‘The Individual Patient Treatment Request (IPTR) Policy and Procedures’

Policy and Procedures for the Use of Medicines *Not Recommended* by the Scottish Medicines Consortium and for Surgical Procedures *Not Recommended* by NHS Policy

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1.0 Introduction

CEL 17 (2010) '*Introduction and Availability of Newly Licensed Medicines in the NHS in Scotland*' was published by the Scottish Government on 17 May 2010.[1] This guidance sets out the policy framework with regard to the introduction and availability of newly licensed medicines in the NHS in Scotland. The key purpose of this guidance is to provide a framework within which NHS Boards are expected to align their local policies regarding access to newly licensed medicines. The framework will provide a solid basis for the development of local policies and is designed to achieve a consistent approach to the introduction of newly licensed medicines across NHS Scotland. The process outlined in this CEL indicates that there should be an independent review of all Scottish Medicines Consortium (SMC) non-approved medicines and approval should be given based on evidence that the patient may benefit, and this should not be by-passed because of budgetary considerations. The Scottish Government issued further guidance SGHD/CMO(2012)1 '*Guidance to further strengthen the safe and effective use of new medicines across the NHS in Scotland*' in February 2012.[2]

This policy remains in place but following the SGHD/CMO(2013)20 (5 November 2013) the decision making is more 'flexible'. The Scottish Government published their Response to the Scottish Parliament Health and Sport Committee Inquiry into Access to New Medicines on 8 October 2013. Individual Health Boards are responsible for their local management of the recommendations, and their policies and processes will be scrutinised. This response was followed on 5 November by SGHD/CMO(2013)20 'Access to New Medicines – Transitional Arrangements for Processing IPTRs, which re-emphasised that *"the concept of exceptionality should not be a factor in any IPTR under consideration in your Board but should be primarily about the individual clinical case. In addition, IPTR panels should exercise flexibility in their decision making in recognition of the issues highlighted in the Health and Sport Committee Report, and of the fact that we are entering a period of transition to a new clinically led peer review process. Patients should not be adversely impacted by this transition. Secondly, we will be seeking input from you and others in putting in place the PACS. To help implement this new system, and to be able to assess the impact and effect of the changes made, we will need information on the types of applications you are currently dealing with. Therefore we are asking that you take the steps necessary within your Board to be able to share information on IPTR applications made in this transitional phase with the Scottish Government."* Process Flowcharts for the IPTR process for NHS Lothian are included as Appendix 1a (NHS Lothian Arrangements for Prescribing Newly Licensed Medicines) and 1b (IPTR Process for NHS Lothian).

The Scottish Government wrote to NHS Board Medical Directors in March 2016 www.sehd.scot.nhs.uk/publications/DC20160321PACS.pdf and advised that the Peer Approved Clinical System (PACS) relates to ultra-orphan medicine that have been reviewed for use and not recommended for use by the Scottish Medicines Consortium and asked NHS Boards to actively contribute to stage two of a pilot process for PACS, stage one of which has been carried out by NHS Greater Glasgow and Clyde.

PACS pilot paperwork and application forms are available from the IPTR Administrator.
All PACS applications should be submitted directly to the IPTR Panel, including those for cancer medicines.

SMC definition of ultra-orphan medicines
A medicine used to treat a condition with a prevalence of 1 in 50,000 or less (or around 100 people in Scotland). The definition applies to the full population of the licensed indication.
www.scottishmedicines.org.uk/Submission_Process/Submission_guidance_and_forms/PACE

This is a standalone policy. This policy should be used in conjunction with the 'Prescribing' sections of the '*NHS Lothian Safe Use of Medicines Policy and Procedures*', December 2009.[3]

Good Practice Statements for NHS Boards Management of IPTRs in the form of guidance have been drafted, entitled '*Implementing CEL 17 (2010): Introduction and availability of newly licensed medicines in the NHS in Scotland*.'[4] This document reflects consensus reached on good practice statements that NHS Boards would be expected to follow when dealing with IPTR. These good practice statements build on the framework contained within CEL 17 (2010). In adhering to this good practice NHS Boards are expected to be able to demonstrate consistency of approach in managing IPTRs.

Patient and public involvement has been secured in the development of this policy, There is a lay member on the IPTR Panel, the IPTR Appeals Panel and the Area Drug and Therapeutics Committee (ADTC). Patients will not be present at any IPTR Panel meeting but may make a written statement in support of their application via their clinician.

An equality impact assessment has been undertaken to ensure that equality and diversity issues have been considered.

1.1 Aim of the Policy

The aim of the policy is to provide a framework and procedures to ensure equitable decisions on access to newly licensed medicines.

An IPTR can only be sought where the clinician fully supports the request. The clinician is defined as the hospital consultant or General Practitioner with overall clinical responsibility for the patient. An IPTR for a new medicine may be made when:

(i) the Scottish Medicines Consortium (SMC) or NHS Healthcare Improvement Scotland (HIS) has issued 'not recommended' advice for the medicine, including medicines 'not recommended' by SMC due to company non-submission;
(ii) or before the SMC or NHS HIS has issued advice on the medicine.

Note. Where no SMC/NHS HIS advice is yet available but is awaited, the policy position across Scotland is that a medicine should not routinely be prescribed. However where the IPTR has been initiated in this circumstance, Health Boards may wish to consider whether a delay in treatment pending SMC/NHS QIS advice would result in significant adverse outcome for the patient.

In addition to the above requirements, the patient's clinical circumstances (condition and characteristics) and potential response to treatment with the medicine must be significantly different to the general population of patients covered by the medicine's licence or the population of patients included in clinical trials for the medicine's licensed indication appraised by the SMC **AND** it is the clinician's professional opinion that the patient is likely to gain significantly more benefit from the treatment than might normally be expected from patients for whom NHS policy is not to use the medicine.

Decisions on medicines, including those not recommended by the SMC and therefore not routinely available in NHS Lothian, are published on the Lothian Joint Formulary website at www.ljf.scot.nhs.uk/FormularyCommittee/NewDrugDecisions/Pages/default.aspx

The IPTR process does not cover unlicensed or off-label medicine use. Applications for the prescribing of these medicines in groups of patients should be submitted to the Lothian Formulary Committee using the Formulary Application Form 'FAF3', available on the Lothian Joint Formulary website at www.ljf.scot.nhs.uk/FormularyCommittee/FormularyApplicationForms/Pages/default.aspx. FAF3 forms should be submitted to the appropriate Drug and Therapeutics Committee prior to being submitted to the Formulary Committee. The ADTC *'Policy for the use of unlicensed (and off-label) medicines in NHS Lothian'* should be referred to for completion of FAF3s.

Please refer to the NHS Lothian policy and procedures for the use of unlicensed medicines www.nhslothian.scot.nhs.uk/OurOrganisation/BoardCommittees/Committees/ADTC/MedicinesGovernancePoliciesADTCPolicyStatements/Documents/NHS%20Lothian%20Policy%20and%20Procedures%20for%20the%20Use%20of%20Unlicensed%20Medicines%20v3%201%20December%202015.pdf

Co-payments are an option at two stages:

- When a clinician does not support an IPTR, or
- When an IPTR submission is rejected on appeal.

Please refer to the Financial Operating Procedure for the Management of Private, Overseas and Co-payment patients in NHS Lothian. This procedure states that NHS and private care are, where possible, delivered separately with clear separation in legal status, liability and accountability; the discrete elements of NHS and private care are agreed and understood by clinicians and patients in advance. If there is any dubiety over any aspects of the separation of elements of care, a decision must be sought from the Medical Director.

CEL 17 (2010)[1] states that its guidance should be considered alongside guidance on Arrangements for NHS patients Receiving Healthcare Services Through Private Healthcare Arrangements issued under CMO(2009)3 on 25 March 2009.[5] Where the patient wishes to obtain treatment from the independent healthcare sector, the clinician will be expected to follow the guidance on Arrangements for NHS Patients Receiving Healthcare Services Through Private Healthcare Arrangements as set out in CMO(2009)3.

Surgical Procedures Not Recommended by NHS Policy

In NHS Lothian, the IPTR process will also consider any surgical procedure indicated in the absence of sufficient evidence to determine whether or not it is effective when it is considered the most appropriate treatment for a particular patient in the following circumstances:

- The patient's clinical circumstances and potential response to surgery are significantly different to the general population of patients for whom NHS Policy is not to recommend the surgery *and*
- The patient is likely to gain significantly more benefit from the surgery than might normally be expected from patients for whom NHS policy is not to carry out the surgical procedure.

Appeals

The facility for appeal against an IPTR Panel decision exists in the following circumstances:

- It is thought that the NHS Lothian IPTR Panel failed to act fairly (this would be where it was felt that due process had not been followed) **OR**
- It is thought that the NHS Lothian IPTR Panel reached a decision which cannot be justified in light of the evidence submitted. [Note: An appeal will not be accepted solely because the patient or a clinician does not agree with the views or conclusions reached] **OR**
- It is thought that the NHS Lothian IPTR Panel has acted outside of its remit or has acted unlawfully.

