‘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]

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).

This is a standalone policy, which has been produced as interim measure. 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], in particular with the specific policy section '*NHS Lothian Policy for the Approval of a Non-Formulary Medicine*'.

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) 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 medicines license 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.

A list of medicines not recommended for use by the SMC and not recommended in NHS Lothian is available on the Lothian Joint Formulary website at www.ljf.scot.nhs.uk/FormularyCommittee/NewDrugDecisions/Documents/smc_not_recommended_drugs.pdf

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.
The only exception to this is in the circumstance that an unlicensed medicine wishes to be used when a licensed version exists for this indication within the UK and is considered to be the most appropriate treatment for a particular patient *and* the patient is likely to gain significantly more benefit/less side effects from the treatment than might from the licensed preparation. In this circumstance an IPTR application will be required.

All orphan medicines, including those approved under risk-sharing agreement with NHS National Services Scotland must be requested via an IPTR application.

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 NHS Lothian's Financial Operating Procedure for the Management of Private, Overseas and co-payment patients in NHS Lothian.

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.

Where a Clinical Director does not support an Oncology Medicines Management Committee (OMMC) application, and the consultant or patient wishes to appeal the decision, the decision should be reviewed by the ADTC to confirm whether due process has been followed. If the ADTC concludes that due process had not been followed, the application should be either referred to the IPTR appeal panel, or the ADTC should decide on an appropriate decision.

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
- Orphan medicines, including those approved under risk sharing agreements with National Services Scotland
- Use of an unlicensed medicine when a licensed version for the indication in question exists.

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

NHS Scotland have produced a patient information leaflet (Appendix 2), which has been developed by Health Rights Information Scotland (HRIS) to describe how newly licensed medicines are introduced in NHS Scotland. The leaflet provides an overview of the arrangements and advises where additional information can be obtained, including from NHS Boards. This leaflet is available at http://www.hris.org.uk/patient-information/information-about-health-services/access-to-new-medicines/

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 how the patient can obtain a copy of the information leaflet, which is in Appendix 2. If the patient does not have access to a computer the clinician should obtain a copy from Health Rights Information Scotland (HRIS) website for the patient.

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 how

the relatives/carers can obtain a copy of the information leaflet (see above and Appendix 2). If the relatives/carers do not have access to a computer, the clinician should obtain a copy from the Health Rights Information Scotland (HRIS) website for the relatives/carers.

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.

Requests for IPTR will be initiated by clinician responsible for the patient using the IPTR standardised application form (Appendix 3). The completed application must be forwarded to the respective Clinical Management Team (CMT) Director of Operations in secondary care (Appendix 4a) or the CH(C)P Clinical Director in primary care (Appendix 4b).

Clinicians may be invited to present the application to the IPTR 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.

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.

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 (Appendix 4).

In the case of IPTR applications approved by the Oncology Medicines Management Committee (OMMC), the relevant CMT Director of Operations is responsible for sign-off of 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. The CMT Director of Operations is responsible for forwarding all IPTR applications from a single OMMC meeting to the Medical Director of NHS Lothian for ratification within 5 working days of 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 5).

Feedback to the clinician will be provided on the Individual Decision Record of IPTR Panel (Appendix 6) or the Individual Decision Record of IPTR Appeal Panel (Appendix 8) as appropriate by the IPTR administrator. The timescale for communication is within 24 hours of the IPTR Panel meeting; or 5 working days of the IPTR Appeal Panel meeting as appropriate.

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 Oncology Medicines Management Committee (OMMC). 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 Oncology.
- The OMMC will have devolved responsibility from the IPTR Panel to review and approve IPTR applications from their speciality. All IPTR decisions from the OMMC will be reviewed retrospectively for ratification by the Medical Director/IPTR Panel.

The membership of this panel includes:

Medical Director (Chair) [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).

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 NHS Lothian Appeal Panel

The appeals Panel will be responsible for accommodate appeals on any of the following grounds:

- The NHS Board has failed to act fairly (this would be where it was felt that due process had not been followed);
- 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 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.); or
- The Board has acted outside of its remit or has acted unlawfully.

