Dear Duncan

ACCESS TO MEDICINES FOR END-OF-LIFE AND VERY RARE CONDITIONS: TRANSITION FROM IPTR TO PACS

Thank you for your letter of 5 March. As requested please find attached a copy of the NHS Lanarkshire Protocol for Individual Patient Treatment Requests. This protocol has been revised to reflect the requirements of the CMO / CPO letters of November and December 2013.

The specific changes that have taken place in the light of the CMO letters are:-

- Requirement for the clinician submitting the IPTR request to provide evidence of peer support for the request as part of the application process, this can be, for example, an Multi-Disciplinary Team report or the opinion of the Clinical Team Lead.

- Additional emphasis is given to peer opinion as part of the decision making criteria. Where the evidence is equivocal, or where the panel is split, or where reasonable doubt exists for rejection of the IPTR criteria, additional emphasis should be placed on peer approval.

- Inclusion of a clinical specialist in the IPTR panel.

I can confirm that in NHS Lanarkshire, in line with the other West of Scotland Boards, IPTR processes align with the person taking responsibility for the patient’s care, and the following principles apply:-

- Where the referral is for advice alone, then the patient’s home board retains responsibility for the patient’s treatment, i.e. NHS Lanarkshire IPTR processes apply.

- Where the referral to another (host) board is for that board to undertake treatment then the processes of that host board apply – including their IPTR process should their clinician seek to request a non-approved medicine.
This is the case in whichever care setting or location the host board clinician is providing the service, including outpatient clinics within the geographical boundary of the home board, e.g. an oncologist from the Beatson Oncology Centre providing clinics within an NHS Lanarkshire site.

I trust this information is helpful.

Yours sincerely

Ian Ross
CHIEF EXECUTIVE
NHS Lanarkshire Protocol for Individual Patient Treatment Requests

<table>
<thead>
<tr>
<th>Author:</th>
<th>Chief Pharmacist</th>
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<td>Medical Director</td>
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<td>Endorsing Body:</td>
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<tr>
<td>Governance or Assurance Committee</td>
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<td>Version Number:</td>
<td>3</td>
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<tr>
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<td>Responsible Person</td>
<td>Chief Pharmacist</td>
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## CONSULTATION AND DISTRIBUTION RECORD

<table>
<thead>
<tr>
<th>Contributing Author / Authors</th>
<th>• Chief Pharmacist</th>
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| Consultation Process / Stakeholders: | • NHS Lanarkshire Area Drug & Therapeutics Committee  
|                                      | • NHS Lanarkshire Prescribing Management Board  
|                                      | • Corporate Management Team |

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## CHANGE RECORD

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1. INTRODUCTION

CEL (2010)17 set out a framework for the introduction and availability of newly licensed medicines in the NHS in Scotland. It is NHS Scotland policy that medicines not recommended by 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 individual patient treatment requests (IPTRs) for such medicines.

In October 2013 the Scottish Government announced that the IPTR process will be replaced by a Peer Approved Clinical System (PACS), however this has not yet been introduced by Government. This protocol sets out the principles and processes for handling IPTR’s in NHS Lanarkshire during this transitional period from IPTR to PACS.

There is an Appeal process which may be instigated when a request is declined and the referring clinician appeals against that decision.

Summary flow diagrams for this process is provided in Appendix 1.

2. AIMS, PURPOSE, OUTCOMES

The purpose of this protocol is to:

- Set out the processes for handling IPTRs
- Clarify the decision criteria against which requests will be considered
- Set out the appeals process that can be initiated if necessary.

This document should be read in conjunction with the NHS Lanarkshire Policy for the Managed Entry of Newly Licensed Medicines.

3. INDIVIDUAL PATIENT TREATMENT REQUEST PROCESSES

3.1 Circumstances under which Individual Patient Treatment Requests will be considered.

The Individual Patient Treatment Request (IPTR) process will relate to NHS patients under the care of an NHS Lanarkshire clinician and an IPTR may be made when:

- The Scottish Medicines Consortium (SMC) or NHS QIS has issued not recommended advice for the medicine, including medicine not recommended by SMC due to company non-submission.
- The request relates to use of the medicine outwith an SMC restriction, for example the patient or their clinical condition does not meet the specified inclusion criteria.
- In the immediate post marketing authorisation period and 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 IPTR process may be applied.