Please refer to section 3.3.9 of this policy for information on the NHS Lothian Appeals Panel, and to sections 3.3.8 and 3.3.9 of this policy for information on the appeals process for the Cancer Medicines Management Committee (CMMC).

1.2 Policy Objectives

This policy and its supporting appendices will address the following items:

- Circumstances under which IPTRs will be considered
- Referral Criteria
- Generic core composition of the IPTR panel
- Evidence
- Timescales for IPTR decisions
- Communicating IPTR Decisions / publication on internet
- IPTR Appeals
- Core composition of appeals panel
- Evidence to be considered by the IPTR appeal panel
- Links to NHS Board Governance
- Patient and public involvement in IPTRs

1.3 Scope

This policy is applicable to patients being treated within primary care and secondary care across NHS Lothian. The Individual Patient Treatment Request (IPTR) process will apply to **new** patients. Submissions to the IPTR Panel will not be required for patients who have already been initiated on a non-SMC medicine although there is an opportunity to monitor and review patients.

The policy supports equitable decisions on access to:

- New indications/medicines that have not yet been assessed by the SMC or for indications with a '*not recommended'* status; or
- Surgical procedures that would not normally be performed in NHS Lothian in the absence of sufficient evidence to determine whether or not it is effective

There are no clinicians (including non-medical prescribers) exempt from this policy when a newly licensed medicine meeting the above criteria is considered for use in a patient.

2.0 Philosophy, Principles and Objectives

CEL 17 (2010) and the Good Guidance Practice on IPTRs seeks to focus on consistency of approach in relation to the introduction and availability of newly licensed medicines across NHS Scotland. This is to insure that all patients across NHS Scotland, regardless of health board, have equal access or opportunity for to be considered for treatment with a medicine even if not recommended by the SMC. All health boards must align their local policies with the framework set out in the guidance and confirm this with the Scottish Government.

3.0 Roles and Responsibilities

3.1 Patients

Information for patients and the public (Appendix 2) has been developed by the Area Drug and Therapeutics (ADTC) Collaborative, hosted by Healthcare Improvement Scotland, in response to a recommendation of the Health and Sport Committee Inquiry 2013 seeking more open and transparent information for patients and the public on decision making on medicines. The ADTC Collaborative team worked with healthcare professionals, public partners, public involvement groups and patient and carer support groups across NHSScotland to develop the medicines factsheet.

The clinician will explain the IPTR application process and the appeal process to the patient. It is helpful to patients who may have limited literacy if the clinician explains in plain English the process that has to be followed. The responsibility of the patient is to ask if they do not understand what they are being told. The clinician will explain that information for patients and the public is available on the Healthcare Improvement Scotland website at www.healthcareimprovementscotland.org/our_work/technologies_and_medicines/ADTC_resources/medicines_factsheet.aspx and included in this policy as Appendix 2. If the patient does not have access to a computer the clinician should obtain a copy from this policy.

A factsheet is available for patients where the medicine being proposed for use is for a very rare disease or condition (known as an ultra-orphan condition) that is not routinely available on the NHS in Scotland, either because it is not recommended for use in NHS Scotland by the Scottish Medicines Consortium (SMC) or because it has yet to be looked at. This factsheet is available from the IPTR Administrator.

Although patients will not be present at any IPTR Panel meeting or IPTR Appeal Panel meeting, they may make a written statement in support of their application via their clinician.

3.2 Relatives and Carers

Relatives and carers are integral to supporting their family member and may act as their representative (where applicable) when an IPTR or appeal is made. The clinician will explain the IPTR application process and the appeal process to relatives and/or carers. It is helpful to relatives and carers who may have limited literacy if the clinician explains in plain English the process that has to be followed. The responsibility of the relatives and carers is to ask if they do not understand what they are being told. The clinician will explain that information for patients and the public is available on the Healthcare Improvement Scotland website at www.healthcareimprovementscotland.org/our_work/technologies_and_medicines/ADTC_resources/medicines_factsheet.aspx and included in this policy as Appendix 2. If the relatives/carers do not have access to a computer, the clinician should obtain a copy for the relatives/carers from this policy.

If relatives or carers are the advocate for the patient they cannot attend the IPTR Panel meeting but they may make a written statement in support of the patient's application via the responsible clinician.

3.3 NHS Lothian Staff

3.3.1 Clinicians

An IPTR can only be sought where the clinician fully supports the request. The clinician is defined as the hospital consultant or General Practitioner with overall clinical responsibility for the patient.

The responsible clinician must ensure that the criteria for initiating an IPTR request are met. These criteria are defined in the IPTR application form (Appendix 3).

(i) The individual for whom the treatment is being sought presents with a clinical condition or patient clinical characteristics which are significantly different to the general population of patients who have the condition in question; and
(ii) The individual for whom the treatment is being sought is likely to gain significantly more benefit from the intervention than might normally be expected from the general population of patients with the condition in question.

If the application is for an ultra-orphan medicine, please refer to the PACS pilot paperwork and use the PACS pilot application form, available from the IPTR Administrator.

A factsheet is available for patients where the medicine being proposed for use is for a very rare disease or condition (known as an ultra-orphan condition) that is not routinely available on the NHS in Scotland, either because it is not recommended for use in NHS Scotland by the Scottish Medicines Consortium (SMC) or because it has yet to be looked at. This factsheet is available from the IPTR Administrator.

The responsible clinician must explain clearly to the patient that co-payments are an option at two stages:

- When the clinician does not support an IPTR, or
- When an IPTR submission is rejected on appeal.

The responsible clinician must refer to NHS Lothian's Financial Operating Procedure for the Management of Private, Overseas and co-payment patients in NHS Lothian, September 2011. This procedure states that NHS and private care are, where possible, delivered separately with clear separation in legal status, liability and accountability; the discrete elements of NHS and private care are agreed and understood by clinicians and patients in advance. If there is any dubiety over any aspects of the separation of elements of care, a decision must be sought from the Medical Director.

Where the patient wishes to obtain treatment from the independent healthcare sector, the clinician will be expected to follow the guidance on Arrangements for NHS Patients Receiving Healthcare Services Through Private Healthcare Arrangements as set out in CMO(2009)3.[5]

The responsible clinician must explain clearly to the patient that once the medicine has been provided via a private self-funding arrangement that the medicine cannot subsequently be supplied on an NHS prescription.

Requests for IPTR will be initiated by clinician responsible for the patient using the IPTR application form (Appendix 3). The completed application must be forwarded to the respective Clinical Management Team (CMT) Director of Operations in secondary care or the CH(C)P Clinical Director in primary care.

Clinicians may be invited to present the application to the IPTR Panel and the IPTR Appeal Panel.

The clinician will be responsible for communicating the IPTR Panel decision to their patient within 10 working days of receipt of IPTR Panel decision form from the IPTR administrator.

An appeal can be requested by the patient or the clinician. If the clinician feels the criteria for an appeal is met then the request for appeal must be submitted to the IPTR Administrator within 90 days of the IPTR Panel initial decision being sent. It must be noted that where new evidence for the medicine/surgical procedure emerges after the original IPTR application or if the decision was based on factual inaccuracy presented, this is not considered an appeal. In this case the clinician will be required to make a new IPTR submission to the IPTR Panel.

Patients admitted to hospital from primary care
Where a patient is admitted to hospital, who is receiving treatment with an SMC 'not recommended' medicine but there is no IPTR approval in place, the clinician with overall clinical responsibility for the patient should review the prescription, where appropriate. If the admission period is too short for the prescription to be reviewed, the patient or relative should be asked to bring in a supply of the medicine.

Patients who are not resident in NHS Lothian
Where a patient is not resident in NHS Lothian, but referred to an NHS Lothian clinician, the NHS Lothian clinician will liaise with the clinician with overall clinical responsibility for the patient in the patient's home Board, and any IPTR application will be made to the IPTR Panel in the patient's home Board. The home Board is responsible for the funding, including continuity of the funding once the patient returns to their home Board of residence.

Where a patient is admitted as an inpatient to an NHS Lothian service, and a short-term supply of a medicine that is subject to IPTR application is required, the patient's own supply of medicine should be used in the first instance. If this is not possible, the medicine will be supplied by NHS Lothian and cross-charged to the Board in which the patient is registered.

3.3.2 Clinical Directors and Associate Divisional Medical Director (secondary care only)

The relevant Clinical Director (CD) is responsible for the review and sign-off of each IPTR application prior to forwarding to the Associate Divisional Medical Director (ADMD).

The ADMD is responsible for the review and sign-off of each IPTR application prior to forwarding to the CMT Director of Operations for final signature prior to submission to the IPTR Administrator, with the exception of cancer services where the Cancer Medicines Management Committee (CMMC) review and authorise each IPTR application.

3.3.3 Clinical Management Team (CMT) Director of Operations or CH(C)P Clinical Director

The relevant CMT Director of Operations or CH(C)P Clinical Director will be responsible for review and sign-off of each IPTR application prior to submission to the IPTR Panel. This signature will be taken to mean that the CMT/CH(C)P accept any associated cost of the treatment requested if the application is approved.

