the processes of NHS G, O and S apply. In this case representation from the referring board should be invited on to the panel. Suggested representation – referring clinician and/or specialist pharmacist.

2 Process of national review in PACS Tier Two

2.1 Introduction

In the event where an agreement on a PACS Tier Two decision cannot be made locally, a National Review Panel (NRP) has been established to independently look at the original decision made by the relevant NHS Board and to consider whether due process had been correctly followed and/or that the decision reached was reasonable on the basis of the evidence presented, to provide consistency for patients across Scotland. This replaces each NHS Board's local appeal process.

NRPs will be convened on a monthly basis. Meetings will be held electronically (WebEx/video and teleconferencing) to support the rapid turnaround of applications. However, ad-hoc meetings of the NRP will be convened when the clinical urgency of the case dictates that this is necessary.

The NRP is a function within HIS that will facilitate support for the Panel. HIS will be responsible for its governance and will provide all the necessary support to the panel. HIS personnel will not be part of the review process.

It is the responsibility of the requesting clinician, with the patient's consent, to submit an application to the NRP by completing Appendix 1 of the PACS Tier Two paperwork submitted to the Board's PACS Tier Two panel. The requesting clinician should provide a robust case for the review, including any substantiation of procedural impropriety and/or that the decision could not have been made reasonably on the basis of the evidence presented. In the event that the clinician is requesting a review because NHS G, O or S failed to follow due process then the clinician should also send the Board's PACS Tier Two process guidance (this document). Any paperwork that is incomplete or has been incorrectly completed will be returned to the requesting clinician and will not be considered by the NRP.

Summary of evidence to be sent to a NRP:

1. The original request submitted to NHS G, O and S PACS Tier Two panel (Parts A - D of the paperwork).
2. Appendix 1 completed by the requesting clinician detailing the case for procedural impropriety or that the decision could not have been made reasonably on the basis of the evidence presented.
3. A copy of the decision making framework used during the NHS G, O and S Tier Two panel discussion ([Annex F](#)).
4. A copy of this policy.

Both the NHS Board and the requesting clinician will be invited to attend and present at the NRP.

2.2 Applications to the NRP

An application to the NRP must be made by the requesting clinician, through a secure NHS Scotland email address. The clinician should also redact information relating to personal information in advance of it being submitted to the NRP (via HIS), in line with data protection requirements. The information which should always be redacted should be as follows:

Part A: Request Details

- Patient's CHI No
- Patient postcode

Part B: Case for Prescribing

- Any person identifiable references to the patient

Part C: Peer Support

- Any personal identifiable references to the patient

Part D: PACS Tier Two Decision record

- Any named references to the patient

HIS will notify the Chief Executive in the relevant NHS Board that a review request has been made.

The review process will accommodate reviews on either of the following grounds:

- The NHS Board had failed to follow due process and the situation cannot be resolved locally **and/or**
- The NHS Board has reached a decision which could be deemed unreasonable in light of the evidence submitted.

A review request will not be accepted solely because the patient or the clinician does not agree with the views or conclusions reached by the local PACS Tier Two panel.

Where a review is requested because a clinician considers that the conclusion reached by the NHS G, O or S PACS Tier Two Panel was not reasonable on the basis of the evidence presented, it will be for the clinician requesting the national review to provide justification for this in their application. The NRP would review the original NHS G, O or S Tier Two decision on this basis. Where a review is requested because the clinician considers that the NHS Board has failed to follow due process then the NRP will only accommodate a review in the event where this cannot be resolved locally.

Where new evidence for the medicine emerges or if the original decision was based on a factual inaccuracy, the application should **not** be referred to the NRP but the clinician should pursue a resubmission through the NHS G, O and S PACS Tier Two process following this guidance.

N.B. No new evidence will be considered by the NRP.

The NRP will use the same decision making framework as the NHS G, O and S Panel which is laid out in this guidance and is used across NHS Boards in Scotland.

2.3 Outcome of the review process

The purpose of the review is to consider the reasonableness of a local PACS Tier Two Panel's decision and/or whether due process has been followed. As regards reasonableness this is in the context of whether the decision in question would be deemed reasonable on the basis of the evidence presented. The review process will therefore establish if the grounds for review are or are not established.

The NRP will either make a finding:

1. That a decision, with reference to the information and/or evidence on which that decision is based, is or is not reasonable; or
2. On whether or not due process has or has not been followed.

In the event that the review panel makes a finding that the grounds for review are not established then NHS G, O and S will not be expected to revisit the original decision.

If the grounds of the review are established then the case will be redirected back to NHS G, O or S who will be expected to convene a new PACS Tier Two panel in order to revisit their original decision, taking into account the NRP reasoning as to why it considered either the original decision was unreasonable in light of the evidence submitted and/or that due process had not been followed.

The NRP will issue its findings and recommendations, using [Annex B, Appendix 2](#) of the paperwork, to the NHS G, O or S Board Chief Executive, Medical Director and Director of Pharmacy, ideally within one working day of the panel meeting. NHS G, O or S must inform the requesting clinician, as soon as practicable taking into consideration any clinical urgency, of the NRP's decision and recommendations. It will be the responsibility of the Medical Director to inform the clinician of the findings and recommendations.

2.4 Final decision

The final decision is for NHS G, O and S to determine. NHS G, O and S should convene a new PACS Tier Two Panel to consider the request and ensure that the final PACS Tier Two decision is communicated within a timescale that takes into account any associated clinical urgency and/or the patient's clinical needs.

It is the responsibility of the requesting clinician to inform the patient of the final decision and there will be no further right to appeal.

3 Process of appeal excluding PACS Tier Two

3.1 Appeals for PACS Tier One and SMC non-submission medicines

Appeals will only be accepted via this route for:

- PACS Tier One Requests.
- Requests for a licensed medicine for a licensed indication which has not been reviewed by the SMC.

3.2 Grounds for appeal

- Assertion or evidence relating to the improper application of the decision making process, i.e. procedural impropriety; and/or
- Where the decision was reached which cannot be justified in light of the evidence submitted.

3.3 Appeals process

- Requesting clinicians wishing to appeal should write to the Chief Executive of NHS G, O or S Board identifying the grounds of their appeal.

- Appeals should be made within three calendar months of the original panel decision being communicated to patients/requesting clinicians.
- Appeals will normally be heard within 20 working days depending on the availability of panel members, representatives and any reports/information being received.

3.4 Appeal panel membership

The panel membership should not include individuals previously involved in the decision making panel.

The panel should include the following post holders or representatives:

- Non-executive Board Member (Chair of the appeal group)
- Chair, Area Clinical Forum or their designated deputy.
- Senior Clinical Manager – Medical or Nursing Director.
- Director of Pharmacy and Medicines Management.
- Lay representative.

3.5 Requesting clinician representation

The requesting clinician will be offered the opportunity to make representation to the appeal group, in person or in writing, regarding the grounds of their appeal.

3.6 Reporting

A report of the appeal panel will be made to the Chief Executive of NHS G, O or S, and will be made available to the requesting clinician and patient within 5 working days. It is the responsibility of the Chair of the appeal panel to ensure that the appropriate Principal/Lead Pharmacist obtains a copy of the report to ensure a record is held by pharmacy.

4 Maintaining accurate records and data capture

4.1 Maintaining accurate records

NHS G, O and S will maintain accurate and up to date information on PACS requests (Tier One and Tier Two) and requests for SMC non-submission medicines, and their outcomes. It will be the responsibility of the appropriate Principal/Lead Pharmacist to keep these records.

4.2 Data capture

NHS G, O and S will capture and share data as retrospective summary management reports (in confidence and in line with General Data Protection Regulation principles) with the Scottish Government as part of the PACS Tier Two process on a quarterly basis.

5 References

Guidance on the implementation of the PEER Approved Clinical System (PACS) Tier Two; Scottish Government 29th of March 2018 and 5th of November 2017.

Scottish Medicines Consortium:

<https://www.scottishmedicines.org.uk/Home>

http://www.scottishmedicines.org.uk/About_SMC/Policy_statements/Orphan_Drugs

6 Glossary

IPTR – Individual Patient Treatment Request.

PACS – Peer Approved Clinical System.

GJF – Grampian (Orkney and Shetland) Joint Formulary.

Licensed medicine – a medicine with a marketing authorisation (product licence) by a medicines regulator. In the UK this is the MHRA (Medicines and Healthcare products Regulatory Agency) and in some cases the EMA (European Medicines Agency).

