Clinical Policy

Prescribing of Non-Formulary Medicines (including Peer Approved Clinical System (PACS) Tier One & Two)

Policy Manager	Policy Group
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1 March 2013	Two Years/May 2020	May 2018

This Policy applies to Medical/Dental Staff

UNCONTROLLED WHEN PRINTED

Prescribing of Non-Formulary Medicines
(including Peer Approved Clinical System (PACS) Tier One & Two)

Version Control

Version Number	Purpose/Change	Author	Date
2.0.	To change the construction of the panel which considers Individual Patient Treatment Requests	Jill Nowell	June 2015
2.1.	Amendments made, flowchart included, and document reformatted.	IPTR Panel WG	November 2015
2.2.	Minor amendments made to terminology (IJB) and addition of timescales regarding submission of applications.	IPTR Panel WG	February 2016
2.3.	Addition of Policy Checklist and Equality Impact Assessment form. Minor amendments made to policy and flowchart (Appendix 1)	Jill Nowell/IPTR Panel	April 2016
2.4	Revision to accommodate PACS Tier one and two process	David Gill	December 17
3.0	Revision to accommodate updated SG guidance for June 2018 commencement of PACS Tier Two process	David Gill	May 2018

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APPENDICES

1. PURPOSE AND SCOPE

The safety, effectiveness and cost-effectiveness of medicines are controlled by regulatory and advisory processes. The two main processes are:

- The regulatory process - the majority of medicines that are prescribed have a marketing authorisation (i.e. licensed medicines). Safety, quality and efficacy are the criteria on which legislation to control human medicines licensing is founded. It is the responsibility of the Medicines and Healthcare Regulatory Authority (MHRA) or the European Medicines Evaluation Agency (EMEA) and the expert advisory bodies to ensure that the sometimes difficult balance between safety and effectiveness is achieved.

- The advisory process - the Scottish Medicines Consortium (SMC) issues advice on the use of newly licensed medicines and new licensed indications, based on the cost-effectiveness of the medicine.

NHS Tayside has had for some time a robust procedure in place for the timely introduction of SMC guidance into the Tayside Area Formulary and clinical use. Newly SMC approved medicines prompt a Local Introduction Form to be completed by a clinician and Principal Pharmacist which is then reviewed by the Medicines Advisory Group, a subgroup of the Area Drug and Therapeutics Committee (ADTC) for inclusion on the formulary/specialist list.

Further to this CEL 17 (2010) (https://www.scottishmedicines.org.uk/files/CEL2010_17.pdf) outlines the need for NHS Boards to have a clear process for introduction of new medicines and consistency of process, as well as outlining NHS Boards responsibilities regarding openness and transparency of process and decisions with the public. Key aspects of considering Individual Patient Treatment Requests are also covered. The Scottish Government Health Department (SGHD) New Medicines Review: Response to the Health and Sport Committee October 2013 included a commitment to early withdrawal of the established Individual Patient Treatment Requests (IPTR) and replace it with a newly envisaged “Peer Approved Clinical System” (PACS).

The Chief Pharmaceutical Officer wrote to NHS Boards on 15th November 2017 providing guidance on the implementation of the Peer Approved Clinical System (PACS) Tier Two to replace existing Board IPTR processes with effect from 1st February 2018. Following some concerns about the criteria used in considering PACS Two submissions, and the national appeal process, revised guidance was issued with an implementation date of 1st June 2018

The scope of this policy extends to the prescription of:

Unlicensed	
Category 1	Unlicensed medicines requests, including special formulations
Licensed	
Category 2	‘Off-label’ medicines requests, i.e. use out with their licensed indications, or medicines where no submission has been made to SMC.
Category 3	Peer Approved Clinical System Tier one (Ultra-orphan) and Tier two requests
Category 4	Non-formulary requests out with NHS Tayside Drug and Therapeutics Committee advice. This includes medicines that are accepted by SMC but are not listed in the formulary/specialist list or local protocols.