The CMT Director of Operations or CH(C)P Clinical Director will be responsible for the timely submission of applications to the ITPR Administrator 2 weeks before each monthly meeting is held. In secondary care the CMT Director of Operations is responsible for copying any submission to the Associate Medical Director for UHD and the relevant CMT Pharmacist.

In the case of IPTR applications approved by the CMMC, the relevant CMT Director of Operations is responsible for signing off each IPTR application approved at a meeting. This signature will be taken to mean that the CMT accept any associated cost of the treatment from their existing budget. Once the CMT Director of Operations has signed off the IPTR application, the CMMC secretary will forward to the IPTR Chair to enable ratification within 48 hours of the meeting. These will be reviewed by the IPTR Panel at the next scheduled meeting for ratification.

3.3.4 Hospital Clinical Pharmacist or Primary Care Pharmacist

Hospital Clinical Pharmacists or Primary Care Pharmacists will be responsible for advising their respective clinicians on any IPTR application. These duties might include:

- Check if the medicine and indication for treatment being considered for IPTR and the patient's circumstances meet the criteria for an IPTR application.
- Check if a previous evidence template briefing has been prepared for the medicine and indication in question with the Lothian Medicines Information Service.
- Where a previous evidence briefing does not exist, assist with preparation of evidence briefing template.

3.3.5 Medicines Information

The Lothian Medicines Information Service (LMIS) have access to other evidence briefing templates prepared across Scotland via the Association of Scottish Medicines Information Pharmacists. LMIS will be responsible for checking if a prior evidence briefing template meeting the medicine/indication being considered has been prepared. If available an electronic copy will be supplied.

3.3.6 NHS Lothian IPTR Administrator

The IPTR Administrator will be responsible for the receipt and logging of IPTR requests and IPTR Appeals.

The IPTR Administrator will capture all relevant information on the IPTR Panel discussion on the IPTR Request Panel Assessment Form (Appendix 4).

Feedback to the clinician will be provided on the Individual Decision Record of IPTR Panel (Appendix 5) by the IPTR Administrator within 24 hours of the IPTR Panel meeting. NHS Boards are asked to maintain accurate and up to date information on IPTR decisions, appeals and their outcomes in order that information can be provided on request.

The IPTR Administrator will perform these duties. In addition, the IPTR Administrator will be responsible for providing hospital/community pharmacies with information on individuals approved to receive a medicine via IPTR approval on an ad hoc basis if required prior to medicine being dispensed.

3.3.7 NHS Lothian IPTR Panel

The remit of the NHS Lothian IPTR Panel is for ratification of decisions and monitoring and validating the processes, including those of the Cancer Medicines Management Committee (CMMC). This panel is responsible for ensuring that the governance processes are transparent and can withstand scrutiny.

The IPTR Panel will:

- Receive and consider IPTR applications from all CMTs with the exception of Cancer, which will be received and considered by the CMMC.

The membership of this panel includes:

Medical Director (Chair) [or nominated deputy]
Chair of Cancer Medicines Management Committee [or nominated deputy]
Director of Pharmacy [or nominated deputy]
Nurse Director [or senior nurse deputising]
Chief Operating Officer [or nominated deputy]
CH(C)P General Manager or director [or nominated deputy]
Director of Strategic Planning [or nominated deputy]
General Practitioner
Chair of Formulary Committee [or nominated deputy]
Public Health representative
Finance representative
Lay Member
Divisional Medical Director
Medicines Management Pharmacist
Associate Medical Director, Primary Care [or nominated deputy]

Co-opted members can be present as required (e.g. independent clinical specialist and/or pharmacist specialist for indication for treatment; primary care pharmacist).

Clinicians may be invited to present the application to the IPTR Panel. Patients will not be present at any IPTR Panel meeting but may make a written statement in support of their application via their clinician.

The NHS Lothian IPTR Panel will meet on a monthly basis unless an emergency case arises. In the event that the meeting is inquorate, a decision will be taken by the Chair. Where an urgent decision is required, the Medical Director would be the point of contact. The Medical Director will assume responsibility for approval; and may use telephone or an e-mail of relevant IPTR Panel members to reach decision.

The final decision of the IPTR Panel will be communicated to requesting clinician within 24 hours of the meeting. It will be the clinician's responsibility to communicate to the patient within 10 working days of receiving reply.

3.3.8 The Cancer Medicines Management Committee (CMMC)

The Cancer Medicines Management Committee Terms of Reference, April 2013, is available on the NHS Lothian intranet.

The CMMC have devolved responsibility from the IPTR Panel to review and approve IPTR applications from their speciality. The exception is for applications which meet criteria for the PACS pilot for ultra-orphan medicines (see page 3 of this policy), which should be submitted directly to the IPTR Panel. The CMMC representative present at the IPTR Panel meeting will provide expertise.

The CMMC will assess each application and indicate their approval for the treatment request. If an application is not successful, reasons will be clearly documented on the CMMC Feedback Form.

All IPTR decisions from the CMMC will be reviewed retrospectively for ratification by the Medical Director/IPTR Panel.

The IPTR applications for Lothian patients considered at each meeting along with the decision given will be forwarded to the medical director/NHS Lothian IPTR panel Chair and deputy for ratification within 48 hours of the meeting. Once the decision is ratified the requesting clinician will be informed. Clinicians should not prescribe/initiate treatment until a decision letter has been issued.

The CMMC also approves and monitors non-formulary medicines requested for use within the adult cancer services, acute sector palliative care services and non-malignant haematology, as well as for solid tumour patients being treated in SCAN cancer units.

CMMC Appeals
Where the CMMC does not support an IPTR application, and the clinician or patient wishes to appeal the decision, the decision should be reviewed by the IPTR Panel to confirm whether due process has been followed. If the IPTR Panel concludes that due process had not been followed, the application should be referred to the IPTR Appeal Panel.

Where a patient is not resident in NHS Lothian, and the CMMC does not support an IPTR application, and the clinician or patient wishes to appeal the decision, the decision should be reviewed by the IPTR Panel of the patient's home Board to confirm whether due process has been followed. If this IPTR Panel concludes that due process has not been followed, the application should be referred to the IPTR Appeal Panel of the patient's home Board.

Where the use of a non-formulary medicine has not been approved for use by the CMMC and the clinician or patient wishes to appeal the decision, the decision will be reviewed by the IPTR Panel to confirm whether due process has been followed. The IPTR Panel will draw in additional expertise where necessary.

Feedback to the clinician will be provided on the Individual Decision Record of IPTR Panel (Appendix 5) by the IPTR Administrator within 5 working days of the IPTR Panel meeting.

3.3.9 NHS Lothian Appeal Panel

The Appeals Panel will be responsible for accommodating appeals if it is thought that:

- The NHS Lothian IPTR Panel failed to act fairly (this would be where it was felt that due process had not been followed)
- The NHS Lothian IPTR Panel reached a decision which cannot be justified in light of the evidence submitted. [Note: An appeal will not be accepted solely because the patient or the clinician does not agree with the views or conclusions reached. However, an appeal can be requested if the patient or the clinician considers that the conclusion reached cannot reasonably be justified. The appeal panel will review the IPTR panel's decision to on this basis]
- The NHS Lothian IPTR Panel acted outside of its remit or has acted unlawfully.

Note: Where new information relating to a specific IPTR application is submitted, or if the original decision was based on a factual inaccuracy, this is not considered an appeal but a resubmission through the initial process.

The membership of the Appeal Panel includes:

Non-Executive Member (Chair)*
Executive Director (Nursing, Public Health, etc.]
Pharmacist
Chair of the Area Drug and Therapeutics Committee (or nominated deputy)

** Note. If the non-executive member is not a lay member then a lay member must also be included.*

The appeal panel must not contain any individual that sat on the original IPTR Panel.

Clinicians may be invited to present the application to the IPTR Appeal Panel. Patients will not be present at any IPTR Appeal Panel meeting but may make a written statement in support of their application via their clinician.

The committee will meet on an as required basis but no more frequently then once a month.

Requests for IPTR appeals will be initiated by clinician responsible for the patient using the IPTR Appeal Application Form (Appendix 6).

The Appeal Panel decision will be communicated by the IPTR Administrator to the patient and clinician within 5 working days of the meeting. This will be provided on the Individual Decision Record of IPTR Appeal Panel (Appendix 7).