NRP – National Review Panel.

SMC – Scottish Medicines Consortium.

Orphan Medicine – medicine used to treat a condition with a prevalence of 5 in 10,000 or less.

Ultra Orphan medicine – medicine used to treat a condition with a prevalence of 1 in 50,000 or less.

Requesting clinician – the clinician who initiates the PACS process who will be the hospital consultant or other expert with overall responsibility for the request.

Formulary medicine – A medicine approved by the NHS G (O and S) Formulary Group for inclusion in the Grampian (Orkney and Shetland) Joint Formulary. New medicines for inclusion are considered based on SMC recommendations and requests from clinicians, or for older medicines on the basis of local clinician requests.

7 Distribution list

NHS Grampian:

Organisational: Senior leadership team

Corporate: Grampian Medicines Management Group

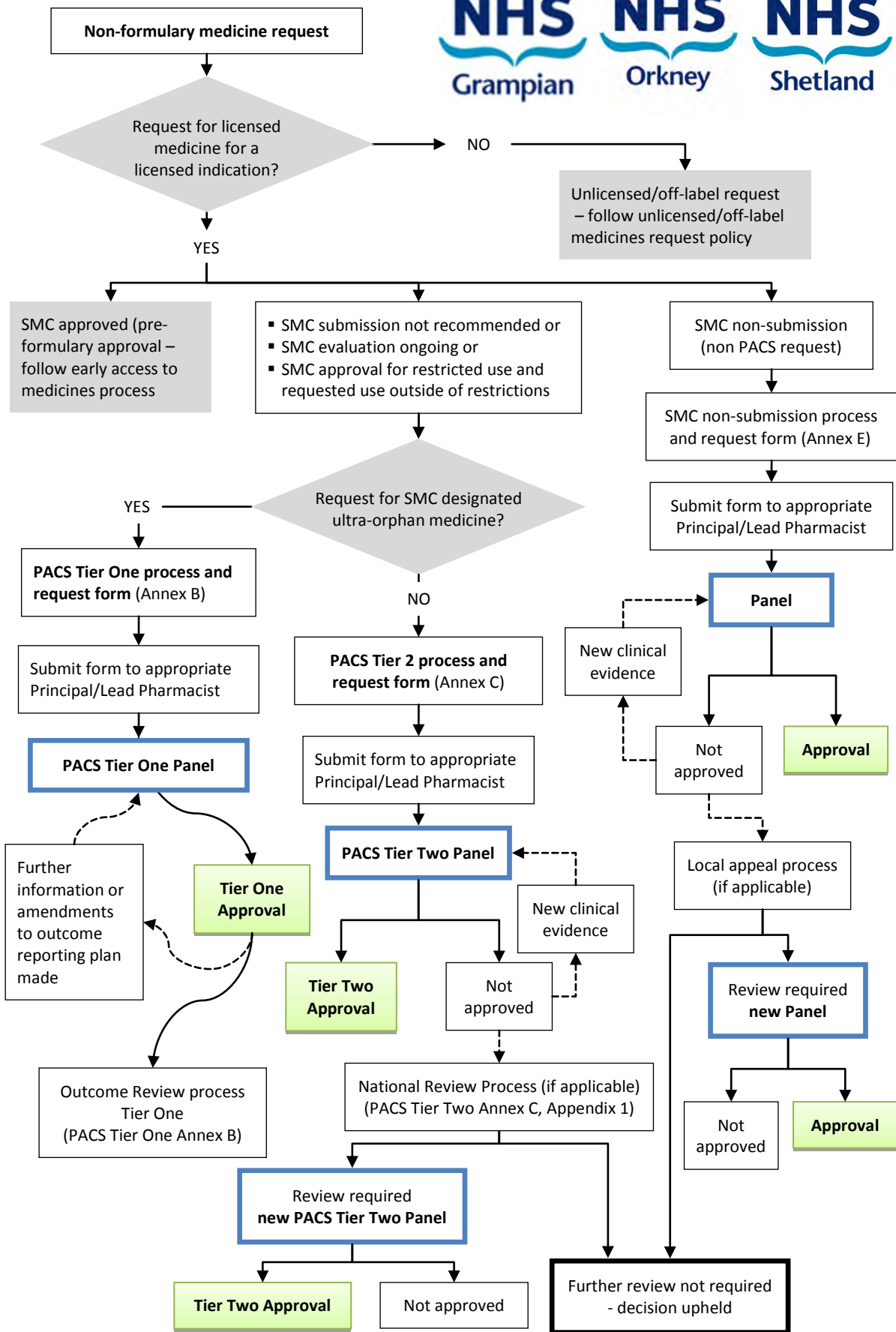
Divisional: Divisional general managers, Unit Operational managers

Departmental: clinical service leads, consultant physicians and surgeons, General Practitioners, Clinical pharmacists (Acute service), Health and Social Care Pharmacists.

NHS Orkney and NHS Shetland:

Executive Management Team, Consultant Physicians and Surgeons, General Practitioners, Clinical Pharmacists (acute service), Health and Social Care Pharmacists.

Annex A: Non-formulary medicines request process



Annex B: Peer Approved Clinical System (PACS) Tier One

PACS Tier One request form and decision record

Please note: This form is only to be used to request access to a medicine which is considered **ultra-orphan** and also fits one of the following:

- is a licensed medicine and indication that has been considered and not recommended for use in NHS Scotland by the Scottish Medicines Consortium (SMC); or
- use of a licensed medicine outwith SMC restrictions; or
- use of a licensed medicine which is awaiting evaluation by the SMC.

Notes for electronic completion:

This document can be completed by adding text to the grey text fields and by checking the tick boxes or selecting from drop-down boxes where applicable. It should be completed, saved and submitted electronically. Paper copies will not be accepted unless in exceptional circumstances.

The form is partitioned into 4 parts and 1 appendix:

- Parts A - B are required to be completed prior to submission to the PACS Tier One Panel.
- Part C is recommended to be completed prior to submission to the PACS Tier One Panel.
- Part D is to be completed by the PACS Tier One Panel only.
- Appendix 1 is required to be completed after a decision has been made and treatment has commenced.

Before submitting:

1. The requesting clinician completes parts A and B.
2. Part C is completed by another clinician who is experienced in treating the condition for which the medicine is being requested.
3. Part D is completed by the PACS Tier One Panel.
4. Appendix 1 is completed by the requesting clinician following the commencement of the medicine.

How to submit the request:

- For NHS Grampian Acute Service requests - forms should be submitted via email to the specialist [pharmacist](#) connected with the clinical area **and** to the Principal Pharmacist (clinical) (kimcruttenden@nhs.net).
- For NHS Grampian Primary Care requests –forms should be submitted via email to the appropriate health and social care partnership Lead Pharmacist for Aberdeen city nhsg.specialsaberdeen@nhs.net, Aberdeenshire nhsg.specialsaberdeenshire@nhs.net or Moray nhsg.specialsmoray@nhs.net
- For NHS Orkney - forms should be submitted to the Principal Pharmacist (wendylcett@nhs.net).
- For NHS Shetland - forms should be submitted to the Principal Pharmacist (mary.mcfarlane@nhs.net).

Immediately following a decision:

1. The Chair of the PACS Tier One panel should inform the requesting clinician of the decision by emailing a copy of Part D of the completed form, which includes the decision and rationale, as soon as possible (no later than 5 working days following decision being made and on the same day in an emergency case).
2. The Chair of the PACS Tier One panel should ensure that a copy of the completed PACS Tier One form and decision is emailed to the appropriate email contacts as above (in how to submit section).
3. The decision should be communicated to the patient/patient representative by the clinician responsible for their care within one working day.
4. The responsible clinician should discuss the outcome, clarify future treatment options with the patient/patient's representative.
5. The patient's clinician should file a copy of the PACS Tier One form and decision in the patient's case notes and retain a copy for future outcome reporting.