Where the prescriber wishes to prescribe in any of the above circumstances, a proforma should be completed (see *Appendices 3 and 4*).

2. DEFINITIONS

2.1. Marketing Authorisation

Previously medicines were described as having a "*product licence*". Under the new arrangements, medicines are now more correctly described as having a marketing authorisation. A marketing authorisation defines the clinical conditions, routes of administration, dosages and precautions for which the licensing authority has approved a medicine.

2.2. Unlicensed Medicines and 'Off-label' Medicines

Prescribing practice involves the use of unlicensed drugs, (products which have not been licensed for human medical use) and off-label drugs (licensed medicines prescribed outside the terms of their marketing authorisation).

2.3. Specials

Special formulations of medicines are produced for clinical reasons where an existing formulation of an available licensed product is not suitable or available for the patient.

3. BACKGROUND INFORMATION

The Licensing of Medicinal Products is covered by the Human Medicines Regulations 2012. The Licensing Body in the UK is the Medicines and Healthcare Products Regulatory Agency (MHRA), but in many cases, the relevant Licensing Body is now the European Medicines Evaluation Agency (EMEA).

A product holding a full Marketing Authorisation (MA) will do so after a full evaluation by the MHRA or EMEA of all data required for the product. The MA holder is required to ensure that full Product Information is supplied to both the prescriber and dispenser of the product. The MA confers liability upon the Holder for the product in use when the terms of the licence are complied with.

The majority of medicines prescribed within NHS Tayside are covered by marketing authorisations and the manufacturer is held liable for any harm caused where the cause can be solely attributed to a defect in the product, and it can be proved that the product was prescribed and used in accordance with the terms of the Marketing Authorisation.

For good clinical reasons, a number of medicines that either do not have a marketing authorisation (Unlicensed medicines) or are prescribed for indications out with their marketing authorisation (Off-label use), are used within NHS Tayside. Were this practice to be curtailed, the treatment of patients would be impeded.

Prescribers of unlicensed medicines have a personal liability for their prescription that cannot be transferred to the manufacturer or importer of the medicine. NHS Tayside carries a liability for the actions of its employees and may accept liability for the prescription of unlicensed medicines provided that this Policy on the Prescribing of Medicines that are Non-Formulary is adhered to.

Where it is intended that treatment will be continued after patient discharge, clear arrangements require to be agreed between primary and secondary care regarding clinical and prescribing responsibilities, using appropriate processes such as shared care arrangements. Prescribers are referred to the NHS Tayside Shared Care Policy. Retention of prescribing responsibility within secondary care should be considered as an option.

4. STATEMENT OF POLICY

The clinical liability associated with the prescribing of unlicensed medicines or medicines prescribed out with their marketing authorisation may be accepted by Tayside Health Board, provided that its employees have followed this policy for the prescribing of such medicines.

The NHS Tayside Drug and Therapeutics Committee have the responsibility to define local policies to guide the prescribing of unlicensed medicines within NHS Tayside. Where a licensed medicine is available, it should be prescribed in preference to any unlicensed equivalent alternative.

The following criteria should be applied, at all levels of the decision making process, prior to the decision to prescribe a non-formulary/non specialist list medicine.

- There is no suitable licensed alternative, if unlicensed, out with licence or pre-SMC or out with SMC.
- The risk-benefit assessment for the patient is in favour of prescription.
- There is a clinical and economic evidence-base to support this usage.
- The patient is an exceptional case.
- Prescribing is supported by multi-professional opinion.
- The patient/carer has been fully informed and has consented or will consent.
- There is a risk associated with waiting for treatment. (Consider when products are about to be licensed or SMC advice is about to be issued.)

Prescribers should only commence a prescription medicine for a non-formulary medicine when the appropriate approval outlined in *Appendix 1* is granted. In an effort to ensure a consistent approach across NHS Tayside, completion of the proforma detailed in *Appendix 1* is essential.