4.0 References

1. Introduction and Availability of Newly Licensed Medicines in the NHS in Scotland. CEL 17 (2010). The Scottish Government. 17 May 2010. www.sehd.scot.nhs.uk/mels/CEL2010_17.pdf

2. Guidance to Further Strengthen the Safe and Effective Use of New Medicines Across the NHS in Scotland. SGHD/CMO(2012)1. The Scottish Government. 13 February 2012. www.sehd.scot.nhs.uk/cmo/CMO(2012)01.pdf

3. NHS Lothian Safe Use of Medicines Policy and Procedures. December 2009. http://intranet.lothian.scot.nhs.uk/NHSLothian/Healthcare/ClinicalGuidance/General/Medicines%20Policy%20and%20procedures%20-%20December%202009.pdf

4. Implementing CEL 17 (2010): Introduction and availability of newly licensed medicines in the NHS in Scotland - Good Practice Guidance for NHS Board's Management of IPTRs. 18 March 2011. www.sehd.scot.nhs.uk/cmo/CMO(2011)03.pdf

5. Arrangements for NHS Patients Receiving Healthcare Services Through Private Healthcare Arrangements. SGHD/CMO(2009)3. The Scottish Government. 25 March 2009. www.sehd.scot.nhs.uk/cmo/CMO(2009)private.pdf

5.0 List of Appendices

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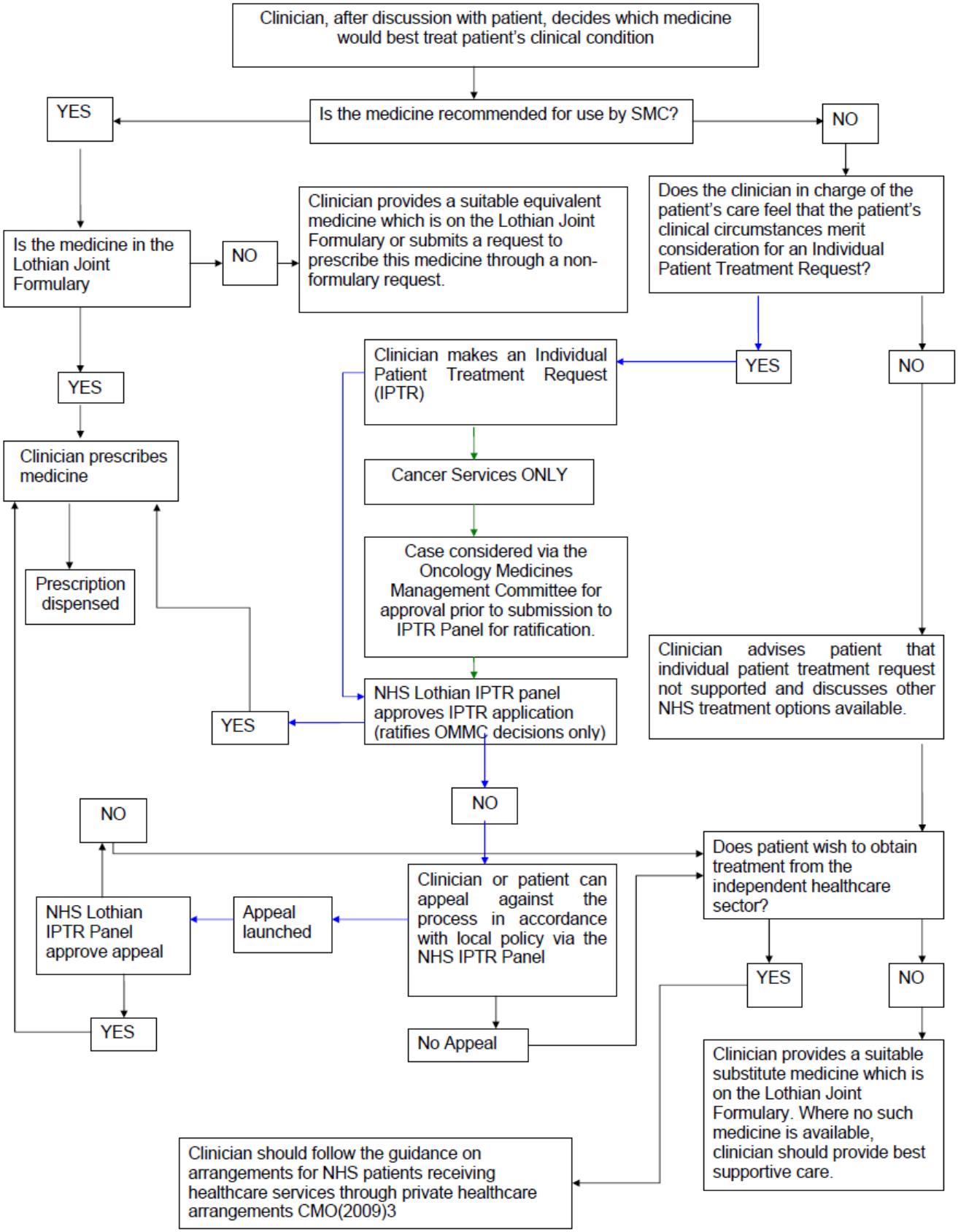
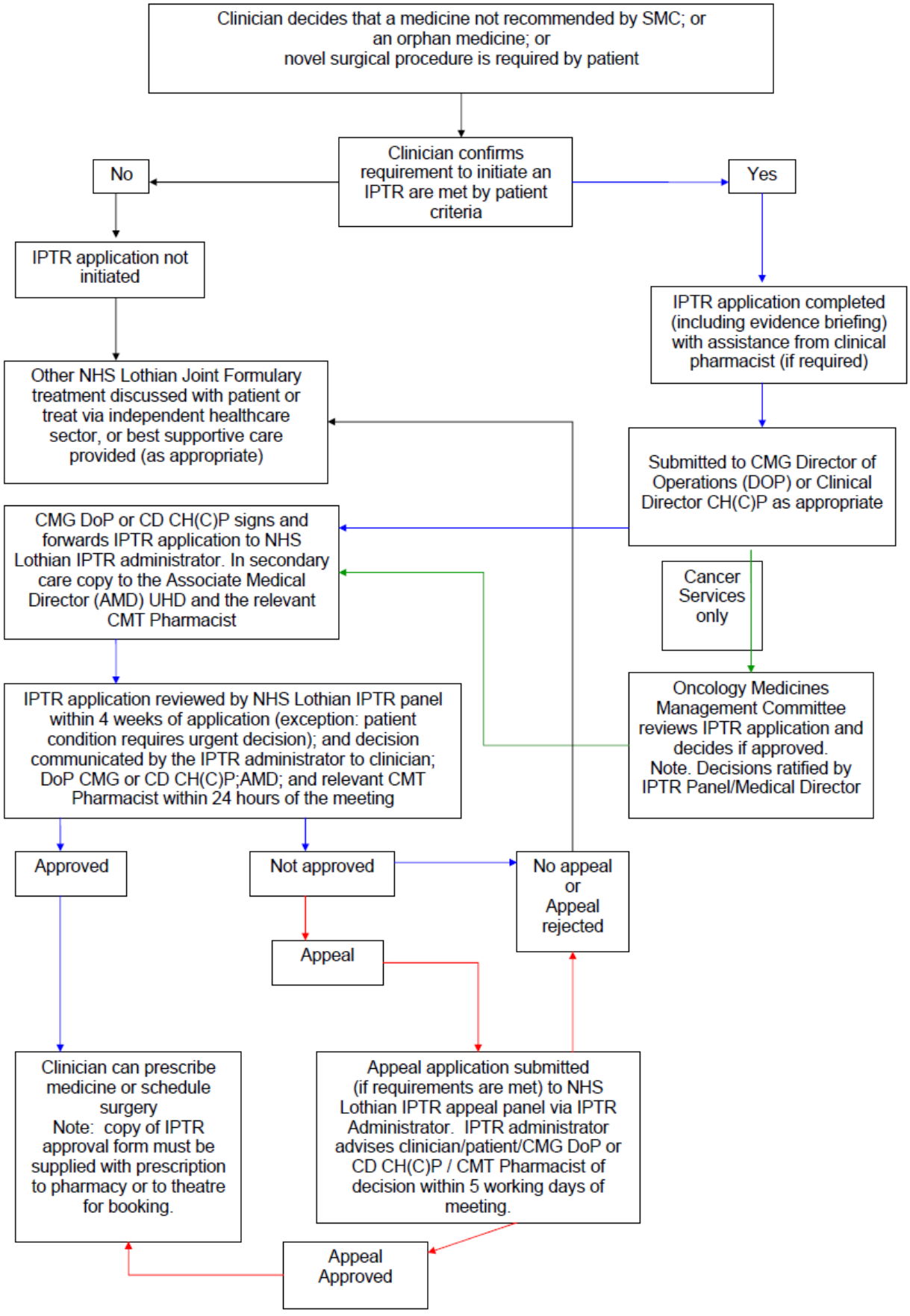
NHS Lothian Arrangements for Prescribing Newly Licensed Medicines
Version 1.0 (September 2011)



Individual Patient Treatment Request (IPTR) Process for NHS Lothian
Version 2.2 (April 2016)



Appendix 2
Information for patients and the public
'*Medicines in Scotland: what's the right treatment for you?*'

Available on the Healthcare Improvement Scotland website at
www.healthcareimprovementscotland.org/our_work/technologies_and_medicines/ADTC_resources/medicines_factsheet.aspx

Healthcare Improvement Scotland

NHS SCOTLAND

Medicines in Scotland: What's the right treatment for me?

Information for patients and the public

You can read and download this document from our website. We are happy to consider requests for other languages or formats. Please contact our Area Drug and Therapeutics Committee Collaborative by email hcis.adtc-collaborative@nhs.net.

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What is this booklet about and how can I use the information?

This booklet explains how you and your doctor (or other healthcare professional) can work together to decide whether you need a medicine and, if so, which to prescribe. The booklet also explains about the likely benefits and possible risks of medicines.