Part A: PACS Tier One ultra-orphan medicines request details

To be completed for **all** requests made by the requesting clinician

Patient's CHI Number:	<input type="text"/>	Patient Postcode:	<input type="text"/>
Health board conducting PACS Tier One: <i>(Please select from the drop-down list)</i>	<input type="text" value="NHS Grampian"/>		
Patient's health board (if different from above): <i>(Please select from the drop-down list)</i>	<input type="text" value="NHS Grampian"/>		
Hospital/site where treatment is to be delivered/initiated:	<input type="text"/>		
Requesting Clinician:	<input type="text"/>		
Position held:	<input type="text"/>		
Email address:	<input type="text"/>		
Telephone/ bleep:	<input type="text"/>		
Acute Services Division:	<input type="text"/>		
Medicine and formulation: <i>(Include strength and dosage, refrain from using abbreviations. Please also include the SMC ID where known)</i>	<input type="text"/>		
Intended indication: <i>(Also include any relevant positioning)</i>	<input type="text"/>		
Clinical urgency: <i>(Please select from the drop-down list)</i>	<input type="text" value="Select"/>		

Please give an explanation for your response regarding clinical urgency:

How does this request relate to the SMC status of this medicine:

(Is the medicine awaiting evaluation by the SMC, has it been not recommended or are you intending to use the medicine outside of the restrictions on use imposed by SMC advice? Please select from the drop-down list)

Select

Under which process(es) was medicine considered by SMC *(This is the status of the medicine according to the SMC classification. Tick all options which apply)*

Ultra-Orphan
 Other (Specify)

The patient understands the process:

(The clinician should explain the process to the patient (including the process for appeals) and ensure that the patient is content that the clinician will represent all of their clinical interests. Tools to support this may include using the national patient leaflet etc.)

Tick here to confirm

In accordance with the Code of Conduct of NHS Grampian, NHS Orkney and NHS Shetland you are required to declare **all interests** you have in the pharmaceutical company who market the medicine you are requesting on this form. It is possible that these may be checked against the national ABPI Interests database. Declared Interests do not directly impact on the process or decision, but are required to be noted to ensure transparency of process.

Declaration of interests:

(Please select from the drop-down list)

Select

- Personal interests may be payments/fees/resources etc. that you have received personally from the company
- Non-personal interests may include payments/fees/resources etc. that your department has received from the company
- Specific interests are those that relate directly to the medicine you are requesting
- Non-specific interests are those that relate to the company, but not directly to the medicine you are requesting

Details of any declared interests:

(Where applicable)

By ticking this box I confirm that I am the clinician named above in charge of the patient's care:

Date:

Part B: PACS Tier One ultra-orphan medicines case for prescribing

This part should only be completed for medicines considered under the ultra-orphan Framework by SMC that are not recommended for use in NHS Scotland by the SMC or where the intended use of the medicine is within the marketing authorisation of the medicine, but outwith restrictions on use imposed as part of the SMC acceptance.

The prescribing clinician should make the case for the prescribing of this medicine focussing on the measurable benefit that the medicine might deliver for the individual patient. 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. These would be expected to be shared with the individual patient and may be shared with others in NHS Scotland (including SMC) to inform future decision making.

Case Summary

Relevant medical history

Brief treatment history:

Overview of evidence base:

Personal experience of using the medicine:

What outcome(s) would you propose to measure to ascertain a response to treatment?

Detail the outcomes you would measure and how you would determine response (e.g. a response may be either an improvement in an outcome, or determined to be stabilisation)

Proposed review schedule to be reported to the PACS Panel:

This should detail the outcomes to be measured and reporting frequency to the approval panel.

Please consider stopping criteria and how these will be discussed with the patient.

Stopping criteria and how these will be discussed with the patient:

Any other information:

Part C: PACS Tier One peer review

- As part of best practice and in order to strengthen the case being made, the requesting clinician must seek peer review for their application from another NHS clinician with suitable experience in treating the condition for which the medicine is being requested. This clinician may be from within the same NHS board, but if there are no other clinicians with suitable expertise locally, then an expert within the NHS from elsewhere in Scotland or the UK can provide the peer review.
- In providing a peer review of the information presented for the patient, the reviewing clinician is considering that (a) any alternative accepted medicines have been considered and excluded as unsuitable treatment options and (b) the patient characteristics detailed and the clinical evidence presented imply that the response to treatment will be at least comparable, if not increased, compared to the population considered by SMC.

Name and position:

Health board/ Employing authority

NHS Grampian

Peer review statement:

The clinician should state his/her opinion relating to the request for this medicine for this condition, indicating whether they are supportive of the request and why.

In accordance with the Code of Conduct of NHS Grampian, NHS Orkney and NHS Shetland you are required to declare **all interests** you have in the pharmaceutical company who market the medicine you are requesting on this form. It is possible that these may be checked against the national ABPI Interests database. Declared Interests do not directly impact on the process or decision, but are required to be noted to ensure transparency of process.

Declaration of interests:

(Please select from the drop-down list)

select

- Personal interests may be payments/fees/resources etc. that you have received personally from the company
- Non-personal interests may include payments/fees/resources etc. that your department has received from the company
- Specific interests are those that relate directly to the medicine you are requesting
- Non-specific interests are those that relate to the company, but not directly to the medicine you are requesting

Details of any declared interests:

(Where applicable)

By ticking this box I confirm that I am the clinician named above:

Date:

Part D: PACS Tier One ultra-orphan decision record

PLEASE NOTE: TO BE COMPLETED BY THE PACS TIER ONE PANEL ONLY

PACS TIER ONE PANEL MEMBERSHIP:

In accordance with Code of Conduct of NHS Grampian, NHS Orkney and NHS Shetland each panel member is required to declare all interests they have in the pharmaceutical company who market the medicine you are requesting on this form.

	Name and position:	Declaration of interests:
Panel Chair (Typically a senior clinician)	<input type="text"/>	select
Panel member and position held:	<input type="text"/>	select
Panel member and position held:	<input type="text"/>	select
Panel member and position held:	<input type="text"/>	select
Panel member and position held:	<input type="text"/>	select

PACS TIER ONE PANEL DISCUSSION:

Date request received: **Date of discussion:**

How panel discussion was conducted:
(Please select from the drop-down list)

Select

Main discussion points of panel:
(Include how evidence and peer perspective were weighted)

DECISION OF REQUEST AND RATIONALE:

PACS TIER ONE PANEL DECISION:
(Please select from the drop-down list)

Select

Terms and conditions of acceptance (optional):
E.g. duration of treatment after which efficacy must be reviewed, monitoring

schedule or stopping criteria. Where applicable, these terms should be clearly conveyed to the patient prior to commencing treatment.

Rationale for submission not supported:

Where a request has been rejected, the reasoning MUST be clearly stipulated in this section to allow the patient and clinician to be able to understand the rationale for the decision made.

Feedback to requesting clinician:

Where the request has been rejected, and there is scope for further review (e.g. there was insufficient information given to allow the panel to make a decision, please indicate what the clinician may do)

Please provide further detail and resubmit as new request

Other (provide additional comment in text box below)

By ticking this box I confirm that I am the PACS TIER ONE Panel Chair as detailed above:

Date:

This form should be emailed to the requesting clinician within 5 working days of the panel decision, or within the same day if possible if it's an emergency case.

Appendix 1: PACS Tier One outcome report form



Peer Approved Clinical System (PACS) Outcome report (ultra-orphan)

Notes for completion:

As part of the approval for access to the medicine, a regular review of response to agreed outcomes is to be conducted.

Clinicians should use this document to record and communicate the outcome measurements to the PACS Panel via the panel chair. The document can be used on a continuous basis, and can be updated following each evaluation.

Up to 5 outcomes can be measured on one form, for up to 6 review periods. Where ongoing review and reporting has been agreed, additional forms may be required.