In addition, where a Clinical Director does not support an Oncology Medicines Management Committee (OMMC) application, and the consultant or patient wishes to appeal the decision, the decision should be reviewed by the ADTC to confirm whether due process has been followed. If the ADTC concludes that due process had not been followed, the application should be either referred to the IPTR appeal panel, or the ADTC should decide on an appropriate decision.

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.

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.

Requests for IPTR appeals will be initiated by clinician responsible for the patient using the IPTR Appeal Application Form (Appendix 7).

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

Feedback to the clinician and patient will be provided on the Individual Decision Record of IPTR Appeal Panel (Appendix 8).

The Appeal Panel decision will be communicated by the IPTR Administrator to the patient and clinician within 5 working days of the meeting.

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. Available at: 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. Available at: www.sehd.scot.nhs.uk/cmo/CMO(2012)01.pdf

3. NHS Lothian Safe Use of Medicines Policy and Procedures. December 2009. Available at: 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. Available at: www.sehd.scot.nhs.uk/cmo/CMO(2011)03.pdf

5.0 Appendices

Appendix 1a: NHS Lothian Arrangements for Prescribing Newly Licensed Medicines

Appendix 1b: NHS Lothian Process Flowchart for Use of Newly Licensed Medicines

Appendix 2: Patient Information Leaflet '*New medicines in Scotland – who decides what the NHS can provide?*'

Appendix 3: IPTR Application Form

Appendix 4a: Clinical Management Team Contacts (Associate Divisional Medical Directors, Clinical Directors and Directors of Operations)

Appendix 4b: CH(C)P Management Contacts

Appendix 5: IPTR Request Panel Assessment Form

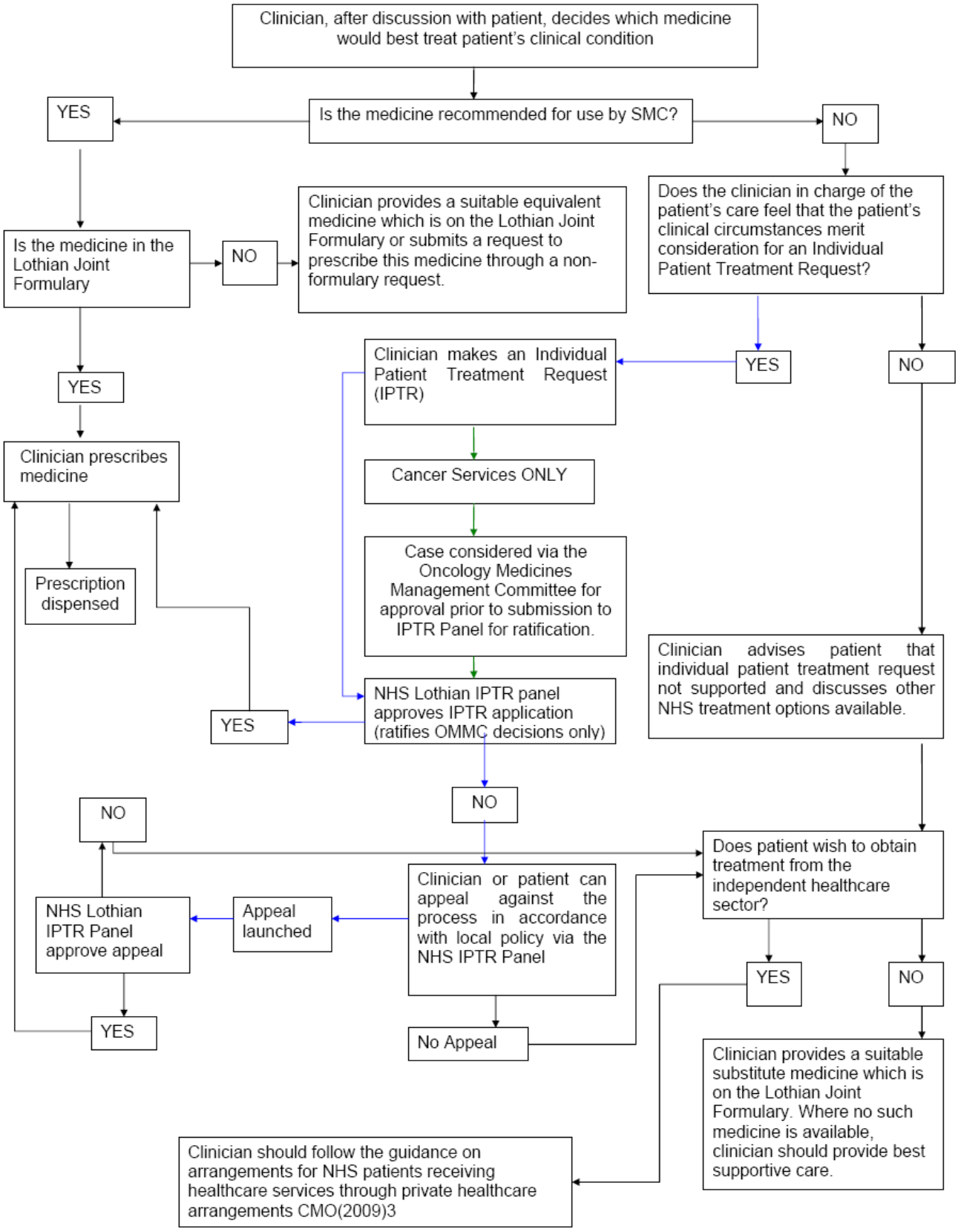
Appendix 6: Individual Decision Record of IPTR Panel