Secondary care prescribers should only request that primary care continues the prescribing of a medicine that is non-formulary when the appropriate approval is granted through this policy, an adequate secondary care trial of medication has established tolerability and benefit of treatment, a shared care agreement/individual patient treatment plan is in place where appropriate and the arrangement has been agreed by the patient's GP.

Whilst Patient Group Directions may be developed for the supply of medicines prescribed out with their marketing authorisation, such cases are likely to be exceptional and it is expected that a clear justification for the use made. Non-medical prescribers are referred to the Tayside Non-Medical Prescribing Policy.

5. POLICY PROCESS

NHS Tayside makes a distinction between prescribing for groups of patients which should be done via submission to the Medicines Advisory Group for inclusion on the Tayside Area Formulary (TAF)/Specialist List and that for Individual Patients.

5.1. Prescriptions for Unlicensed Medicines, including Special Formulations (Category 1)

5.1.1. Unlicensed Medicines

The NHS Tayside Drug and Therapeutics Committee expects that all **prescriptions for a new unlicensed medicine** should be brought to attention of the prescribers Clinical Group and the proforma outlined at *Appendix 3* should be used to seek this approval from the appropriate Clinical Group/Directorate committee. The decision to prescribe or otherwise should be documented in the patients notes and the non-formulary data-base should be completed.

5.1.2. Special Formulations

The prescription of unlicensed special formulations or 'Specials' is uncommon within NHS Tayside. A 'Special Formulation' is defined by the Medicines and Healthcare Products Regulatory Agency (MHRA) as an "unlicensed relevant medicinal product placed on the market". These are prescribed in both secondary and primary care.

A 'Special' should only be prescribed where no licensed formulation is available to meet a prescription presented by a patient for:

- Unusual strengths of existing licensed products
- Unusual presentations of existing active principles
- Imported products (not otherwise available in the United Kingdom)
- Preservative-free alternatives to licensed formulations
- Other products not otherwise commercially available.

Where an unlicensed special formulation is prescribed and dispensed, the following additional conditions are noted:

- The prescriber must be appraised by the pharmacist that he or she bears clinical responsibility for prescribing an unlicensed product, and that full prescribing information about the product is probably unavailable. This approach should be made when the first prescription or order is received.
- The pharmacist supplying the product shares clinical responsibility for the suitability of the product for the individual patient. He or she also bears responsibility for the quality of the product, and is also obliged to be certain that the product is fit for safe use by the patient. Community pharmacists should be aware of and follow the NHS Tayside policy on permission to supply specials.

The prescribing of a special formulation of a Tayside formulary medicine does not require submission of a non-formulary request form.

5.2. Licensed Medicines (Categories 2, 3 & 4)

The prescription of medicines, **outside their marketing authorisation,** is not common within NHS Tayside, however patients may require medicines for conditions not specified or at dosages not recognised by current licences. On occasion, a clinician may be unaware that the intended use is not a licensed use. This can occur where medicines within the same class do not have the same range of licensed indications. Many medicines prescribed in paediatrics are not licensed for prescription in neonates or children (see Section 5.3. 'Prescribing in Paediatrics').

For **routinely prescribed licensed medicines in an unlicensed context or routinely prescribed unlicensed medicines**, it is acknowledged that it is very difficult to maintain a comprehensive approach and to secure approval via the application form at *Appendix 3* in a timely and efficient manner. Application for inclusion in the formulary or specialist list would be considered if medicine routinely prescribed in a reasonable number of patients and there is good evidence base, safety profile and established practice. (Link to: 'What medicines to be included on formulary').

The risk assessment process is reflected only in the commonality of approach adopted by a wide range of clinicians. In any case of liability assessment, this would be the basis of defence i.e. that peer group practice clearly supported the prescriber. A list of such medicines should be held within each Clinical Group.