PATIENT, CLINICIAN AND MEDICINE DETAILS

Patient's CHI Number:	<input type="text"/>	Patient Postcode:	<input type="text"/>
Name of reporting clinician and position:	<input type="text"/>	Bleep/contact number:	<input type="text"/>
Medicine relating to this report:	<input type="text"/>		

OUTCOME 1:

Measured outcome:	<input type="text"/>		
Baseline assessment:	Measure prior to commencing treatment e.g. height, LFTs etc.)		
Expected response:	(Detail what the response was expected to be as outlined in the PACS request, e.g. improvement in measurement or lack of further deterioration etc.)		
Review 1 (date):	<input type="text"/>	Outcome response or measure:	<input type="text"/>
Review 2 (date):	<input type="text"/>	Outcome response or measure:	<input type="text"/>
Review 3 (date):	<input type="text"/>	Outcome response or measure:	<input type="text"/>
Review 4 (date):	<input type="text"/>	Outcome response or measure:	<input type="text"/>
Review 5 (date):	<input type="text"/>	Outcome response or measure:	<input type="text"/>
Review 6 (date):	<input type="text"/>	Outcome response or measure:	<input type="text"/>

OUTCOME 2:

Measured outcome:		
Baseline assessment:	Measure prior to commencing treatment e.g. height, LFTs etc.)	
Expected response:	(Detail what the response was expected to be as outlined in the PACS request, e.g. improvement in measurement or lack of further deterioration etc.,)	
Review 1 (date):	<input type="text"/>	Outcome response or measure: <input type="text"/>
Review 2 (date):	<input type="text"/>	Outcome response or measure: <input type="text"/>
Review 3 (date):	<input type="text"/>	Outcome response or measure: <input type="text"/>
Review 4 (date):	<input type="text"/>	Outcome response or measure: <input type="text"/>
Review 5 (date):	<input type="text"/>	Outcome response or measure: <input type="text"/>
Review 6 (date):	<input type="text"/>	Outcome response or measure: <input type="text"/>

OUTCOME 3:

Measured outcome:		
Baseline assessment:	Measure prior to commencing treatment e.g. height, LFTs etc.)	
Expected response:	(Detail what the response was expected to be as outlined in the PACS request, e.g. improvement in measurement or lack of further deterioration etc.,)	
Review 1 (date):	<input type="text"/>	Outcome response or measure: <input type="text"/>
Review 2 (date):	<input type="text"/>	Outcome response or measure: <input type="text"/>
Review 3 (date):	<input type="text"/>	Outcome response or measure: <input type="text"/>
Review 4 (date):	<input type="text"/>	Outcome response or measure: <input type="text"/>
Review 5 (date):	<input type="text"/>	Outcome response or measure: <input type="text"/>
Review 6 (date):	<input type="text"/>	Outcome response or measure: <input type="text"/>

OUTCOME 4:

Measured outcome:		
Baseline assessment:	Measure prior to commencing treatment e.g. height, LFTs etc.)	
Expected response:	(Detail what the response was expected to be as outlined in the PACS request, e.g. improvement in measurement or lack of further deterioration etc.,)	
Review 1 (date):		Outcome response or measure:
Review 2 (date):		Outcome response or measure:
Review 3 (date):		Outcome response or measure:
Review 4 (date):		Outcome response or measure:
Review 5 (date):		Outcome response or measure:
Review 6 (date):		Outcome response or measure:

OUTCOME 5:

Measured outcome:		
Baseline assessment:	Measure prior to commencing treatment e.g. height, LFTs etc.)	
Expected response:	(Detail what the response was expected to be as outlined in the PACS request, e.g. improvement in measurement or lack of further deterioration etc.,)	
Review 1 (date):		Outcome response or measure:
Review 2 (date):		Outcome response or measure:
Review 3 (date):		Outcome response or measure:
Review 4 (date):		Outcome response or measure:
Review 5 (date):		Outcome response or measure:
Review 6 (date):		Outcome response or measure:

Annex C: Peer Approved Clinical System (PACS) Tier Two

PACS Tier Two request form and decision record

Please note: This form is only to be used to request access to a licensed medicine that:

- is a medicine for an indication that has been considered and not recommended for use in NHS Scotland by the Scottish Medicines Consortium (SMC); or
- is a medicine accepted for restricted use by SMC but the intended use is out with SMC restrictions; or
- is a medicine which has been submitted and is awaiting/undergoing evaluation by the SMC.

Access to ultra-orphan medicines, unlicensed medicines, use for indications outside of the marketing authorisation (off-label) and medicines which are non-submissions or have not yet been submitted to SMC are not covered by PACS Tier Two.

Notes for electronic completion:

This document can be completed by adding text to the grey text fields and by checking the tick boxes or selecting from drop-down boxes where applicable. It should be completed, saved and submitted electronically. Paper copies will not be accepted unless in exceptional circumstances.

The form is partitioned into 4 parts and 2 appendices:

- Parts A - C are to be completed prior to submission to the PACS Tier Two Panel.
- Part D is to be completed by the PACS Tier Two Panel only.
- Appendix 1 is to be completed when referring a decision to the National Review Panel.
- Appendix 2 is for completion by the National Review Panel only.

Before submitting:

1. The requesting clinician completes Parts A and B.
2. Part C is completed by another NHS clinician who is experienced in treating the condition for which the medicine is being requested.
3. Part D is completed by the PACS Tier Two Panel.
4. Appendix 1 is completed by the clinician in the event of referral to the National Review Panel.
5. Appendix 2 is completed by the National Review Panel.

Please note that paperwork that is incomplete or has been completed incorrectly will be returned to the requesting clinician and will not be considered by the National Review Panel.

How to submit the request:

- For NHS Grampian Acute Service requests - forms should be submitted via email to the specialist pharmacist connected with the clinical area **and** to the Principal Pharmacist (clinical) (kimcruttenden@nhs.net).
- For NHS Grampian Primary Care requests –forms should be submitted via email to the appropriate health and social care partnership Lead Pharmacist for Aberdeen city nhsg.specialsaberdeen@nhs.net, Aberdeenshire nhsg.specialsaberdeenshire@nhs.net or Moray nhsg.specialsmoray@nhs.net
- For NHS Orkney - forms should be submitted to the Principal Pharmacist (wendylcett@nhs.net).
- For NHS Shetland - forms should be submitted to the Principal Pharmacist (mary.mcfarlane@nhs.net).

On reaching a decision:

1. The record of the PACS Tier Two decision must be documented in Part D of this form. The Chair of the PACS Tier Two panel should inform the requesting clinician of the decision by emailing a completed copy of Part D of this form within 5 working days, or if possible on the same day if clinical urgency demands this.
2. The Chair of the PACS Tier Two panel should ensure that a copy of the completed PACS Tier Two form and decision is emailed to the appropriate pharmacist (detailed above).
3. Decisions should be communicated to the patient/patient representative by the requesting clinician responsible for their care within a timescale previously agreed with the patient/patient representative.
4. The responsible clinician should discuss the outcome in detail, clarify future treatment options and discuss grounds for review, if appropriate, with the patient/patient's representative.
5. The patient's clinician should file a copy of the PACS Tier Two form and decision in the patient's case notes and retain a copy for future outcome reporting. (This paperwork will be required in the event of a referral to the National Review Panel or information requests from Scottish Ministers).

Part A: PACS Tier Two request details

To be completed for all requests made by the requesting clinician

Patient's CHI Number:	<input type="text"/>	Patient Postcode:	<input type="text"/>
NHS board conducting PACS Tier Two: <i>(Please select from the drop-down list)</i>	<input type="text" value="NHS Grampian"/>		
Patient's NHS board (if different from above): <i>(Please select from the drop-down list)</i>	<input type="text" value="NHS Grampian"/>		
Hospital/site where treatment is to be delivered/initiated:	<input type="text"/>		
Requesting Clinician:	<input type="text"/>		
Position held:	<input type="text"/>		
Email address:	<input type="text"/>		
Telephone/pager:	<input type="text"/>		
Acute Services Division:	<input type="text"/>		
Medicine and formulation: <i>(Include strength and dosage, refrain from using abbreviations. Please also include the SMC ID where known)</i>	<input type="text"/>		
Intended indication: <i>(Also include any relevant positioning)</i>	<input type="text"/>		
Clinical urgency: <i>(Please select from the drop-down list)</i>	<input type="text" value="Select"/>		
Please give an explanation for your response regarding clinical urgency:	<input type="text"/>		
How does this request relate to the SMC status of this medicine: <i>(Has the medicine not been recommended by SMC or is it awaiting/undergoing evaluation by the SMC, or is the intention to use the</i>	<input type="text" value="Select"/>		

medicine outside of the restrictions on use imposed by SMC advice? Please select from the drop-down list)

Under which process(es) was medicine considered by SMC

(This is the status of the medicine according to the SMC classification. Tick all options which apply)

- Orphan
- End-of-life
- None

The patient understands the process:

(The clinician should explain the process to the patient (including the process for review) and ensure that the patient is content that the clinician will represent all of their clinical interests. Tools to support this may include using the national patient leaflet etc.

Tick here to confirm

Multidisciplinary team support:

(If the patient is under the care of the multidisciplinary team the clinician has discussed the request and gained their agreement and support).