Medicines are usually prescribed by a doctor. However, other healthcare professionals can also prescribe medicines (for example dentists and some nurses, pharmacists and physiotherapists). In this booklet, "healthcare professional" is used to describe the person prescribing the medicine.

Medicines aren't just those you get on a prescription or buy yourself. Herbal medicines, vitamin supplements and alternative medicines are also counted as medicines.

The booklet may help you to think about:

- your choices
- the best treatment for you, including whether you should start a medicine in the first place, and
- what questions to ask your healthcare professional about your medicines.

I have an appointment with a healthcare professional to discuss a problem. Is a medicine the best treatment option for me?

The healthcare professional will listen to what you say about your problem, and may examine you or do some tests, before deciding what treatment, if any, you need. In some cases, you may not need medicine and the healthcare professional may:

- reassure you that there is nothing to worry about
- advise you on lifestyle choices, for example healthy diet, less alcohol and more exercise
- suggest other types of treatment, for example physiotherapy, or
- advise you to keep a check on your symptoms and make another appointment if they do not get better.

If I need a medicine, how does the healthcare professional decide which medicine to prescribe?

If you need a medicine, the healthcare professional will speak to you about your options and listen to what is important to you.

The healthcare professional will firstly consider the type of medicine you need (for example medicine for high blood pressure or pain relief). Sometimes more than one medicine can treat a medical condition. The healthcare professional will advise on the most appropriate medicine from the different medicines available to treat your medical condition. If you decide that you want to take the medicine your healthcare professional will also advise on the best dose of the medicine for you.

To help decide which medicine and dose will be best for you, the healthcare professional will consider your opinions, preferences and many other things, for example:

- any findings from examining you or from tests that have been done
- your age and family history
- other medical conditions that you already have (including how well your kidneys and liver are working)
- whether you are pregnant or breast feeding
- any other medicines you are taking (including herbal medicines and medicines you buy yourself) and how these might react with a new medicine
- the likely benefits of a medicine
- whether it is safe for you to take the medicine (including the possible side effects and risks of a medicine), and
- any treatment guidelines for your medical condition.

Your healthcare professional can advise you on the likely benefits and possible risks of your treatment options and how likely these are to happen to you. You can find more information about the benefits and risks of medicines on page 8, 9 and 10.

The healthcare professional will usually prescribe a medicine by its generic (chemical) name instead of by its brand name (for example ibuprofen rather than Nurofen®).

The healthcare professional will also usually choose a medicine that is included in your health board's local 'formulary'.

What is a formulary?

A formulary is a list of medicines that are available for routine use in a health board. It offers a choice of medicines for healthcare professionals to prescribe for common medical conditions.

The list of medicines is usually accompanied by other information (for example treatment guidelines for medical conditions) to help healthcare professionals make decisions when treating an individual.

Clinical experts in each health board consider whether to add new medicines to their formulary. They use advice published by the Scottish Medicines Consortium (SMC) (www.scottishmedicines.org.uk). When SMC considers a new medicine for the NHS in Scotland, it looks at:

- how well the medicine works
- which patients might benefit from it
- whether it is as good or better than medicines the NHS already uses to treat the medical condition, and
- whether it is good value for money.

Sometimes established medicines are a better choice than new medicines. If clinical experts in your health board decide not to make a medicine available for use, other medicines are usually available on the formulary to treat the specific medical condition.

Health boards publish their formulary on their website. You can also find this information in the medicines information section of NHS inform (www.nhsinform.scot/medicines).

Can I be prescribed a medicine that's not on my health board's formulary?

If a medicine is not included on your health board's formulary and there are no suitable alternatives on the formulary, a healthcare professional can request to prescribe another medicine if they think you will benefit from using it.

All health boards have procedures in place to consider requests when a healthcare professional feels another medicine would be right for a particular person.

How can a medicine benefit me?

A benefit is the way a medicine may help you.

Examples of likely benefits of medicines include:

- treatment of a long term condition (a medical condition which lasts more than one year), for example asthma, epilepsy or diabetes
- treatment of an infection
- relief of symptoms, for example constipation or hay fever
- being pain free or having less pain
- being more mobile or being able to do more physical activities, for example walking, sports or gardening, and
- reduced risk of an early death, for example from stroke or heart attack by lowering cholesterol or blood pressure.

Some medicines are given as a short course of treatment (for example antibiotics to treat infections). Other medicines may be taken longer term, even if you don't have any symptoms (for example medicines for high blood pressure or insulin for type 1 diabetes).

Not everyone gets better with a medicine. Sometimes you may need to try different medicines to find the right one for you. Sometimes a medicine can stop working as well as it did. You can talk to your healthcare professional if you don't think your medicine is working or if you are worried about side effects. You should also tell your healthcare professional if you do not want to take a medicine, even one that may have benefits for you.

What risks are there with taking medicines?

Risk is the chance of harm from a medicine. All medicines can cause harm. Some medicines can cause more harm than others.

Examples of possible risks of medicines include:

- getting side effects
- a new medicine reacting with other medicines, alcohol or some foods
- not getting the results that were expected from a medicine, and
- suddenly stopping some essential medicines without talking to your healthcare professional.

You may be at increased risk if:

- you are under 18 or over 70 years of age
- you are taking more than five medicines or are taking some combinations of medicines
- you have more than one medical condition
- you have a long term medical condition, or
- your kidneys or liver don't work properly.

Your healthcare professional can help you understand about the risks and what you can do to reduce the risks.

You may also come to harm if you do not take your medicine as prescribed. For example, if you have been given an antibiotic for an infection, it is important that you finish the full course of treatment, even if you start to feel better after a few days.

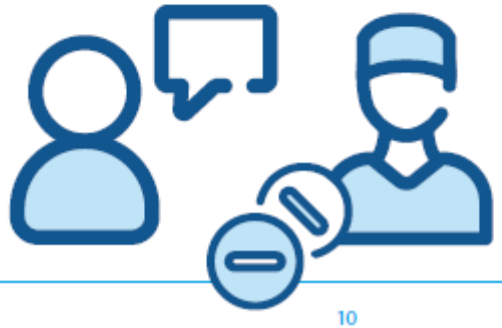
What do a medicine's benefits and risks mean for me?

You will have your own views about medicines and how taking a medicine fits in with your daily life. You may be unsure about the benefits and risks of taking a medicine.

People may have different opinions and preferences about what is important to them when taking a medicine (the benefits) and about the side effects they are willing to accept from a medicine (the risks).

Side effects can be unpleasant but you may be more willing to live with them if the medicine gives you benefits that are important to you. This depends on your circumstances and what matters to you. For example, some medicines for depression can cause drowsiness which could help if you can't sleep.

You can talk to a healthcare professional about whether a medicine is right for you. You should tell them about the things that matter to you (for example, how your symptoms affect your quality of life or worries about getting side effects from medicine).



How can I get the best from the consultation with my healthcare professional?

You might want to ask some questions such as:

- Why do I need the medicine?
- Are there other treatment options and how will they help me?
- What are the benefits of each treatment option and how many people do they normally work for?
- What are the side effects of each treatment option and how likely are they to happen to me?
- Will the benefits or side effects reduce with time?
- How will I know if the medicine is working?
- How long will it take before the medicine starts to work?
- Do I need any check-ups for my medicine or medical condition?
- What will happen if I decide not to start the medicine?

Asking these questions will help you get the right information to make decisions about your health.

To help you remember how to take your medicine safely, you can use the table at the back of this booklet to write down information about your medicines and their benefits and risks. It may also be helpful if you give your family and friends a list of any medicines you are taking.

I have been given a medicine and I'm not sure how to take it. How can I find out how to take the medicine properly?

You can ask a healthcare professional at any time if you have questions about your medicine. The healthcare professional will advise you how to use the medicine safely. They will tell you:

- what the medicine is called
- what it is used for
- how you should take it
- possible side effects, and
- whether you can stop any of the other medicines you are taking.

It is important that you follow the advice you've been given on how to take your medicine so you take it safely and get the most benefit from it.

You should also get a leaflet with your medicine. The leaflet will give you more information about the medicine. You can ask a healthcare professional to explain anything about your medicine you are unsure about.

A credit card sized *Not Sure? Just Ask!* card is available with some useful questions for you to ask about your medicines. A healthcare professional may be able to get the card for you. It is also available from www.spsp.scot/programmes/medicines/Not-sure-just-ask

Your medicines have been prescribed specifically for you. Even if two people have the same medical condition they may not be able to take the same medicine so:

- never share your medicines with anyone, and
- don't take medicines that have been prescribed for other people.

A community pharmacist can give you information on medicines you have been prescribed or would like to buy. They can advise you how to get the most from your medicine. You can also find information on medicines and search for your nearest community pharmacy on the NHS inform website (www.nhsinform.scot/medicines).

If all the community pharmacies are closed and you have an urgent query about your medicine then you can contact NHS 24 by dialling 111 from either a landline or mobile.

I don't think my medicine is working. What should I do?

If you do not think your medicine is working properly, you should speak to a healthcare professional.

The healthcare professional will talk to you about your medicine. They will check that it is working for you and may suggest some changes to your medicine or how you take it. You should follow the advice you have been given on how to take your medicine so you get the most benefit from it.