The Area Drug and Therapeutics Committee expects that **all unusual and not well-understood unlicensed prescription of licensed medicines** (Category 2) should be brought to attention of the prescribers Clinical Group and Lead Clinician for that speciality. Such medicines and prescribing practice should be formalised by that clinical area. A prescription for an item not on the formulary/specialist list should not be produced until approval is granted through the application form in *Appendix 3*. The decision to prescribe or otherwise should be documented in the patient's medical notes and an entry included in the Clinical Group/Directorate non-formulary database.

If clinicians wish to prescribe a medicine for an individual patient that

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

they should make a case using Peer Approved Clinical System Tier Two (PACS2) and complete the proforma at *Appendix 4* (see Item 6 for further information). The decision to prescribe or otherwise should be documented by the clinician in the patient's medical notes and an entry included in the PACS database.

The Area Drug and Therapeutics Committee expects that, in exceptional circumstances, when a **non-medical prescriber wishes to prescribe a medicine for an unlicensed purpose**, a supporting decision is gained under the non-formulary process using the proforma at *Appendix 3*. The decision to prescribe or otherwise should be documented in the patient's medical notes.

To reiterate, in all of the above situations, it is expected that approval for prescription is granted either via the application form at *Appendix 3 'Request to Prescribe a Non Formulary Medicine' or the PACS application form at Appendix 4* which will be considered in the first instance by the Lead Pharmacist for the Clinical Group or Integrated Joint Board (IJB). The Lead Pharmacist is expected to give advice on the appropriateness of the request and to identify realistic alternatives, to progress the application to the non-formulary panel as appropriate and also ensure completion of the non-formulary database. Both forms can also be accessed from the TAF front page.

5.3. Prescribing in Paediatrics

Due to the number of medicines that are not licensed for paediatric use, it is recognised that the routine obtaining of consent for unlicensed prescribing in **paediatric practice** is not usual.

Prescribers in paediatric practice must be able to provide justification for their actions if they do not provide suitable information to the patient and carer and gain their consent. It is therefore recommended that prescribing follows nationally accepted practice and reflects the advice given in the British National Formulary for Children (BNFC).

It is also recommended that routine prescribing practice out with BNFC guidance be held on specialist list for paediatric prescribing. However, if the medicine is unlicensed or off-label and not prescribed routinely (an unusual and not well understood unlicensed prescription) within paediatrics, then prescribing should only follow approval via the proforma at *Appendix 3*.

The final decision to prescribe or otherwise should be documented in the patient's medical notes and an entry included in the non-formulary/ database.

6. PEER APPROVED CLINICAL SYSTEM (PACS) TIER ONE & TWO (CATEGORY 3)

There may be occasions where a prescriber feels that his/her patient will benefit from a licensed medicine that has been recommended not to be used in NHS Scotland, i.e. medicines either awaiting SMC guidance or the SMC has recommended should not be routinely used in NHS Scotland. Requests for such non-formulary medicines are covered by the PACS Tier Two process and can only be progressed if the clinician responsible for the patients care supports this action. Requests for Ultra-orphan Medicines that have been considered by SMC and not recommended for use in Scotland by SMC are covered by the PACS Tier One process, which uses the same principles outlined below. At this point the patient or their carer should be given the leaflet 'New medicines in Scotland – who decides what the NHS can provide?', as well as explaining the timeframes for decision making and that they are the patients point of contact in NHS Tayside for this process. This should be documented in the patient's case notes.

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

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

A PACS request will only be considered when the application is fully completed and submitted electronically to the appropriate key contact identified in Section 10.

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

Factors submitted from clinicians to evidence both criteria may include:

- an increased capacity to benefit
- an overriding clinical need
- features which suggest a likelihood to benefit from treatment
- expected survival rates
- intolerable side effects from conventional treatment
- ineligibility for a clinical trial
- the balance between benefit and risk (for example adverse effects or contraindications)
- Specific genetic sub-types where clinical evidence is stronger
- Individual characteristics are present which have been shown to have a positive influence on response.