Tick here to confirm

In accordance with the Code of Conduct of NHS Grampian, NHS Orkney and NHS Shetland you are required to declare all interests you have in the pharmaceutical company which markets the medicine you are requesting on this form. It is possible that these may be checked against the national ABPI Interests database. Declared Interests do not directly impact on the process or decision, but are required to be noted to ensure transparency of process.

Declaration of interests:

(Please select from the drop-down list)

Select

- Personal interests may be payments/fees/resources etc that you have received personally from the company
- Non-personal interests may include payments/fees/resources etc. that your department has received from the company
- Specific interests are those that relate directly to the medicine you are requesting
- Non-specific interests are those that relate to the company, but not directly to the medicine you are requesting

Details of any declared interests:

(Where applicable)

By ticking this box I confirm that I am the clinician named above in charge of the patient's care:

Date:

Part B: PACS Tier Two case for prescribing

To be completed for **all** requests

The responsibility for a request through the PACS Tier Two process rests with the clinician who supports prescribing the requested medicine. It is the requesting clinician who is expected to demonstrate the clinical case for the patient to be prescribed the medicine within its licensed indication(s) where the following criteria apply:

1. The clinician can demonstrate that a reasonable attempt, or appropriate consideration, has been made to treat the patient in the first instance with medicines currently accepted by the SMC for routine use in NHS Scotland for this condition and for the patient in question that these medicines are deemed unsuitable or have been found to be ineffective; and
2. The clinician can present an evidence-based case to demonstrate the potential that the patient will achieve a measurable clinical benefit at least comparable to if not better than that experienced by the population considered by SMC.

PLEASE NOTE: Only the information detailed on this form will be used to inform the panel's decision (and the review panel should that be required) and you will not have any further opportunity to clarify or provide further information. It should be noted that a lack of relevant detail relating to the patient may result in the panel not having sufficient information to ascertain that the request meets the referral criteria noted above.

Information directly relating to referral criteria:

Please provide information to demonstrate that a reasonable attempt, or appropriate consideration, has been made to treat the patient with routinely available medicines normally of similar or better efficacy, including why they are deemed unsuitable for the patient or have been found to be ineffective.

Considering any existing SMC advice (if available), please demonstrate the likelihood that the patient will achieve measurable clinical benefit

(You should include all relevant factors such as performance status, previous response to other medicines and individual clinical characteristics that suggest that the patient will derive increased benefit. Please provide full citations for any clinical papers referred to)

Further information relating to patient:

Previous treatment received by patient for this indication where available and why this is not being continued

(Including approximate durations)

Are there any supportive treatments, diagnostic tests or monitoring needed for this treatment?

(provide detail, including whether the tests etc are routinely available)

What are the potential adverse effects of the medicine requested?

What outcome(s) would you propose to measure to ascertain a response to treatment?

Detail the outcomes you would measure and how you would determine response (e.g. a response may be either an improvement in an outcome, or determined to be stabilisation)

Under what circumstances would the requested treatment be reviewed or discontinued?

Considering the outcomes that are proposed to be monitored, how would these be used to determine stopping criteria?

Information directly relating to the medicine:

Relevant NICE advice

(available from www.nice.org.uk)

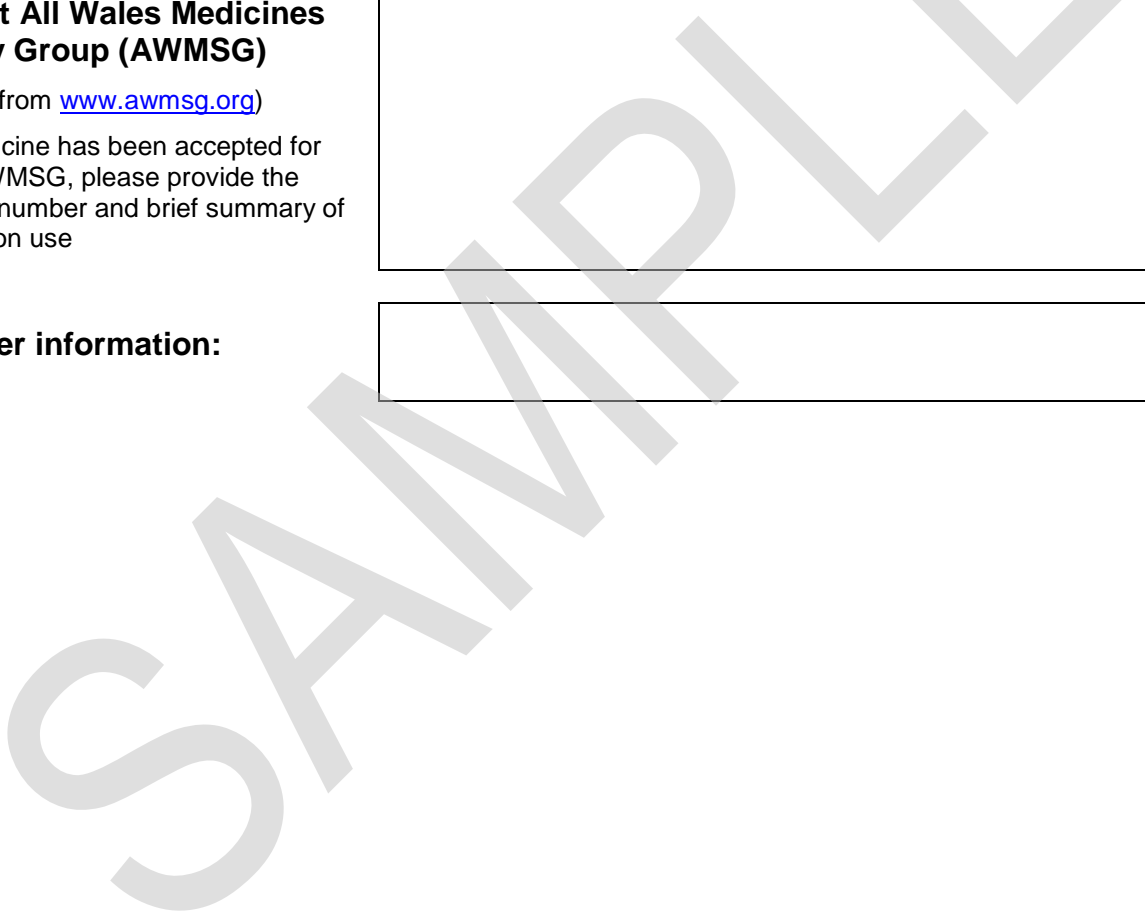
If the medicine has been accepted for use by NICE, please provide a reference (e.g. NICE TA number) and brief summary of guidance on use

Relevant All Wales Medicines Strategy Group (AWMSG)

(available from www.awmsg.org)

If the medicine has been accepted for use by AWMSG, please provide the reference number and brief summary of guidance on use

Any other information:



Part C: PACS Tier Two peer review

- As part of best practice and in order to strengthen the case being made, the requesting clinician must seek peer review for their application from another NHS clinician with suitable experience in treating the condition for which the medicine is being requested. This clinician may be from within the same NHS board, but if there are no other clinicians with suitable expertise locally, then an expert within the NHS from elsewhere in Scotland or the UK can provide the peer review.
- In providing a peer review of the information presented for the patient, the reviewing clinician is considering that (a) any alternative accepted medicines have been considered and excluded as unsuitable treatment options and (b) the patient characteristics detailed and the clinical evidence presented imply that the response to treatment will be at least comparable, if not increased, compared to the population considered by SMC.

Name and position:

NHS board/ Employing authority

NHS Grampian

Peer review statement:

The clinician should state his/her opinion relating to the request for this medicine for this condition, indicating whether they are supportive of the request and why.

In accordance with the Code of Conduct of NHS (*insert local Health Board*) you are required to declare all interests you have in the pharmaceutical company who market the medicine you are requesting on this form. It is possible that these may be checked against the national ABPI Interests database. Declared Interests do not directly impact on the process or decision, but are required to be noted to ensure transparency of process.