Some medicines do not work immediately. For example, it may take a few days before you start to feel better if you have been given an antibiotic or it may be a few weeks before you feel better with some medicines used to treat depression.

Do not suddenly stop some essential medicines without talking to your healthcare professional. Some medical conditions have no symptoms (for example high blood pressure) but taking your medicine helps reduce the risk of an early death (for example stroke).

I think I'm experiencing side effects from my medicine. What should I do?

If you experience any side effects and are worried about them, you should speak to a healthcare professional. They will be able to advise you what to do.

The leaflet which comes with your medicine will give you information on possible side effects of the medicine. All medicines can cause side effects. Some side effects are very rare but some can be more common.

You and your healthcare professional can report side effects through the Yellow Card Scheme which is run by the Medicines and Healthcare products Regulatory Agency (MHRA). The Yellow Card Scheme helps the MHRA monitor the safety of medicines.

You can find information on reporting side effects and completing a Yellow Card form on the Yellow Card Centre Scotland website (www.yccscotland.scot.nhs.uk/patients). You can also ask your pharmacist or call the Yellow Card hotline on 0808 100 3352 (weekdays 10am to 2pm).

I have medicines I no longer need. What should I do with them?

You can take medicines you no longer need to a community pharmacy. They will destroy them safely for you.

You should not flush medicines down the toilet or put them in a household bin. All medicines should be kept out of the reach of children.

If you have a repeat prescription, only order the medicine you need and tell your healthcare professional if you no longer take any of the medicines.

How do I make a suggestion or give feedback about my care?

You should speak to your healthcare professional about any concerns you may have as soon as possible. Not everyone will find this easy so you can ask a friend or family member to do this for you or ask another healthcare professional for a second opinion.

You can also give feedback on the service or care you received. Each GP practice, dental surgery, hospital, community pharmacy and other places where you get NHS care has someone responsible for looking into comments and suggestions. They can give you a leaflet with information on how to make a suggestion or give feedback. You can also find information on your health board's website about giving feedback.

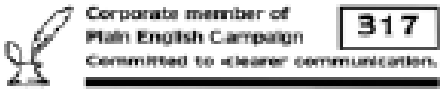
My medicines

Use this table to write down information about your medicines and their benefits and risks.

For example how you're feeling while taking the medicine, what you don't like about the medicine or if you need a check-up.

Name of medicine and what it is for	How and when do I take it?	How long do I take it for?		Why do I need it (the benefits)?	What are the main side effects to watch out for (the risks)?	Additional comments

Healthcare professionals involved in my care:
(for example the name and phone number of your doctor and community pharmacist)



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www.healthcareimprovementscotland.org

INDIVIDUAL PATIENT TREATMENT REQUEST (IPTR) APPLICATION
Version 2.4 (June 2016)

NHS Lothian

How to complete this form:

This form should be completed by the requesting consultant where:

- A medicine indicated as medicines with a SMC not recommended indication or has not yet been assessed by the SMC (including medicines not recommended by the SMC due to non-submission by company) and is considered to be the most appropriate treatment for a particular patient **AND** the patient's clinical circumstances (condition and characteristics) and potential response to treatment with the medicine are significantly different to the general population of patients covered by the medicine's licence or the population of patients included in clinical trials for the medicine's licensed indication appraised by the SMC **AND** the patient is likely to gain significantly more benefit from the treatment than might normally be expected from patients for whom NHS policy is not to use the medicine **OR**
- A surgical procedure is indicated in the absence of sufficient evidence to determine whether or not it is effective; is considered the most appropriate treatment for a particular patient; the patient's clinical circumstances and potential response to surgery are significantly different to the general population of patients for whom NHS Policy is not to recommend the surgery, and the patient is likely to gain significantly more benefit from the surgery than might normally be expected from patients for whom NHS policy is not to carry out the surgical procedure.
- All sections of the form must be completed, and agreement to prescribe obtained prior to prescribing/requesting the medicine to ensure that delays in treatment are minimised.

What to do with the form once complete:

- Within primary care, the application should be sent to the CH(C)P Clinical Director. It will be the responsibility of the CH(C)P Clinical Director to submit the application to the NHS Lothian IPTR Administrator.
- Within secondary care (with the exception of Cancer Services), the requesting consultant should send the original form to the relevant Clinical Director (CD) for signature. The CD will then forward to the Associate Divisional Medical Director (ADMD) and the Clinical Management Team (CMT) Director of Operations (DOP) for signature. It will be the responsibility of the CMT DOP to submit the application to the NHS Lothian IPTR Administrator. In secondary care a copy must be made to the Divisional Medical Director and the relevant CMT Pharmacist
- Within Cancer Services, the Cancer Medicines Management Committee (CMMC) will have devolved authority to review the IPTR application and indicate their support for approval. All IPTR applications reviewed at the meeting along with the decisions made will be forwarded to the CMT Director of Operations for signature before submission to the Medical Director/NHS Lothian IPTR Panel for ratification.

Communication of decision from NHS Lothian IPTR Panel:

- For all CMTs except Cancer, the decision will be communicated to the requesting clinician in a time-frame within 4 weeks of application (exception if patient condition requires a more timely response in which case the Medical Director will confer as appropriate). Cancer Services decisions will be communicated by the CMMC within 7 days of meeting (after ratification by Medical Director/NHS Lothian Individual Patient Treatment Request Panel).
- Once the decision has been returned to the requesting clinician, if for a medicine a copy should be sent to the relevant hospital pharmacy department/community pharmacy accompanied by the prescription/medicine request. **The medicine cannot be prescribed or supplied until formal notification of approval has been received.**

SECTION 1: CONSULTANT, PATIENT & TREATMENT DETAILS

APPLICATION NUMBER (for office use only):	

Patient Details:
Attach addressograph or use patient CHI number and postcode.
CHI Number:

Postcode:

Ward or Department :					
REH		**RIE**		**RHSC**	
Roodlands		**RV**		**WGH**	
AA		**Liberton**		**ECC**	
GP Surgery or Other Hospital:					

Patient's Health Board: (Please indicate the Health Board that the patient currently resides)

NHS LOTHIAN		**NHS FIFE**		**NHS BORDERS**		**OTHER** (specify)	

Name of Consultant: (print clearly in capitals)

Email:

Clinical Management Grouping or CH(C)P: (please specify)

Medicine name & formulation OR Surgical Procedure:

Indication:

Medicine requests – complete section below

Surgical procedure – go to Clinical Rationale section of form

Is this a licensed indication for this medicine?
NB: If the medicine is a licensed medicine that is being used out with its marketing authorisation, the prescriber carries the responsibility of the patient's welfare and may be called to justify his/her actions in the event of an adverse reaction.

YES	**Proceed with application**	**NO**	**IPTR application not required –** please use appropriate approval process, e.g. non-formulary request

SMC Guidance: (Please tick)

	Not accepted for use by SMC for this indication	**Proceed with application**	**SMC Advice ID Number (e.g. 653/10):**
	New medicine that is awaiting SMC guidance (and is within SMC remit)		
	New medicine that is out with SMC remit	**IPTR application not required**	
	Accepted by SMC for this indication, but use is non-Formulary		

BACK TO CONTENTS PAGE

Clinical rationale for use in this patient, including expected outcome: (please use Appendix 1 briefing template to assist in preparing this evidence and submit any referenced clinical papers with this form)	*NHS Lothian policy is that surgical procedures without sufficient evidence of effectiveness should only be undertaken in exceptional circumstances. Details of the surgical procedure including any papers or peer support for procedure, and any suspected side effects must be detailed below.* *Formulary medicines will meet the needs of the vast majority of patients but it is acknowledged that individual patients may have a need for a medicine which is non-formulary.* *The following criteria must be met for an IPTR to be considered:* • *The patient's clinical circumstances (condition and characteristics) and potential response to treatment with the medicine are significantly different to the general population of patients covered by the medicine's licence or the population of patients covered by the indication appraised by SMC* ***and*** • *The patient is likely to gain significantly more benefit from the intervention than might normally be expected from patients for whom NHS policy is not to use the medicine.* *The applicant should clearly document in the space below exactly how this IPTR meets this referral criteria. For example, show that the patient is in a subgroup of the population which was considered and demonstrate using clinical evidence (RCTs, etc.) that this subgroup are likely to respond better.* **Continue on a separate sheet if necessary**
Previous treatment for this indication: (including duration)	
Estimated treatment duration: (e.g. estimated theatre time or cycles for oncology medicines)	
Estimate of expected cost: (indicate what cost is for e.g. the treatment period or per year. Detail equipment costs and length of hospital stay)	
Are there any supportive treatments needed for this treatment:	

Reason formulary medicine or alternatives to surgery not selected:	
What will be used if this medicine/surgery is not used:	
Planned review: (please state when and how response to treatment will be measured)	
Where is the treatment to be delivered and does it impact on other areas? (e.g. within acute sector or intended to be continued in primary care; indicate whether the use of this medicine will impact on other directorates or on primary care)	
Any other information: (if you need to provide any further information in support of your request or need additional space to answer the previous questions please use this area)	

Additional Patient Statement (Appendix 2) **YES:** ☐ **NO:** ☐

SIGNATURE OF THE REQUESTING CONSULTANT AND DECLARATION OF INTERESTS:

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 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 medicine 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.		