1 CMO(2013)20: Arrangements For Processing Individual Patient Treatment Requests Access To New Medicines – Transitional
3.2 IPTR Submission Process

An IPTR will only be considered where both the NHS clinician and the patient fully support the request. An agreed template for submission of the IPTR has been established to promote consistency of approach. (See appendix 2).

Peer review forms part of the evidence base considered by the IPTR Panel and so the requesting consultant should seek peer support for the request via, for example, discussion at MDT and with their Clinical Director prior to submission.

The requesting consultant should submit the completed request form to their Associate Medical Director for consideration. The Associate Medical Director will then submit the form to the Divisional Medical Director.

The requesting clinician will be required to complete a declaration of interest for each submission.

The Divisional Medical Director will review the submission to ensure all mandatory sections have been completed and will consider what, if any, additional expertise is required within the Panel to enable the request to be determined.

The request will be considered by the IPTR Panel within a maximum of 20 working days from receipt of a completed submission. The requesting clinician is responsible for informing the patient of the date of the meeting.

3.3 Information Presented to IPTR Panels

3.3.1 Responsibilities of Requesting Clinician

It is the responsibility of the requesting clinician who has raised the IPTR to prepare and present the clinical case. The submission for the clinical case should include:-

- detail of previous investigations and treatment
- prognosis without the proposed new treatment
- likely success of the new treatment
- published supporting evidence for the use of the drug/treatment
- detail of any administration/infrastructure requirements
- whether treatment is expected to be time limited or indefinite and what arrangement will be put in place for monitoring / review
- evidence of peer support e.g. an MDT report or the opinion of the Clinical Team Lead.

All information and papers prepared for the panel meeting will be made available to all participants.

3.3.2 Patient Involvement

Patient (or patient representative) involvement is through discussion with the clinician submitting the request for the medicine and who will represent the patient’s interests.

Patients (or patient representatives) who wish to may submit a written statement to the panel. Patients or representatives should not feel under any pressure to do so and the absence of such a statement will not present a disadvantage. Such statements are not a necessary addition to the information to be considered by the panel and will not form part of the evidence.
3.3.3 Review of Evidence Base

Pharmacy will provide support to the IPTR Panel by producing an impartial review of the evidence base for the medicine requested. This review will be the responsibility of a named clinical pharmacist, with support from Medicines Information and input where required from a specialist adviser / specialist interest group / MCN. The named clinical pharmacist will be required to complete a declaration of interest for each evidence review undertaken.

To facilitate preparation of the evidence review a regional approach has been adopted to provide consistency in presentation, irrespective of the medicine or clinical situation.

3.3.4 Evidence Register

A regional approach will be adopted to create an IPTR Evidence Register as an internal NHS reference which will:

- Avoid repeated review of evidence
- Promote consistency of approach in presentation of evidence
- Improve the efficiency of decision making

This Evidence Register will be hosted by the NHS e-Library for ease of access by a range of authorised personnel across the NHS Boards. Each entry in this register will focus on the evidence, providing a generic analysis in a consistent format in a specific clinical indication. This database will not hold any patient identifiable data or any IPTR outcomes.

3.3.5 Decision criteria against which requests will be considered

The onus of responsibility rests with the requesting clinician to demonstrate the clinical case for the individual patient within the licensed indication, such that the following criteria are both satisfied:

- the patient’s clinical circumstances are significantly different from either:
  - the population of patients covered by the license
  - the subpopulation of patients included in clinical trials considered by the SMC
- these circumstances imply that the patient is likely to gain significantly more benefit from the medicine than normally would be expected

Where the evidence is equivocal, or where the panel is split, or where reasonable doubt exists for rejection of the IPTR criteria, additional emphasis should be placed on peer approval.