Declaration of interests:

(Please select from the drop-down list)

Select

- Personal interests may be payments/fees/resources etc that you have received personally from the company
- Non-personal interests may include payments/fees/resources etc. that your department has received from the company
- Specific interests are those that relate directly to the medicine you are requesting
- Non-specific interests are those that relate to the company, but not directly to the medicine you are requesting

Details of any declared interests:

(Where applicable)

By ticking this box I confirm that I am the clinician named above:

Date:

Part D: PACS Tier Two decision record

PLEASE NOTE: TO BE COMPLETED BY THE PACS TIER TWO PANEL ONLY

PACS TIER TWO PANEL MEMBERSHIP:

In accordance with Code of Conduct of NHS Grampian, Orkney and Shetland each panel member is required to declare **all interests** they have in the pharmaceutical company who market the medicine you are requesting on this form.

	Name and position:	Declaration of interests:
Panel Chair (Typically a senior clinician)	<input type="text"/>	Select
Panel member and position held:	<input type="text"/>	Select
Panel member and position held:	<input type="text"/>	Select
Panel member and position held:	<input type="text"/>	Select
Panel member and position held:	<input type="text"/>	Select
Panel member and position held:	<input type="text"/>	Select

PACS TIER TWO PANEL DISCUSSION:

Date request received:	<input type="text"/>	Date of discussion:	<input type="text"/>
How panel discussion was conducted: (Please select from the drop-down list)	Meeting		
Main discussion points of panel: (Include how evidence and peer perspective were weighted)	<input type="text"/>		

DECISION OF REQUEST AND RATIONALE:

PACS TIER TWO PANEL DECISION: (Please select from the drop-down list)	Select
Terms and conditions of acceptance (optional): <i>E.g. duration of treatment after which efficacy must be reviewed, monitoring schedule or stopping criteria. Where applicable, these terms should be clearly conveyed to the patient prior to commencing treatment.</i>	<input type="text"/>
Rationale for submission not supported:	<input type="text"/>

Where a request has been rejected, the reasoning **MUST** be clearly stipulated in this section to allow the patient and clinician to be able to understand the rationale for the decision made.

Feedback to requesting clinician:

Where the request has been rejected, and there is scope for further review (e.g. there was insufficient information given to allow the panel to make a decision, please indicate what the clinician may do)

Please provide further detail and resubmit as new request

Other (provide additional comment in text box below)

By ticking this box I confirm that I am the PACS TIER TWO Panel Chair as detailed above:

Date:

This form should be emailed to the requesting clinician within 5 working days of the panel decision, or if possible on the same day if clinical urgency demands this.

Appendix 1: Application to National Review Panel

Date of original application:

Date of PACS TIER TWO Panel
advice:

Basis for review request:

(NOTE: a review will not be accepted on the grounds that the patient or clinician does not agree with the views or conclusions reached)

Select

Case for review request:

The requesting clinician should provide a robust case for the review, including any substantiation of procedural impropriety and/or that the decision could not have been made reasonably on the basis of the evidence presented.

By ticking this box I confirm that I am the clinician in charge of the patient's care and that the patient supports the decision to request a review:

Date:

Appendix 2: National Review Panel advice

Please note: to be completed by the national review panel only

NATIONAL REVIEW PANEL MEMBERSHIP:

In accordance with the Code of Conduct of NHS (insert local Health Board) each panel member is required to declare **all interests** they have in the pharmaceutical company who market the medicine you are requesting on this form.

	Name:	Declaration of interests:
Panel Chair and position held	<input type="text"/>	<input type="text" value="Select"/>
Panel Member and position held:	<input type="text"/>	<input type="text" value="Select"/>
Panel Member and position held:	<input type="text"/>	<input type="text" value="Select"/>
Panel Member and position held:	<input type="text"/>	<input type="text" value="Select"/>

NATIONAL REVIEW PANEL DISCUSSION:

Date request received:	<input type="text"/>	Date of discussion:	<input type="text"/>
How review panel discussion was conducted: <i>(Please select from the drop-down list)</i>	<input type="text" value="Meeting"/>		

Basis for review request:
(NOTE: a review will not be accepted on the grounds that the patient or clinician does not agree with the views or conclusions reached)

Main discussion points of review panel:

OUTCOME AND RATIONALE:

NATIONAL REVIEW PANEL FINDING <i>(Please select from the drop-down list)</i>	<input type="text" value="Select"/>
--	-------------------------------------

Rationale:
(state why the panel feels a review is or is not necessary based on original evidence submitted)

By ticking this box I confirm that I am the Review Panel Chair as detailed above: **Date:**

Annex D: Patient information letter for PACS Tier Two process

Information about your doctor's treatment request

This leaflet explains the Peer Approved Clinical System (PACS) Tier Two process.

My doctor wants me to get a medicine that is not routinely available within the NHS in Scotland. What happens next?

Your doctor believes that you may benefit from a medicine that is not currently routinely available within the NHS in Scotland for your condition.

Your doctor will:

- Discuss with you why they think this medicine might help with the treatment of your condition.
- Advise you on the risks and benefits of the medicine, and
- Discuss any alternative treatment options you could consider.

If, following this discussion, you feel that you would like the doctor to apply on your behalf, they will complete the request form for this medicine.

Why does this happen?

The medicine your doctor wants to prescribe for you is not recommended for use or has yet to be considered for use by the NHS in Scotland. The process for considering new medicines is carried out by the Scottish Medicines Consortium (SMC) on behalf of the NHS in Scotland. Reasons why medicines might not be recommended by SMC can be found at: www.scottishmedicines.org.uk/about-us/

Who decides if my treatment request is accepted or rejected?

Your treatment request will be considered by a panel of healthcare professionals, including a senior doctor and a senior pharmacist, within your NHS board.

What does the NHS board consider?

Your doctor will explain why they believe you should get the medicine. This will include information about what other medicines have been tried or considered for you and why your doctor thinks you will benefit from the medicine. Your doctor will include other medical details about you and will provide details of clinical trials or evidence that support these points. Another doctor with experience in your condition will also provide the panel with more information about the request. The panel will consider all of this and other implications for the wider NHS.

Who will put forward my case?

Your doctor will put forward your case to a panel of healthcare professionals on your behalf. In doing so, they should make sure that you understand the process and the information being submitted on your behalf, and that you agree to them acting for you.

How long will it take to hear back?

Your doctor is responsible for letting the panel know about the level of urgency of the request. The panel will consider the urgency of the request and come to a decision at the earliest opportunity.

How will I find out if the request has been successful?

Your doctor will let you know the panel's decision. If the request is successful, your doctor can now prescribe the medicine for you on the NHS.

My doctor's request for the medicine has been turned down. What happens next?

Your doctor will explain the reasons why the request has been turned down and will discuss any alternative treatment options with you. You and your doctor may also consider whether there are grounds for a review of the decision. If you both believe this to be the case, your doctor can ask for the decision to be reviewed by the National Review Panel.

What is the National Review Panel?

The National Review Panel is independent from your NHS board and is made up of healthcare professionals with relevant expertise and a public partner. Public partners are recruited volunteers who are trained and supported to be panel members, to bring a public perspective to the National Review Panel process.

What are the requirements for a review by the National Review Panel?

Your doctor can submit a request if they consider that:

- the NHS board failed to follow the correct process, and/or
- the NHS board reached a decision which was not reasonable on the basis of the information presented.

How often does the National Review Panel meet?

The National Review Panel meets every month. If the request is urgent then the panel can meet earlier to ensure you receive an early response.

How will I know the outcome of the review?

Your doctor will let you know the outcome of the National Review Panel and any action the NHS board has to take to make its final decision on the treatment request.

Where can I get more information on the National Review Panel?

More information on the National Review Panel is available on the National Review Panel page of the Healthcare Improvement Scotland website:

www.healthcareimprovementscotland.org

Can I complain about the way my treatment request was handled by the NHS board?

If you are concerned about the way your request was handled, please contact your doctor or local NHS board who will advise you about their complaints procedure.

Where can I get support while my treatment request is being considered?

NHS board nominated contact(s):

NHS Grampian:

NHS Orkney:

NHS Shetland:

Can I complain about the way the review of my treatment request was handled by the National Review Panel?

If you are concerned about how your request was handled by the National Review Panel, please contact Healthcare Improvement Scotland. Full details of our complaints procedure can be found on our website: www.healthcareimprovementscotland.org.

Annex E: SMC non-submission

SMC non-submission medicine request form and decision record

Please note: This form is only to be used to request access to:

- A licensed medicine and indication which has been a non-submission to the SMC.
(Access to ultra-orphan medicines, unlicensed medicines and use for indications outside of a marketing authorisation (off-label) are not covered by this request)

Notes for electronic completion:

This document can be completed by adding text to the grey text fields and by checking the tick boxes or selecting from drop-down boxes where applicable. It should be completed, saved and submitted electronically. Paper copies will not be accepted unless in exceptional circumstances.