6.1. Making a PACS Application - Support from Peers/Multidisciplinary Teams

As part of best practice and in order to strengthen the case being made, the requesting clinician must seek peer support for their application from another NHS Clinician with suitable experience in treating the condition for which the medicine is being requested. The reviewing clinician may

be from the same NHS Board, but if there are no other clinicians with suitable expertise locally, then experts within the NHS from elsewhere in Scotland or the UK can provide the peer review.

In providing a peer review of the information presented for the patient, the reviewing clinician is considering that (a) the alternative accepted medicines have been considered and excluded as suitable treatment options and (b) the patient characteristics detailed and the clinical evidence presented imply that the response to treatment will be at least comparable to, if not increased, compared to the population considered by SMC

Part C of the PACS tier two paperwork must be completed by the reviewing clinician

Similarly, where the care of the patient in question is under the care of a multi-disciplinary team, clinicians should seek their support for the PACS Tier Two application.

6.2. Panel Constitution

An NHS Tayside PACS panel is currently convened on a monthly basis to consider all PACS requests (Category 3). PACS Requests must be submitted according to the timescale shown on the Non Formulary request area of TAF to the lead contact as detailed at item 10. 'Key Contacts'. The PACS Panel will be chaired by a senior clinician

The PACS Panel will be comprised of the following members:

PACS 2 Panel Constitution	**Current Member as of May 2018**
Senior Clinician eg Consultant Medicines Directorate	James Cotton (Chair)
Senior Clinician eg Consultant Specialist Services	Gillian Stewart
Senior clinician e.g. Consultant Haematology	David Meiklejohn
Clinician member of Area Drug and Therapeutics Committee (or an alternative clinical lead)	Jacob George
Senior Pharmacist, Prescribing Support Unit (Professional Secretary) (or deputy)	David Gill
Senior Pharmacist, Oncology	Katherine Cowie

A senior pharmacist from the Prescribing Support Unit will act as the professional secretary for the group and will ensure all applications are appropriately completed and prepared and the decisions made are accurately recorded and communicated within the agreed timescales.

The PACS Panel will meet to consider the application. In order to make a decision four members of the group must be present (including the Chair or Deputy Chair, one other clinician, and one pharmacist).

The professional secretary will complete the PACS decision record section on the application form.

Where an application is not supported by the PACS Panel the requesting clinician will be advised of the appeals process.

6.3. Patient Involvement in the PACS Tier Two process

In addressing patient and public involvement in PACS Tier Two, NHS Boards and requesting clinicians should undertake the following:

- the requesting clinician should provide the patient with the PACS Tier two national patient information sheet as soon as a decision has been taken to make a request through PACS Tier Two
- The requesting clinician will present the case to the panel for the medicine on behalf of the patient (or patient's representative) using the standardised national paperwork (outlined at Annex C). In doing so, they will have ensured that the patient understands the application which is being submitted on their behalf and has consented to its submission;
- Verbal and written statements by patients must not be submitted to the panel;
- Where appropriate, the clinician should provide the contact details of suitably trained personnel within the NHS Board who can provide further advice and support to the patient/patient representative and could including any other patient information and support mechanisms available.

6.4. Communicating PACS Decisions

On reaching a decision, the note of the PACS decision (Part D of the panel paperwork) should be emailed to the requesting clinician on the original electronic application within 5 working days, or within the same day if possible if clinical urgency demands this. The record should include the rationale for the decision including where possible a detailed breakdown of the panel's assessment of the application against the decision making criteria and should be as comprehensive as possible to aid understanding of the decision.

PACS Tier Two decisions should be communicated to the patient/patient representative by the requesting clinician responsible for their care within a timescale previously agreed with the patient/patient representative

The requesting clinician should discuss the outcome of the PACS request in detail, and clarify the options open to the patient for their future treatment. If felt appropriate the clinician can make an application for a national review of the PACS Tier Two decision via the National Review Panel (see Annex B for specific information on the review application process).