SECTION 2: AUTHORISED SIGNATURES

PLEASE DO NOT SIGN FORM OFF WITHOUT APPROPRIATE COSTING INFORMATION

The CMT Director of Operations or CH(C)P Clinical Director must sign the application before forwarding the to the NHS Lothian IPTR panel for approval before the treatment is prescribed/initiated.

CMT Director of Operations or CH(C)P Clinical Director (or nominated deputy) authorisation:

Name: (if nominee, please also state position)	
Signature:	**Date:**

For Cancer Services Appendix 3 must be completed by the Cancer CMMC prior to CMT DOP Signature and submission to the Medical Director/ NHS Lothian IPTR Panel for ratification.

Within secondary care only, the following signatures are required before submission to the CMT DOP:

Clinical Director's (or nominated deputy) authorisation:

Name: (if nominee, please also state position)	
Signature:	**Date:**

Assistant Divisional Medical Director (or nominated deputy) authorisation:

Name: (if nominee, please also state position)	
Signature:	**Date:**

APPENDIX 1 - IPTR EVIDENCE BRIEFING TEMPLATE

Previously completed evidence reviews in response to IPTR requests are held in a central repository on the NHS Knowledge Network. Please contact your clinical pharmacist or the local Medicines Information Service on 0131 242 2920 (ext. 22920) to check whether a review has previously been conducted for the medicine for the indication in question.

The following information should be included in an evidence briefing provided to support the IPTR process.

Name of Medicine
Licensed Indication
Relevant licensed indication as per Summary of Product Characteristics (SPC) in the electronic medicines compendium (eMC) www.medicines.org.uk/emc/
Indication under review
A medicine may be licensed for a number of licensed indications which may be subject to differing SMC advice. Some submissions may also be for off-label use of medicines. The exact indication that is the subject of the application should be detailed here.
SMC Status http://www.scottishmedicines.org.uk/Home
Whether the medicine is "not recommended" or "accepted for use" within specific restrictions should be described. For recently launched medicines where no SMC advice is as yet available, the SMC work programme can provide an estimate of when advice will be available.
Other relevant national advice
National Institute for Health and Care Excellence (NICE) http://www.nice.org.uk
MTAs Note 1,2 Multiple health technology assessments (MTAs) issued by NICE are reviewed by NHS Healthcare Improvement Scotland (NHSHIS) who then give advice to NHS Boards about the status of these assessments within Scotland. Where issued, this guidance supersedes any existing SMC advice on the medicine. This is communicated in the SMC website. . **STAs** Note 1,2 The process for NICE Single Technology Assessments (STAs) is broadly similar to that adopted by SMC and as such STAs decisions have no standing in NHS Scotland. STA advice very rarely comes before or differs from that issued by the SMC but it can be useful to review NICE STAs to establish prescribing policy elsewhere in the UK.
All Wales Medicines Strategy Group (AWMSG) Note 2 http://www.awmsg.org
Where no SMC or NICE advice exists it may be helpful to identify whether any relevant advice has been issued by this group which has a similar role to the SMC in Scotland. It should be noted that, in Wales, any NICE advice supersedes that issued by AWMSG.
SIGN Guidelines www.sign.ac.uk
For some medicines, particularly those used in chronic disease management, it may be appropriate to describe any relevant SIGN advice. It should be noted, however, that SIGN do not currently consider cost effectiveness when considering the evidence base for any medicine.
Other professional guidelines Note 3
Guidelines issued by relevant clinical or professional bodies that may influence the use of a medicine should be described.

Dose and Administration

This information should be documented as per the SPC for the indication under review. If the medicine is to be used off-label, information may be obtained from the pivotal clinical trials. Any information on administration that may impact on service delivery should be described (e.g. chemotherapy clinic time, theatre time)

Background

A brief summary of the disease being treated and its usual management may be helpful for the panel, who are not likely to be specialists in the treatment of the disease and medicine under consideration.

Summary of evidence of comparative efficacy and adverse effects

Where SMC advice has been issued, it may only be necessary to make reference to the Detailed Advice Document (DAD). Note 7 However, where the clinician making the request has made the case that the patient's situation is different, it may be necessary to provide a more detailed review of the evidence surrounding this niche indication. Where no SMC, NICE or AWMSG advice is available a detailed independent review of the literature may be required.

Clinical Effectiveness

This section should include a comment on any relevant issues in relation to how the clinical efficacy data may translate into clinical practice. For example, the patient population within the trials may differ significantly from that encountered locally.

In addition, any wider policy issues in relation to how the medicine has been used elsewhere may be important.

A comment on potential success criteria, monitoring and stopping rules should be considered.

Health Economics

Where SMC advice has been issued, relevant information from the Detailed Advice Document (DAD) should be detailed. Note 7 In some boards, specialist advice from health economists may be available. Where no SMC advice is available (or where the medicine is to be used in a different patient group than that reviewed by SMC) and specialist input is also unavailable, any relevant published health economic data may be described. Note 4

Cost

The NHS cost of the medicine should be included. This should be the cost for one year. Note 5 The cost of any consumables or sundries should also be considered where relevant.

References

The main references used in the preparation of the briefing should be included.

Search Strategy

It is good practice to document the search strategy undertaken when preparing the briefing. Note 6

Author's details

The name of the author, checker and the date written should be included in the document

Notes

1. The first page of NICE technology assessments published in the last 2-3 years **should** state on the front page whether they are STAs or MTAs. e.g. "This guidance was developed using the single technology appraisal process." However, this may not always be clear. The status of these TAs for NHS Scotland can be confirmed on NHS Healthcare Improvement Scotland (HIS) website www.healthcareimprovementscotland.org/programmes/nice_guidance_and_scotland.aspx
2. www.evidence.nhs.uk routinely publishes advice issued by SMC, NICE and AWMSG and may, therefore, be a quick link to these websites
3. There is no comprehensive method of searching for these guidelines. Some may be archived within www.evidence.nhs.uk ; others may be picked up from general review articles on the topic. In some cases it may be necessary to search the website of any relevant professional bodies.
4. In some cases NICE may have carried out health economic reviews of patient subgroups within the trials that may have relevance to the application. Rarely, relevant heath economics studies may be published in the medical literature (identifiable via a Embase® or Medline® search or from the Cochrane Library)
5. For a medicine that is expected to be continued in Primary Care, the basic NHS cost as per the BNF or MIMS should be used. For medicines to be prescribed in acute care only, the NHS hospital cost should be used.
6. It may be agreed locally that the search strategy is not included in the published briefing but is held in the archived copy for information.
7. The Detailed Advice Document is published by the Scottish Medicines Consortium for each of the medicines considered by its committees. It includes details of the medicine and indication reviewed the advice to NHS boards and a clinical appraisal of the clinical and economic data submitted by the pharmaceutical company. It includes sections on: indications, dosing information, product availability date, comparative efficacy, comparative safety, clinical effectiveness, comparative health economics, relevant guidelines, comparative costs (NHS list price) and budget impact.

APPENDIX 2: PATIENT (OR PATIENT'S REPRESENTATIVE) STATEMENT

The patient (or their representative) should use this space to comment on this treatment request: (Continue on a separate sheet if necessary)	Continue on a separate sheet if necessary
Name:	
Signature:	**Date:**

Appendix 4
IPTR Request Panel Assessment Form

NHS LOTHIAN
INDIVIDUAL PATIENT TREATMENT REQUEST (IPTR) Request Panel Assessment Form (September 2011)

Date of meeting:	/ /
Application number:	
IPTR Panel Membership:	
Medical Director (or nominated deputy):	
Director of Pharmacy (or nominated deputy):	
Nurse Director (or senior nurse deputising):	
Chief Operating Officer (or nominated deputy):	
CH(C)P General Manager or director (or nominated deputy):	
Director of Strategic Planning (or nominated deputy**):**	
Public Health representative:	
General Practitioner:	
Divisional Medical Director (or nominated deputy):	
Associate Medical Director Primary Care (or nominated deputy):	
Chair of Formulary Committee (or nominated Deputy):	
Public Health representative:	
Finance representative:	

Medicines Management Pharmacist:	
Lay Member:	
Co-opted member(s) (e.g. independent clinical specialist and/or pharmacist specialist for indication for treatment; primary care pharmacist):	

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:	☐	Meeting:	☐
Main discussion points of 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	

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

Name: *(If nominee, please also state position)*			
Signature:		**Date:**	

Appendix 5
Individual Decision Record of IPTR Panel

NHS LOTHIAN INDIVIDUAL DECISION RECORD OF INDIVIDUAL PATIENT TREATMENT REQUEST (IPTR) PANEL (SEPTEMBER 2011)

SECTION 1: IPTR DETAILS

Medicine name and formulation:

Patient's CHI Number: ☐☐☐☐☐☐☐☐☐☐

Patient's home NHS Board: NHS Lothian: ☐ Other Health Board: (please specify)

Clinician submitting IPTR:

Date IPTR Received: / /

Date of IPTR Panel Decision: / /

Application number: ☐☐☐☐☐☐

Date decision communicated to requesting clinician and patient; and Director of Operations for Clinical Managed Team OR Clinical Director CH(C)P. In secondary care will also be copied to the Divisional Medical Director, Associate Divisional Medical Director, Clinical Director and relevant CMT Pharmacist: / /

SECTION 2A: DECISION

IPTR Accepted:	☐	IPTR Rejected:	☐

SECTION 2B: 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)

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SECTION 2C: 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	

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

Name: *(If nominee, please also state position)*			
Signature:		**Date:**	

A COPY OF THIS FORM SHOULD BE RETURNED TO THE CLINICIAN AND PATIENT WHO SUBMITTED THE APPEAL; AND THE CMT DOP OR THE CH(C)P CD (AS APPLICABLE). IN SECONDARY CARE IT WILL ALSO BE COPIED TO THE DIVISIONAL MEDICAL DIRECTOR, ASSOCIATE DIVISIONAL MEDICAL DIRECTOR, CLINICAL DIRECTOR AND RELEVANT CMT PHARMACIST. THE ORIGINAL COPY WILL BE RETAINED BY THE IPTR ADMINISTRATOR FOR AUDIT PURPOSES.