The form is partitioned into 4 parts:

- Parts A - C are required to be completed prior to submission to the panel.
- Part D is to be completed by the reviewing panel only.

Before submitting:

1. The requesting clinician completes parts A and B.
2. Part C is completed by another clinician who is experienced in treating the condition for which the medicine is being requested.
3. Part D is completed by the Panel.

How to submit the request:

- For NHS Grampian Acute Service requests - forms should be submitted via email to the specialist pharmacist connected with the clinical area and to the Principal Pharmacist (clinical) (kimcruttenden@nhs.net).
- For NHS Grampian Primary Care requests –forms should be submitted via email to the appropriate health and social care partnership Lead Pharmacist for Aberdeen city nhsg.specialsaberdeen@nhs.net, Aberdeenshire nhsg.specialsaberdeenshire@nhs.net or Moray nhsg.specialsmoray@nhs.net
- For NHS Orkney - forms should be submitted to the Principal Pharmacist (wendylycett@nhs.net).
- For NHS Shetland - forms should be submitted to the Principal Pharmacist (mary.mcfarlane@nhs.net).

Immediately following a decision:

1. The Chair of the panel should inform the requesting clinician of the decision by emailing a copy of Part D of the completed form, which includes the decision and rationale, as soon as possible (no later than 5 working days following decision being made and on the same day in an emergency case).
2. The Chair of the panel should ensure that a copy of the completed form and decision is emailed to the appropriate pharmacist (detailed above).
3. The decision should be communicated to the patient/patient representative by the clinician responsible for their care within one working day.
4. The responsible clinician should discuss the outcome, clarify future treatment options and discuss grounds for appeal, if appropriate, with the patient/patient's representative.
5. The patient's clinician should file a copy of the request form and decision in the patient's case notes and retain a copy for future outcome reporting.

**Part A: Request details
(SMC non-submission requests)**



To be completed for all requests made by the requesting clinician

Patient's CHI Number:

**Patient
Postcode:**

Health board:

(Please select from the drop-down list)

NHS Grampian

Patient's health board

(if different from above):

(Please select from the drop-down list)

NHS Grampian

**Hospital/site where
treatment is to be
delivered/initiated:**

Requesting Clinician:

Position held:

Email address:

Telephone/pager:

Acute Services Division:

Medicine and formulation:

*(Include strength and dosage,
refrain from using
abbreviations.)*

Intended indication:

*(Also include any relevant
positioning)*

Clinical urgency:

(Please select from the drop-down list)

Select

Please give an explanation for your response regarding clinical urgency:

The patient understands the process:

(The clinician should explain the process to the patient (including the process for appeals) and ensure that the patient is content that the clinician will represent all of their clinical interests.

Tick here to confirm

Multidisciplinary team support:

(If the patient is under the care of the multidisciplinary team the clinician has discussed the request and gained their agreement and support).

Tick here to confirm

In accordance with the Code of Conduct of NHS Grampian, Orkney and Shetland you are required to declare **all interests** you have in the pharmaceutical company who market the medicine you are requesting on this form. It is possible that these may be checked against the national ABPI Interests database. Declared Interests do not directly impact on the process or decision, but are required to be noted to ensure transparency of process.

Declaration of interests:

(Please select from the drop-down list)

Select

- Personal interests may be payments/fees/resources etc. that you have received personally from the company
- Non-personal interests may include payments/fees/resources etc. that your department has received from the company
- Specific interests are those that relate directly to the medicine you are requesting
- Non-specific interests are those that relate to the company, but not directly to the medicine you are requesting

Details of any declared interests:

(Where applicable)

By ticking this box I confirm that I am the clinician named above in charge of the patient's care:

Date:

**Part B: Case for prescribing
(SMC non-submission requests)**

To be completed for all requests

The responsibility for a request rests with the clinician who supports prescribing the requested medicine. It is the clinician who is expected to demonstrate the clinical case for the patient to be prescribed the medicine within its licensed indication(s) where the following criteria apply:

1. The clinician can demonstrate that a reasonable attempt, or appropriate consideration, has been made to treat the patient in the first instance with medicines currently accepted by the SMC for routine use in Scotland by the NHS where these medicines are normally likely to offer similar or better clinical benefit than the not-recommended medicine now being considered; and
2. The clinician can demonstrate the likelihood that the patient will achieve increased clinical benefit from the medicine being requested based on performance status, previous response to medication and individual clinical characteristics

PLEASE NOTE: Only the information on this form will be permitted to be referred to as part of the request by the clinician i.e. additional material and evidence should not be tabled on the day of the panel meeting. It should be noted that a lack of relevant detail relating to the patient may result in the panel not having sufficient information to ascertain that the request meets the referral criteria noted above.

Information directly relating to referral criteria:

Please provide information to demonstrate that a reasonable attempt, or appropriate consideration, has been made to treat the patient with routinely available medicines of similar or better efficacy, including why they are not appropriate for the patient.

Considering any existing advice, please demonstrate the likelihood that the patient will achieve increased clinical benefit

(You should include all relevant factors such as performance status, previous response to other medicines and individual clinical characteristics that suggest that the patient will derive increased benefit.

Please provide full citations for any clinical papers referred to)

Please provide information to demonstrate that awaiting SMC advice would lead to the patient missing an opportunity for cure, long-term remission (5 years), a significant extension of life or avoidance of permanent disability.

(this could include situations where the medicine requested is a bridging treatment to other treatments which would provide the benefits above or where alternative medicine choice would be associated with significant patient harm)

Empty box for providing full citations for clinical papers referred to.

Further information relating to patient:

Previous treatment received by patient for this indication where available and why this is not being continued

(Including approximate durations)

Empty box for providing previous treatment received by patient for this indication.

Are there any supportive treatments, diagnostic tests or monitoring needed for this treatment?

(provide detail, including whether the tests etc. are routinely available)

Empty box for providing supportive treatments, diagnostic tests or monitoring needed for this treatment.

What are the potential adverse effects of the medicine requested?

What outcome(s) would you propose to measure to ascertain a response to treatment?

Detail the outcomes you would measure and how you would determine response (e.g. a response may be either an improvement in an outcome, or determined to be stabilisation)

Under what circumstances would the requested treatment be reviewed or discontinued? Considering the outcomes that are proposed to be monitored, how would these be used to determine stopping criteria?

Information directly relating to the medicine:

Relevant NICE advice

(available from www.nice.org.uk)

If the medicine has been accepted for use by NICE, please provide a reference (e.g. NICE TA number) and brief summary of guidance on use

Relevant All Wales Medicines Strategy Group (AWMSG)

(available from www.awmsg.org)

If the medicine has been accepted for use by AWMSG, please provide the reference number and brief summary of

guidance on use

Any other information:

SAMPLE

**Part C: Peer review
(SMC non-submission requests)**

- As part of best practice and in order to strengthen the case being made, the requesting clinician must seek peer review for their application from another NHS clinician with suitable experience in treating the condition for which the medicine is being requested. This clinician may be from within the same NHS board, but if there are no other clinicians with suitable expertise locally, then an expert within the NHS from elsewhere in Scotland or the UK can provide the peer review.
- In providing a peer review of the information presented for the patient, the reviewing clinician is considering that (a) any alternative accepted medicines have been considered and excluded as unsuitable treatment options and (b) the patient characteristics detailed and the clinical evidence presented imply that the response to treatment will be at least comparable, if not increased, compared to the population considered by SMC.

Name and position:

Health board/ Employing authority

Peer review statement:

The clinician should state his/her opinion relating to the request for this medicine for this condition, indicating whether they are supportive of the request and why.

In accordance with the Code of Conduct of NHS Grampian, Orkney and Shetland you are required to declare **all interests** you have in the pharmaceutical company who market the medicine you are requesting on this form. It is possible that these may be checked against the national ABPI Interests database. Declared Interests do not directly impact on the process or decision, but are required to be noted to ensure transparency of process.