3.4 Individual Patient Treatment Request Panel Membership

The core membership of the panel will be multi-professional from the division from which the request originates and will include:-

- Associate Medical Director (chair)
- Clinical specialist
- Senior pharmacist
- General Manager/Service Manager
- Deputy Director of Finance or their representative

The IPTR Panel will co-opt others as necessary to provide additional expertise and advice pertaining to the individual request under consideration. The panel must invite clinical input
as a standard contribution to review the evidence, either via MDTs, other peer groups or individual specialists with a particular interest.

3.5 Individual Patient Treatment Request Panel Process

It is acceptable for the panel to meet by virtual means and teleconferencing will be supported.

All IPTR Panel members will be required to declare any interests.

The IPTR panel will:

- Receive and consider the request for treatment from the clinician on behalf of their patient.
- Consider the information received from the clinician(s) involved in the patient’s care.
- Assess the evidence base as provided by pharmacy.
- Agree a collective decision and produce clear documented reasons for their decision, using the checklist included in Part 2 of the IPTR Submission Form.
- The Chair will provide verbal feedback to the requesting clinician. A written response will be provided at the earliest opportunity and within a maximum of 5 working days.
- Inform the clinician of their right to appeal if the request has not been approved.
- Keep under regular review those cases where treatment has been approved to ensure that treatment remains clinically appropriate and efficacious.

3.6 Process for NHS Lanarkshire Patients Referred to Another Board

NHS Lanarkshire may request the involvement of another board in a patient’s care; that request can be for advice, or treatment, or both. It has been agreed via the West of Scotland Regional Planning Group that when a patient has been referred by their home board to another (host) board the relevant processes align with the person taking responsibility for the prescribing and the following principles apply:

- Where the referral is for advice alone, the patient’s home board retains responsibility for the patient’s treatment, i.e. NHS Lanarkshire IPTR processes apply.
- Where the referral to another (host) board is for that board to undertake treatment then the processes of that host board apply – including their IPTR process should their clinician seek to request a non-approved medicine.

This is the case in whichever care setting or location the host board clinician is providing the service, including outpatient clinics within the geographical boundary of the home board, e.g. an oncologist from the Beatson Oncology Centre providing clinics within an NHS Lanarkshire site.

The patient’s home board has the right to full membership of the host board’s IPTR Panel or Appeal Panel when the medicine cost threshold of £25,000 per patient per annum is exceeded.

4. APPEALS PROCESS

4.1 Introduction

The referral for an appeal panel can only be made by the clinician responsible for the patient’s care. The appeal process will accommodate appeals on the grounds that:

i. There is evidence that the request has not been considered in line with the processes outlined in this document.

ii. The NHS Board has reached a decision which cannot be justified in light of the evidence submitted. An appeal will not be accepted solely because the patient or the clinician does not agree with the view or conclusion reached. However an appeal can
be requested if the clinician considers that the conclusion reached cannot be reasonably justified.

iii. The Board has acted outside of its remit or has acted unlawfully.

**Please Note:** Where new evidence for the medicine emerges or if the original decision was based on a factual inaccuracy, this is not considered an appeal but a resubmission through the initial process. An appeal on these grounds will be referred back to the IPTR Panel that previously considered the request.

The appeal must be made in writing to the NHS Lanarkshire Medical Director within 5 **working** days of written notification of the outcome of the panel’s decision.

### 4.2 The Appeal Panel Membership

The IPTR Appeal Panel will not include individuals who were involved in considering the original request. The IPTR Appeal Panel will be multi professional and will include in its core membership:

- NHS Lanarkshire Medical Director or Director (Chair)
- NHS Lanarkshire Chief Pharmacist, or nominee
- A Lay member – e.g. member from PPF Reference Group
- Specialist Clinician
- Director of Finance or nominee

The Appeal Panel will co-opt others as necessary to provide additional expertise and advice pertaining to the individual request under consideration.

All Appeal Panel members will be required to declare any interests.

### 4.3 Appeal Panel Meeting

The circumstances of the appeal will be considered in terms of clinical urgency to ensure that an appropriate response time is maintained. The Appeal Panel will meet within a maximum of 20 working days of the patient or their clinician being informed that their appeal request has been accepted unless further information is required.