Appendix 6
IPTR Appeal Application Form

NHS LOTHIAN
INDIVIDUAL PATIENT TREATMENT REQUEST (IPTR) APPEAL APPLICATION
Version 1.0 (September 2011)

How to complete this form:

This form should be completed by the requesting consultant where:

- It is thought that the NHS Lothian IPTR Panel failed to act fairly (this would be where it was felt that due process had not been followed) **OR**
- It is thought that the NHS Lothian IPTR Panel reached a decision which cannot be justified in light of the evidence submitted. [Note: An appeal will not be accepted solely because the patient or a clinician does not agree with the views or conclusions reached] **OR**
- It is thought that the NHS Lothian IPTR Panel has acted outside of its remit or has acted unlawfully.
- **Please note that where new evidence for the medicine/surgical procedure emerges after the original IPTR application or if the decision was based on factual inaccuracy presented, this is NOT considered an appeal. In this case a new submission to the IPTR Panel must be made.**
- All appeals must be made within 90 days of original IPTR decision record being sent by IPTR Administrator.

What to do with the form once complete:

- Within secondary care, the requesting consultant should send the original form to the relevant Clinical Director (CD) for signature. The CD will then forward to the Associate Divisional Medical Director (ADMD) and the Clinical Management Team (CMT) Director of Operations (DOP) for signature. Within primary care, the application should be sent to the CH(C)P Clinical Director. It will be the responsibility of the CMT DOP or the CH(C)P Clinical Director (as appropriate) to submit the application to the NHS Lothian IPTR Administrator. In secondary care a copy must be made to the Divisional Medical Director and the relevant CMT Pharmacist.

Communication of Decision from IPTR Appeal Panel:

- The decision will be communicated to the requesting clinician and patient in a time-frame within 5 working days of the meeting of the IPTR Appeal Panel.
- If the appeal has been accepted the requesting and IPTR request is for a medicine, a copy should be sent to the relevant hospital pharmacy department/community pharmacy accompanied by the prescription/medicine request. **The medicine cannot be prescribed or supplied until formal notification of approval has been received.**

SECTION 1: CONSULTANT, CMT, PATIENT & TREATMENT DETAILS

Patient Details:
Attach addressograph or use patient CHI number and postcode
CHI Number:

Postcode:

Ward or department:

Hospital: (please tick)

REH		RIE		RHSC	
ROODLANDS		RV		WGH	
AA		LIBERTON		ECC	

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If addressograph not used:

Patient's Street Address: **Town:**	GP Surgery or Other Hospital (specify):

Patient's Health Board: (Please indicate the Health Board that the patient currently resides in)

NHS Lothian: ☐ NHS Fife ☐ NHS Borders ☐

Other: (*please specify*

Name of Consultant: (print clearly in capitals)

Page/contact number:

Clinical Management Grouping: (please tick)

Medicine: ☐ REAS/MOE: ☐ Labs, Anaesthetics, Critical Care and HSDU ☐ Not applicable since primary care application (*please specify CHP, etc below):* ☐

Surgery: ☐ Radiology, Cancer, H&N: ☐ Women's & Children's and DCN: ☐

.....

Medicine name and formulation requested or surgical procedure:

Date of original IPTR application: / /

Date of IPTR Panel Decision: / /

Basis for appeal:

Please detail the basis for appeal here. The ONLY criteria for appeal are:

- *NHS Lothian IPTR Panel failed to act fairly (this would be where it was felt that due process had not been followed)* ***OR***
- *NHS Lothian IPTR Panel reached a decision which cannot be justified in light of the evidence submitted. [Note: An appeal will not be accepted solely because the patient or a clinician does not agree with the views or conclusions reached]* ***OR***
- *NHS Lothian IPTR Panel has acted outside of its remit or has acted unlawfully.*

Continue on a separate sheet if necessary

If Appeal Initiated by Patient completion of Statement in Appendix 1 attached Yes ☐ No ☐

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:		

SECTION 2: AUTHORISED SIGNATURES

The CMT Director of Operations or CH(C)P Clinical Director must sign the application before forwarding the to the NHS Lothian Appeal panel.

CMT Director of Operations or CH(C)P Clinical Director (or nominated deputy) authorisation:

Name:
(If nominee, please also state position)

Signature: **Date:**

Within secondary care only, the following signatures are required before submission to the CMT DOP:

Clinical Director's (or nominated deputy) authorisation:

Name:
(If nominee, please also state position)

Signature: **Date:**

Assistant Divisional Medical Director (or nominated deputy) authorisation:

Name:
(If nominee, please also state position)

Signature: **Date:**

SECTION 3: NHS LOTHIAN INDIVIDUAL PATIENT TREATMENT APPEAL PANEL

IPTR Panel Membership:

Non-executive member (Chair):

Executive Director (e.g. Nursing, Public Health, etc):

Senior Pharmacist:

Chair of ADTC (or nominated deputy):	
Lay member (only required if non-executive member is not a lay member**):**	

APPEAL PANEL DECLARATION OF INTERESTS

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

IPTR APPEAL PANEL DISCUSSION:

How was the IPTR Appeal panel conducted:	Virtual (e.g. Email):	☐	Meeting:	☐
Main discussion points of IPTR Appeal panel:				

DECISION

Appeal accepted	☐	**Appeal rejected**	☐

TERMS OF ACCEPTANCE (WHERE APPLICABLE)

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

REASON FOR APPEAL REJECTION (WHERE APPLICABLE)

Further details regarding the rejection of the IPTR	

Non-executive member of NHS Lothian Board authorisation on behalf of panel:

Name:			
Signature:		**Date:**	

APPENDIX 1: PATIENT (OR PATIENT'S REPRESENTATIVE) STATEMENT

The patient (or their representative) should use this space to detail the basis of their appeal: (Continue on a separate sheet if necessary)	Continue on a separate sheet if necessary

Name:			
Signature:		**Date:**	

Appendix 7
Individual Decision Record of IPTR Appeal Panel

NHS LOTHIAN INDIVIDUAL DECISION RECORD OF INDIVIDUAL PATIENT TREATMENT REQUEST (IPTR) APPEAL PANEL

SECTION 1: IPTR APPEAL DETAILS

Medicine name and formulation OR Surgical Procedure:	
Patient Name:	
Patient Address:	
Patient's CHI Number:	☐☐☐☐☐☐☐☐☐☐
Patient's home NHS Board:	NHS Lothian: ☐ Other Health Board: (please specify)
Clinician Details:	
Date of original IPTR decision:	/ /
Date of IPTR Appeal Panel:	/ /
Application number:	☐☐☐☐☐☐
Date decision communicated to requesting clinician and patient; and Director of Operations for Clinical Managed Team OR Clinical Director CH(C)P. In secondary care will also be copied to the Divisional Medical Director, Associate Divisional Medical Director, Clinical Director and relevant CMT Pharmacist:	/ /

SECTION 2A: DECISION

IPTR Appeal Accepted:	☐	**IPTR Appeal Rejected:**	☐

SECTION 2B: 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)	

SECTION 2C: REASON FOR REJECTION (WHERE APPLICABLE)

Further details regarding the rejection of the IPTR	

Non-executive member of NHS Lothian Board authorisation on behalf of panel:

Name:			
Signature:		**Date:**	

A COPY OF THIS FORM SHOULD BE RETURNED TO THE CLINICIAN AND PATIENT WHO SUBMITTED THE APPEAL; AND THE CMT DOP OR THE CH(C)P CD (AS APPLICABLE). IN SECONDARY CARE IT WILL ALSO BE COPIED TO THE DIVISIONAL MEDICAL DIRECTOR, ASSOCIATE DIVISIONAL MEDICAL DIRECTOR, CLINICAL DIRECTOR AND RELEVANT CMT PHARMACIST. THE ORIGINAL COPY WILL BE RETAINED BY THE IPTR ADMINISTRATOR FOR AUDIT PURPOSES.