Appendix 7: IPTR Appeal Application Form

Appendix 8: Individual Decision Record of IPTR Appeal Panel

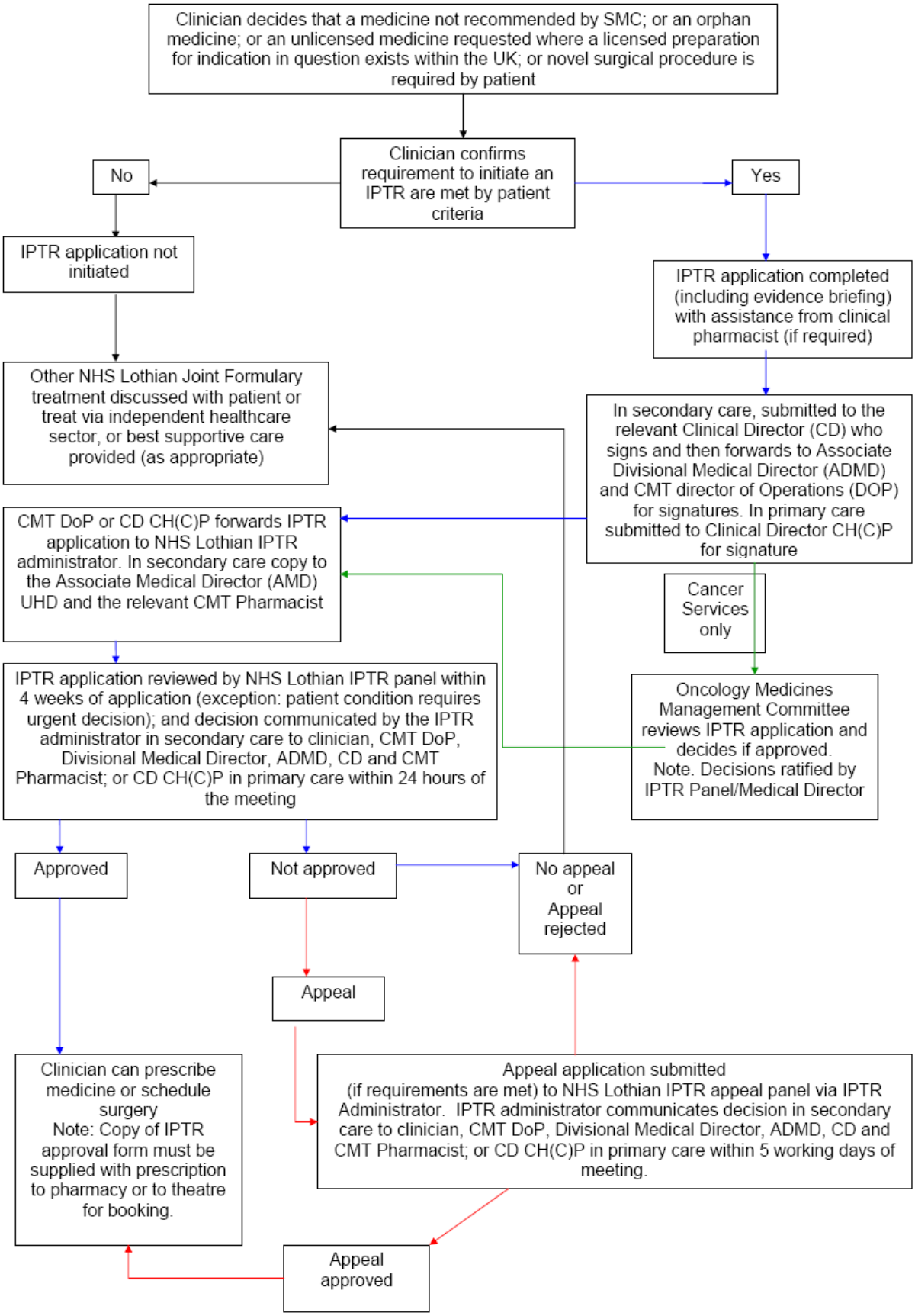
Appendix 1a

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



Appendix 1b

Individual Patient Treatment Request (IPTR) Process for NHS Lothian
Version 1.0, September 2011



Appendix 2

NHS SCOTLAND

New medicines in Scotland

– who decides what the NHS can provide?

What is this factsheet about?

This factsheet explains the process that medicines go through before NHS doctors in Scotland can routinely prescribe them.

The person prescribing a medicine must make sure the patient knows how to use it safely. Medicines are usually prescribed by a doctor. In this factsheet, we use the word "doctor" to describe the person prescribing the medicine. The doctor is responsible for choosing the medicine used.

If you have questions about the medicines you have been prescribed or you wish to discuss any part of your NHS treatment, you can ask the doctor in charge of your care.

What happens before a medicine can be prescribed?

- In Scotland, a medicine usually has to have a licence (also known as a marketing authorisation) before it can be prescribed to treat people.
- A licence will only be granted if there is evidence from a clinical trial that the medicine is safe, of good quality, and worked for those people taking part in the trial. Medicines are usually licensed for use in adults who have a particular illness or condition.
- As well as being licensed, a medicine usually needs to be recommended for use by the NHS in Scotland before it can be prescribed by your doctor.

Version 1 Produced in April 2010 Revision date April 2012

Who gives a licence to new medicines?

Two agencies license medicines:

- The **Medicines and Healthcare products Regulatory Agency (MHRA)** licenses medicines for use in the UK.
- The **European Medicines Agency (EMA)** licenses medicines for use in all countries of the European Union.

The pharmaceutical company that developed the medicine has to apply to one of these agencies for a licence. Before granting the licence, experts at the agency look at the research to check the medicine's safety and quality, and make sure it works in the way it is supposed to.

Can my doctor prescribe a medicine that doesn't have a licence?

- Unlicensed medicines may not have gone through the full licensing process.
- Normally your doctor will only prescribe a medicine that has a licence.
- However, your doctor can prescribe a medicine that doesn't have a licence if he or she thinks it will benefit you (or your child). But your doctor must let you know that the medicine doesn't have a licence, and get your agreement. And your doctor must take responsibility for the prescription and your (or your child's) care during the time you are taking the medicine.

Can my doctor prescribe any newly licensed medicine?