### 4.4 Responsibilities and Duties

The Appeal Panel will consider whether:

i. Proper procedures have been followed when considering the IPTR **and whether**

ii. All of the evidence presented to the IPTR Panel has been properly and fully considered; **and whether**

iii. The IPTR Panel came to a reasonable decision based on the above factors.

### 4.5 Evidence Available to the Appeal Panel

The Appeal Panel will have all the documents available to the IPTR panel, as well as the record of the decision and reasoning.

The appellant is not permitted to introduce new or additional evidence to support the appeal. It is the responsibility of the IPTR Panel to review new or additional information as a resubmission.

The entire case may be received in writing by the Appeal Panel without representation from the original IPTR Panel or the applicant being present. If however if the Appeal Panel considers that it would be beneficial to have either present at the hearing then the other will be invited to present also.
4.6 Appeal Panel Decision

In private session, the Appeal Panel will consider the evidence and will reach their decision, typically on the same day of the appeal being heard.

While the panel is responsible for the decision in principle, specialist clinical colleagues may inform the final wording of the outcome, through advice on timescales for review, monitoring criteria and ‘stopping rules’.

4.7 Communication of Decision

The priorities for communication of the outcome are:

- Patient / carer / patient representative / family members
- Clinical personnel caring for the patient
- Director / Service Manager / Lead Pharmacist
- Relevant personnel in home Health Board (if external to NHS Lanarkshire)

4.8 Completion of Report

A full report to record the detail of the proceedings, the evidence presented, the issues highlighted and the rationale for the decision will be prepared.

5. EQUALITY AND DIVERSITY IMPACT ASSESSMENT

This policy meets NHS Lanarkshire’s EDIA
INDIVIDUAL PATIENT TREATMENT REQUEST

How to complete this form:
- This form should be completed by the requesting consultant where a medicine which has not been approved by the Scottish Medicines Consortium (SMC) is considered to be the most appropriate treatment for a particular patient.
- All sections of PART 1 of the form must be completed, and agreement to prescribe obtained prior to prescribing the medicine to ensure that delays in treatment are minimised.
- This form is not intended for use by Specialist Oncology Services, who have their own process and documentation.
- This form is for licensed indications only. For unlicensed or off-label use please contact pharmacy for advice.

What to do with the form once complete:
- The requesting consultant should send the original form to the relevant Associate Medical Director for consideration after prior discussion at MDT and with their Clinical Director. The Associate Medical Director will then submit to the Divisional Medical Director where consideration will be given by an agreed Individual Patient Treatment Request (IPTR) Panel.
- The Chair of the IPTR panel will complete the decision record (Part 2 of this form) and communicate the decision to the requesting consultant within 20 working days from receipt of the request, taking into account the patient's condition.
- The original form, including Part 2 the Decision Record should be retained by the Divisional Medical Director, copies should sent to the requesting consultant, the on-site pharmacy and the Chief Pharmacist's Office at Kirklands Hospital.

PART 1: CONSULTANT, CLINICAL DIVISION, PATIENT & MEDICINE DETAILS

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<th>Ward or department:</th>
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<tr>
<th>Medicine name and formulation requested</th>
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This a licensed indication for this medicine? This form is for licensed indications only. For unlicensed or off-label use please contact pharmacy for advice.

<table>
<thead>
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<th>YES:</th>
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<td>Not accepted for use by SMC:</td>
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SMC guidance:
(please tick)

- New medicine that is awaiting SMC guidance:
- The medicine has been accepted by SMC however this request relates to use outwith SMC restriction, for example either the patient or their clinical condition does not meet specified inclusion criteria.

Other relevant national guidance:
(please tick)

- Medicine is recommended in a relevant NICE Multiple Technology Appraisal:
- Medicine is recommended in a relevant SIGN Guideline:

Jan 2014
Clinical rationale for use in this patient, including expected outcome:
(please submit any clinical papers referenced with this form)

It is NHS Lanarkshire policy that medicines not recommended by SMC should not routinely be made available.

Previous treatment for this indication:
(Including duration)

Expected duration of treatment:

Estimate of expected cost:
(indicate what cost is for e.g. treatment period or per year)

Are there any supportive treatments needed for this treatment?