Declaration of interests:

(Please select from the drop-down list)

- Personal interests may be payments/fees/resources etc. that you have received personally from the company
- Non-personal interests may include payments/fees/resources etc. that your department has received from the company
- Specific interests are those that relate directly to the medicine you are requesting
- Non-specific interests are those that relate to the company, but not directly to the medicine you are requesting

Details of any declared interests:

(Where applicable)

By ticking this box I confirm that I am the clinician named above:

 Date:

**Part D: Decision record
(SMC non-submission requests)**



PLEASE NOTE: TO BE COMPLETED BY THE PANEL ONLY

PANEL MEMBERSHIP:

In accordance with Code of Conduct of NHS Grampian, Orkney and Shetland each panel member is required to declare **all interests** they have in the pharmaceutical company who market the medicine you are requesting on this form.

	Name and position:	Declaration of interests:
Panel Chair (Typically a senior clinician)	<input type="text"/>	select
Panel member and position held:	<input type="text"/>	select
Panel member and position held:	<input type="text"/>	select
Panel member and position held:	<input type="text"/>	select
Panel member and position held:	<input type="text"/>	select

PANEL DISCUSSION:

Date request received:	<input type="text"/>	Date of discussion:	<input type="text"/>
How panel discussion was conducted: <i>(Please select from the drop-down list)</i>	Meeting		
Main discussion points of panel: <i>(Include how evidence and peer perspective were weighted)</i>	<input type="text"/>		

DECISION OF REQUEST AND RATIONALE:

PANEL DECISION: <i>(Please select from the drop-down list)</i>	Select
--	--------

Terms and conditions of acceptance (optional):

E.g. duration of treatment after which efficacy must be reviewed, monitoring schedule or stopping criteria. Where applicable, these terms should be clearly conveyed to the patient prior to commencing treatment.

Rationale for submission not supported:

Where a request has been rejected, the reasoning MUST be clearly stipulated in this section to allow the patient and clinician to be able to understand the rationale for the decision made.

Feedback to requesting clinician:

Where the request has been rejected, and there is scope for further review (e.g. there was insufficient information given to allow the panel to make a decision, please indicate what the clinician may do)

Please provide further detail and resubmit as new request

Other (provide additional comment in text box below)

By ticking this box I confirm that I am the Panel Chair as detailed above:

Date:

This form should be emailed to the requesting clinician within 5 working days of the panel decision or within the same day if possible if it is an emergency case.

Annex F: Decision making framework - PACS Tier Two



To be used when considering requests for medicines for individual patient use.

PACS 2 reference [Click here to enter text.](#)

(Where there are options Y/N please delete as appropriate, additional text space is provided to include information which is not contained on the request form)

The panel should consider and note:

1. Clinical effectiveness

- a) Has the clinician demonstrated that a reasonable attempt, or appropriate consideration, has been made to treat the patient in the first instance with medicines currently accepted by the SMC for routine use in NHS Scotland for this condition and for the patient in question that these medicines are deemed unsuitable or have been found to be ineffective?

N (if negative the process should not continue)

Y [Click here to enter text.](#)

- b) Has the clinician presented an evidence-based case to demonstrate the potential that the patient will achieve a measurable clinical benefit at least comparable to if not better than that experienced by the population considered by the SMC

N (if negative the process should not continue)

Y [Click here to enter text.](#)

- c) Is the patient expected to achieve a clinical benefit better than experienced by the population or sub populations, considered by the SMC e.g. are there any individual patient characteristics for example genetic sub-types where the clinical evidence is stronger?

N

Uncertain

Y [Click here to enter text.](#)

- d) The strength of the available evidence (tick those that apply)

- SMC DAD
- Clinical Trials
- Additional case studies etc.

[Click here to enter text.](#)

Additional relevant information e.g. briefing from MI

[Click here to enter text.](#)

- e) Nature of the benefit, when will occur and duration of benefit?

[Click here to enter text.](#)

- f) Likely response rate and/or attributable risk reduction and how this differs from the population reviewed by SMC (if applicable)?

[Click here to enter text.](#)

2. Risk Benefit

- a) Are there any safety considerations in using this medicine in this individual case that would affect the risk benefit e.g. side effects/ health risks and likelihood of occurrence?

[Click here to enter text.](#)

3. Equity

- a) Has this medicine been approved for use in the same or similar circumstances within your NHS Board?

N

Y [Click here to enter text.](#)

- b) Has this medicine been approved for use in the same or similar circumstances within UK?

N

Y [Click here to enter text.](#)

4. Operational Impact

- a) Service Impact – for example chair time, clinic capacity etc.

[Click here to enter text.](#)

- b) Other considerations e.g. administration, regimen, travel etc.

[Click here to enter text.](#)

- c) Nursing impact – training/ expertise/ capacity

[Click here to enter text.](#)

- d) Pharmacy impact – is it in stock/ used before/ protocols in place? Impact on aseptic services/ capacity?

[Click here to enter text.](#)

- e) Other factors – space, equipment, diagnostics, etc.

[Click here to enter text.](#)

- f) Does this contribute to any NHS priorities e.g. care closer to home, waiting time reduction etc.

[Click here to enter text.](#)

5. Assessment of benefit to the NHS - health gain versus resource consumed

Impact of the requested treatment on healthcare, e.g. cost effectiveness and affordability, and the balance of benefit and risk in the context of what is the wider benefit to the NHS?

[Click here to enter text.](#)

Note of meeting taken by [Click here to enter text.](#)

Signed [Click here to enter text.](#)

Date [Click here to enter text.](#)

Annex G: Decision making framework - SMC non-submission requests

To be used when considering requests for medicines for individual patient use.

Reference [Click here to enter text.](#)

(Where there are options Y/N please delete as appropriate, additional text space is provided to include information which is not contained on the request form)

The panel should consider and note:

1. Clinical effectiveness

- a) Has the clinician demonstrated that a reasonable attempt, or appropriate consideration, has been made to treat the patient in the first instance with medicines currently accepted by the SMC for routine use in NHS Scotland for this condition and for the patient in question that these medicines are deemed unsuitable or have been found to be ineffective?

N (if negative the process should not continue)

Y [Click here to enter text.](#)

- b) Has the clinician presented an evidence-based case to demonstrate the potential that the patient will achieve a significant measurable clinical benefit from the requested treatment?

N (if negative the process should not continue)

Y [Click here to enter text.](#)

- c) Has the clinician demonstrated that awaiting SMC advice (if applicable) would lead to the patient missing an opportunity for cure, long-term remission (5 years), a significant extension of life or avoidance of permanent disability? This could include situations where the medicine requested is a bridging treatment to other treatments which would provide the benefits above or where alternative medicine choice would be associated with significant, permanent patient harm and the risk of that harm is high enough to preclude the alternative medicine as a treatment option.

N (if negative the process should not continue)

Uncertain

Y [Click here to enter text.](#)

- d) The strength of the available evidence (tick those that apply)

- Clinical Trials
- Additional case studies etc.

[Click here to enter text.](#)

Additional relevant information e.g. briefing from MI

[Click here to enter text.](#)

- e) Nature of the benefit, when will occur and duration of benefit?

[Click here to enter text.](#)

- f) Likely response rate and/or attributable risk reduction and how this differs from the population(s) included in the research presented (if applicable)?

[Click here to enter text.](#)

2. Risk Benefit

- a) Are there any safety considerations in using this medicine in this individual case that would affect the risk benefit e.g. side effects/ health risks and likelihood of occurrence?
Click here to enter text.

3. Equity

- a) Has this medicine been approved for use in the same or similar circumstances within your NHS Board?
N
Y Click here to enter text.
- b) Has this medicine been approved for use in the same or similar circumstances within UK?
N
Y Click here to enter text.

4. Operational Impact

- a) Service Impact – for example chair time, clinic capacity etc.
Click here to enter text.
- b) Other considerations e.g. administration, regimen, travel etc.
Click here to enter text.
- c) Nursing impact – training/ expertise/ capacity
Click here to enter text.
- d) Pharmacy impact – is it in stock/ used before/ protocols in place? Impact on aseptic services/ capacity?
Click here to enter text.
- e) Other factors – space, equipment, diagnostics, etc.
Click here to enter text.
- f) Does this contribute to any NHS priorities e.g. care closer to home, waiting time reduction etc.
Click here to enter text.

5. Assessment of benefit to the NHS - health gain versus resource consumed

Impact of the requested treatment on healthcare, e.g. cost effectiveness and affordability, and the balance of benefit and risk in the context of what is the wider benefit to the NHS?

Click here to enter text.

Note of meeting taken by Click here to enter text.

Signed Click here to enter text.

Date Click here to enter text.