Usually your doctor will prescribe a licensed medicine only after it has been:

- recommended for use in Scotland by the **Scottish Medicines Consortium**, and
- accepted by your local NHS board for use in your board area.

What is the Scottish Medicines Consortium?

The **Scottish Medicines Consortium (SMC)** advises on the use of new medicines in the NHS in Scotland.

- Before the SMC accepts a medicine for use by the NHS in Scotland, it needs to find out:
  - how effective the medicine is
  - which patients would benefit
  - whether it is as good as or better than medicines the NHS already uses to treat the particular condition
  - what it costs, and
  - whether it is good value for money.

The SMC looks at detailed information from the pharmaceutical company about the medicine. This includes any evidence from clinical trials, and research from countries where the medicine is already being used. The SMC does this as soon as possible after the medicine is licensed.

- If the SMC accepts the medicine for use by the NHS in Scotland, it will publish this on the SMC website (**www.scottishmedicines.org.uk**). NHS boards and doctors take account of this advice when deciding which medicines should be prescribed.
- Sometimes the SMC accepts more than one medicine for treating a certain condition or disease. Your NHS board can decide which of them your doctor should normally prescribe.
- When NHS boards decide which medicines can be used in their area, they make a list of them. This list is called a 'local formulary'.

Are other organisations involved in approving medicines for use?

- The National Institute for Health and Clinical Excellence (NICE) advises the NHS in England and Wales about the use of medical devices and medicines. It does not give official advice to Scotland on medicines.
- However, in Scotland an organisation called NHS Quality Improvement Scotland (NHS QIS) considers some of the advice that NICE gives the NHS in England and Wales. If NHS QIS thinks the advice is relevant to patients in Scotland, they will publish it on their website. NHS boards in Scotland must consider this advice when deciding what medicines to recommend.
- The Scottish Intercollegiate Guidelines Network (SIGN) is part of NHS QIS. It writes guidelines for health professionals on the best tests and treatments available. Generally SIGN advises on groups of medicines but it does occasionally recommend a specific medicine. The SMC and SIGN work together to make sure the NHS in Scotland receives the same advice on new medicines.

So if the SMC or NHS QIS accepts a medicine for use by the NHS in Scotland, will my doctor prescribe it for me?

- Your doctor will usually only prescribe medicines that have been accepted by your NHS board, and are included in the board's 'local formulary'.
- Even if a medicine is not on the board's 'local formulary', your doctor might still be able to prescribe it if he or she feels it is the best treatment for you.
- If your NHS board agrees that the medicine should be prescribed for you, your NHS board will pay for it.

Can my doctor prescribe a licensed medicine if it hasn't been accepted for use in Scotland?

- If your doctor believes you would benefit from a medicine that has not been accepted by the SMC or NHS QIS, he or she can ask your NHS board if they will provide it.
- Your doctor will need to tell your NHS board how and why you are likely to benefit from the medicine. Your NHS board will consider your doctor's request and make a decision.
- You can ask your NHS board to direct you to a source of help and support through this process.
- If your NHS board decides to provide the medicine, you will not need to pay for it.
- If your NHS board decides not to provide the medicine, your doctor will explain the reasons for this and advise you whether there are grounds for an appeal.

If I cannot get a medicine from the NHS, can I pay privately for it instead?

- Yes, you can pay privately for a medicine that is not available to you from the NHS.
- However, there are likely to be particular reasons why your NHS board has refused to give you the medicine. Your doctor should explain these to you before you decide whether to pay privately for the medicine.

Is it possible to get NHS and private care at the same time?

- If you pay privately for your medicine, you will continue to receive the NHS care you are entitled to, and you will not be charged for it as long as it can be kept separate from your private care.
- Your doctor will tell you if it is not possible to keep your NHS and private care separate. In this case, your doctor will explain your treatment options.
- If you do decide to pay privately for the medicine, you should discuss this with your doctor or someone at your NHS board. They will be able to advise you on how to arrange this (see the section 'Need more information?' for contact details).

What if I'm unhappy about a decision by my NHS board or my doctor?