Reason why an SMC approved drug not selected:

What will be used if this drug is not authorised?
IPTR REQUEST FORM

Planned review:
(please state when and how response to treatment will be measured)

Any other information::
If you need to provide any further information in support of your request, or need to additional space to answer the previous questions please use this area.

e.g. an MDT report or the opinion of the Clinical Team Lead

Confirmation of Peer Support for this request
Peer support for the use of the medicine must be assured prior to an IPTR being considered please provide details

SIGNATURE OF THE REQUESTING CONSULTANT AND DECLARATION OF INTERESTS:

Consultant signature: ___________________________ Date: ___________________________

You are required to declare any current interests you have in the pharmaceutical company who market the medicine you are requesting on this form. Tick one of the four boxes below that best describe the interests you have in the pharmaceutical company who make the requested medicine (e.g. personal, and specific). Current interests are those that have you have received within the last 12 months. If you have no declared interests, please write “NO INTERESTS” in the details box below.

SPECIFIC INTERESTS
These are interests relate directly to the medicine you are requesting

NON-SPECIFIC INTERESTS
These are interests that relate to the company, but not directly to the drug you are requesting

PERSONAL INTERESTS
Payments/fees/resources etc that you have received personally from the company

NON-PERSONAL INTERESTS
Payments/fees/resources etc that your department has received from the company

DETAILS OF INTERESTS:
Give details of your interests in this section: ___________________________
The Divisional IPTR Panel (chaired by the Divisional Medical Director) need to approve the treatment request before the medicine is prescribed and supplied. Approval may be subject to conditions of use (such as review of effectiveness etc). If the treatment request is rejected, reasons should be clearly documented on this form and fed back to the requesting consultant.

NB: If the use of this medicine will have an impact on any other services or on Primary Care, then this should be discussed with the relevant person(s) prior to the medicine being prescribed. If the cost of the medicine is in excess of £25,000 and the patient resides in a health board other than NHS LANARKSHIRE, the home board MUST be consulted prior to a decision.

**IPTR DETAILS**

Medicine name and formulation:

Patient’s CHI Number:

Patient’s home NHS Board: NHS Lanarkshire: Other health board: (please specify)

Clinician submitting IPTR:

Date IPTR Received: / / Date of IPTR Panel Decision: / /

**IPTR PANEL MEMBERS**

Divisional Medical Director (or nominated deputy):

Senior Pharmacist: (or nominated deputy):

General/Service Manager (or nominated deputy):

Deputy Director of Finance (or nominated deputy):

Other relevant specialist:

If patient from other board, name and position of home board representation:

**PANEL DECLARATION OF INTERESTS**

Please document any interests of panel members in the concerned medicine or manufacturer:
IPTR PANEL DISCUSSION:

How was the panel conducted: Virtual (e.g. teleconference, email): ✗ Meeting: ✗

Main discussion points of panel:

IPTR PANEL DECISION

IPTR Accepted: ✗ IPTR Rejected: ✗

TERMS OF ACCEPTANCE (WHERE APPLICABLE)

Terms and conditions of acceptance: (e.g. duration of treatment after which efficacy must be reviewed and reported on to the panel)

REASON FOR REJECTION (WHERE APPLICABLE)

Application failed to meet the referral criteria: ✗

The referral criteria of the IPTR were met, but there were other reasons for rejecting the request (document below):

The IPTR was incomplete and/or did not contain sufficient detail to make an objective decision: ✗

Further details regarding the rejection of the IPTR:

Divisional Medical Director (or nominated deputy) authorisation on behalf of panel:

Name:
(If nominee, please also state position)

Signature: Date:

IMPORTANT NOTICE FOR DIVISIONAL MEDICAL DIRECTORS

Once the decision section of this form is complete (regardless of whether the request has been accepted or not), the original form should be returned to the consultant who requested the medicine and simultaneously, a photocopy should be forwarded on to the Chief Pharmacist’s Office along with any supporting documents that were submitted with the application.

CHIEF PHARMACIST, NHS LANARKSHIRE HEADQUARTERS, KIRKLANDS HOSPITAL, FALLSIDE ROAD, BOTHWELL, G71 8BB