- If you are unhappy with a decision, you can ask for a second opinion. If you are still unhappy, you can make a complaint. The leaflet '**Making a complaint about the NHS**' explains how to do this. You can get a copy from:
  - GP and dental surgeries, hospitals and other places where you get NHS care
  - the NHS helpline on **0800 22 44 88** (textphone 18001 0800 22 44 88)
  - your local citizens advice bureau (www.cas.org.uk), or
  - www.hris.org.uk

Need more information?

This factsheet gives guidance only. If you want to know more about your right to get a new medicine, please speak to your doctor.

You can also get more information by:

- contacting your local NHS board – each NHS board has someone who can offer you help and advice.

  To find contact details for your local NHS board:
  - phone the NHS helpline on **0800 22 44 88**, or
  - look on the internet at **www.hris.org.uk**
- phoning the NHS helpline on **0800 22 44 88** (textphone 18001 0800 22 44 88) for information on health conditions and services
- contacting your local citizens advice bureau for free confidential and independent advice on many things, including NHS services and your rights. To find your nearest branch, look in your phone book or on Citizens Advice Scotland's website (www.cas.org.uk).

Medicines and Healthcare products Regulatory Agency (MHRA)

10–2 Market Towers
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SW8 5NQ

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(Mondays to Fridays, 9am to 5pm)
Phone 020 7210 3000
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Scottish Medicines Consortium (SMC)
Delta House (8th floor)
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Phone 0141 225 6989
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Website www.scottishmedicines.org.uk

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Phone 0131 623 4300

Email hta.qis@nhs.net
Website www.nhshealthquality.org

National Institute for Health and Clinical Excellence (NICE)
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Phone 0845 003 7780
Email nice@nice.org.uk
Website www.nice.org.uk

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Elliott House
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EH7 5EA

Phone 0131 623 4720
Email sign@sign.ac.uk
Website www.sign.ac.uk

Email ask@hris.org.uk to ask for this information in another language or format.

We have tried our best to make sure this information is correct. However, it is for guidance only so you should not rely on it as a complete statement of the law. If you are thinking about taking legal action, you should contact a solicitor, a citizens advice bureau or another advice agency.

This information is available on the Scottish Government website (www.scotland.gov.uk) and on the Health Rights Information Scotland website (www.hris.org.uk).

Produced by Health Rights Information Scotland, a project of Consumer Focus Scotland, on behalf of the Scottish Government Health Directorates.

Consumer Focus Scotland

The Scottish Government

Clear English Standard

Appendix 3

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

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 medicines license 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
- An unlicensed medicine wishes to be used when a licensed version exists for this indication within the UK and is considered to be the most appropriate treatment for a particular patient AND the patient is likely to gain significantly more benefit/less side effects from the treatment than might from the licensed preparation OR
- To request orphan medicines (including those approved under risk sharing agreement with National Services Scotland) 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 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. 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.
- Within Cancer Services, the Oncology Medicines Management Committee (OMMC) 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 Individual Patient Treatment Request Panel for ratification. The Associate Medical Director and the will be copied in on the submission.

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 OMMC 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, CMT, 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:

Hospital: (please tick)

REH		RIE		RHSC	
ROODLANDS		RV		WGH	
AA		LIBERTON		ECC	

GP Surgery or Other Hospital (specify):

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

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:

Indication:
(if surgical procedure please go to clinical rationale for performing after completing this section)

Is this a licensed indication for this medicine?
NB: If the medicine is a licensed medicine that is being used outwith 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: ☐ NO: ☐

SMC guidance:
(please tick)

Accepted by SMC for this indication, but use is non-Formulary: ☐

Not accepted for use by SMC for this indication: ☐

New medicine that is awaiting SMC guidance (if known): ☐

Other relevant national guidance:

Medicine is recommended in a relevant NICE Multiple Technology Appraisal: ☐

(please tick)

	Medicine is recommended in a relevant SIGN Guideline:

Clinical rationale for use in this patient, including expected outcome: (For medicines please use Appendix 1 briefing template to assist in preparing this evidence and submit any referenced clinical papers with this form)	*NHS Lothian policy states that non-Formulary medicines should only be used in exceptional circumstances. Likewise, NHS Lothian policy is that surgical procedures without sufficient evidence of effectiveness should only be undertaken in exceptional circumstances* *In order to demonstrate exceptionality, the following referral 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 medicines license 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 intervention than might normally be expected from patients for whom NHS policy is not to use the medicine/surgery* *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.* *Appendix 1 gives a detailed template of how to prepare the evidence briefing for medicines to guide the submitting clinician. For surgical procedures, details of the surgical procedure including any papers or peer support for procedure any suspected side effects must be detailed below.* Continue on a separate sheet if necessary
Previous treatment for this indication: (Including duration)	
Expected duration of treatment (or cycles for oncology medicines); or for surgical procedures the estimated theatre time	
Estimate of expected cost: (indicate what cost is for e.g. For medicines the treatment period or per year for medicine; for surgical procedures the 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 authorised?	
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) submitted 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 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 Oncology Medicines Management Committee 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 - INDIVIDUAL PATIENT TREATMENT REQUEST (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 your 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 www.scottishmedicines.org.uk/smc/CCC_FirstPage.jsp
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 Clinical excellence (NICE) www.nice.org.uk/Guidance/TA/Published
MTAs Note 1,2 Multiple health technology assessments (MTAs) issued by NICE are reviewed by NHS Health 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. . **STAs** Note 1,2 The process for NICE Single Technology Assessments (STAs) is broadly similar to that adopted by the 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 www.wales.nhs.uk/sites3/page.cfm?orgid=371&pid=24773
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 eMC 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.

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 'exceptional', 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 may be the cost for one month's treatment or one treatment course. [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 the NHS Healthcare Improvement Scotland (HIS) website www.healthcareimprovementscotland.org/programmes/nice_guidance_and_scotland.aspx
2. The National Electronic Library for Medicines www.nelm.nhs.uk/en 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 the NeLM website. 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, previous SMC advice, comparative costs 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 3: ONCOLOGY MEDICINES MANAGMENT COMMITTEE

The Oncology Medicines Management Committee (OMMC) have devolved authority by the Medical Director and the NHS Lothian IPTR Panel to render decisions for cancer related treatments. The OMMC need to assess the application and indicate their approval for the treatment request. Support for approval may be subject to conditions of use (such as review of effectiveness etc). If the treatment request is not supported, reasons should be clearly documented on this form.

The applications considered at each meeting along with the decision given will be sent to the CMT Director of Operations (if not present at the meeting) for signature and then will be forwarded to the medical director/NHS Lothian IPTR panel for final ratification within 7 days of meeting. Clinicians should not prescribe/initiate treatment until a decision letter has been issued.

Date of meeting:	/ /
Patient details:	Name: Address: Date of Birth: CHI Number:
Consultant:	
Patient diagnosis and disease Stage:	

Previous systematic therapy:

	Therapy	Best response	Duration
First			
Second			
Third			
Forth			

Clinical trial available? Please indicate why patient is not eligible	

Oncology Medicines Management Committee Membership:

Head of Service Cancer/Palliative Care (or nominated deputy):	
Consultant Haematologist:	
Consultant Clinical Oncologist:	
Consultant Medical Oncologist:	
Lead Pharmacist, SCAN (or nominated deputy)	

Principal Pharmacist, ECC (or nominated deputy)	

Management Accountant	

Application approved:	Yes: ☐	No: ☐
If YES, conditions of use: (e.g. authorised for use for a specific time period)		
If NO, then please indicate the main reason for not supporting the IPTR:	Application failed to demonstrate exceptionality in relation to referral criteria above: *(Please document in detail below)*	☐
	The referral criteria of the IPTR are met, but there are other reasons for rejecting the request: *(please document in detail below)*	☐
	Incomplete form and/or insufficient detail to make an appropriate decision: *(please document in detail below)*	☐
Please clearly document in this area why the IPTR was not supported.		

Authorisation on behalf of committee:

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

Appendix 4a

Clinical Management Team Contacts
Associate Divisional Medical Directors, Clinical Directors and Directors of Operations
August 2011

MEDICINE & ASSOCIATED SERVICES		
Associate Divisional Medical Director		Casey Stewart
Clinical Directors	Emergency Medicine	Dave Caesar
	Acute Medicine, Psych, Metabolic & Toxicology, RIE	Randy Smith
	Acute Medicine, Metabolic & RIDU, WGH	Mark Strachan
	Acute Medicine, SJH	Andy Williams
	Cardiology and Cardiac Surgery	Neal Uren
	Dermatology	Roger Aldridge
	Respiratory Medicine	Alastair Innes

Director of Operations - Lyn McDonald

SURGICAL SERVICES		
Associate Divisional Medical Director		Tracey Gillies
Clinical Directors	Renal Medicine/Vascular Surgery	Caroline Whitworth
	Transplant & Gen Surgery	Steven Wigmore
	GI/Rheumatology	Vacant
	Urology/Colorectal	David Anderson
	Orthopaedics	John Keating

Director of Operations - Jane Todd

REAS & Medicine of the Elderly		
Associate Divisional Medical Director		Peter Lefevre
Clinical Directors	Forensic/Rehab/Psychotherapy	John Crichton
	General Adult Psychiatry and Old Age Psychiatry	Ihsan Kader
	Child and Adolescent Psychiatry and Eating Disorders	Duncan Manders
	MOE Rehab	Patricia Cantley
	MOE Acute	Conor Maguire

Director of Operations – Tim Montgomery

WOMEN'S, CHILDREN & DCN		
Associate Divisional Medical Director		Edward Doyle
Clinical Directors	Obstetrics	Rhona Hughes
	Gynaecology	Paul Dewart
	DCN	Mike Fitzpatrick
	Surgery, Anaesthetics ITU and Theatres	Mary Rose
	Medical Paediatrics	Paul Eunson
	CCH	Vacant

Director of Operations - Fiona Mitchell

ANAESTHETICS, THEATRES & CRITICAL CARE		
Associate Divisional Medical Director		Brian Cook
Clinical Directors	A&T, RIE	David Watson
	A&T, WGH	Talat Aziz
	A&T, SJH	Mike Brockway
	Critical Care	Mike Gillies
	HAN	Tim Morse

Director of Operations, Clinical Services - Michael Pearson

CANCER, HEAD & NECK AND IMAGING SERVICES		
Associate Divisional Medical Director		Victor Lopes
Clinical Directors	Ophthalmology	Jas Singh
	Radiology RIE & RHSC	Paul Allan
	Radiology WGH & SJH	Paul Allan
	Breast & Plastics (including hands)	Elaine Anderson
	Med Oncology, Haem & Palliative	David Cameron (Acting)
	Clinical Oncology	David Cameron (Acting)
	Max Fac, ENT & EDI	Victor Lopes (Acting)

Director of Operations - Sandra Mair

ALLIED HEALTH PROFESSIONALS (AHP)	
AHP Manager, Acute Services	Robert Packham

Appendix 4b

CH(C)P Management Contacts

CITY OF EDINBURGH CHP		
Associate General Manager		David White
Clinical Director		Ian McKay
Chief Nurse		Linda Cowie
Prescribing Lead		James Cowan
AHP Manager		Angela Lindsay

EAST LOTHIAN CHP		
General Manager		David Small
Clinical Director		Ian Johnston
Chief Nurse		Liz Cregan
AHP Manager		Morag Barrow

MIDLOTHIAN CHP		
General Manager		David Small
Acting Clinical Director		Hamish Reid
Chief Nurse		Liz Cregan
AHP Manager		Morag Barrow

WEST LOTHIAN CHCP		
General Manager		Marion Christie, Head of Health Jim Forrest, Director
Clinical Director		James McCallum
Chief Nurse		Gill Cottrell
AHP Manager		Sally Westwick

Appendix 5

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 6

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)

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 7

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	

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 8

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.