In addition to the national review process, if a patient is not satisfied with the way the PACS Tier Two process was handled, they can progress their concerns via the NHS complaints process.

There is no right of appeal currently for PACS Tier One applications however if the panel does not support the application it should seek further information from the requesting clinician.

7. REVIEW PROCESS

7.1. Non formulary requests

An Appeals Process has been set up to allow any prescriber to appeal against the decision made by the Clinical or IJB Group. An Appeal may be requested where it is considered that:

- The Clinical/IJB Group or non-formulary panel has failed to act fairly and in accordance with its procedures.
- The Clinical/IJB Group or non-formulary panel has prepared advice that is perverse in light of the evidence submitted.
- The Clinical/IJB Group or non-formulary panel has exceeded its powers.
- The appeal panel will exercise additional 'flexibility' in cases where the decision is in the balance or where further clinical opinion is considered desirable, by deferring to designated clinical specialists from other boards for a second opinion on specific questions. This will be influential in the final outcome.

Appeals against rejected non-formulary requests will be heard by the NHS Tayside Executive Appeals Panel, which should be made up of the following personnel:

- NHS Tayside Chief Executive or executive director deputy
- Chair of the Drug and Therapeutics Committee
- NHS Tayside Medical Director
- Director of Pharmacy
- Non-Executive Director
- Chair of the relevant Clinical/IJB Group panel where decision was turned down
- Appellant

The appeal should be submitted in writing to the Medical Director and heard by the Appeals Panel within 20 working days (Monday to Friday) of receipt, unless it is clinically essential to be earlier as stated on the request form.

The decision of the Appeals Panel should be forwarded to the Appellant verbally immediately after the meeting and, in writing, within 48 hours (Monday to Friday).

Decisions should be documented in the patient's notes by the Appellant. An entry should also be included in the non-formulary database.

7.2. PACS Tier Two Review Process

In the event where a requesting clinician and patient feel they have grounds for a review of a local PACS Tier Two decision, a National Review Panel will be established to independently review and make recommendations to the relevant NHS Board on their original decision.

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

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

The Panel will undertake a review of the evidence presented and will consider whether due process has been correctly followed and/or that the decision reached was reasonable on the basis of the evidence presented

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

National Review Panel is a function within Healthcare Improvement Scotland (HIS) who will facilitate support to the Panel. HIS personnel will not be part of the review process.

It is the responsibility of the requesting clinician, with the patient's consent, to submit an application to the National Review Panel, by completing Appendix 1 of the original PACS Tier Two paperwork submitted to the Board's PACS Tier Two Panel. The requesting clinician should provide a robust case for the review, including any substantiation of procedural impropriety and/or that the decision could not have been made reasonably on the basis of the evidence presented. In the event that the clinician is requesting a review because the NHS Board failed to follow due process then the clinician should also send the Board's PACS Teir Two process.

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

As with a PACS Tier Two request, NHS Boards should put in place appropriate mechanisms for clinicians in advance of making a request for national review to ensure applications are

submitted as effectively and efficiently as possible. This includes advice regarding appropriate evidence and completion of paperwork.

7.3. Applications

An application to the National Review Panel must be made by the clinician, through a secure NHS Scotland email address. The clinician should also redact information relating to patient identifiable information in advance of it being submitted to the National Review Panel (via Healthcare Improvement Scotland), in line with data protection requirements. The information which should be redacted should be as follows:

Part A: Request Details:

- Patient's CHI No
- Patient postcode
- Part B: Case for Prescribing
- Any person identifiable references to the patient
- Part C: Peer Support
- Any personal identifiable references to the patient
- Part D: PACS Tier Two Decision record
- Any named references to the patient

Healthcare Improvement Scotland will notify the Chief Executive, Medical Director and Director of Pharmacy in the relevant NHS Board that an application for a PACS Tier Two Review has been made.

Where new evidence for the medicine emerges or if the original decision was based on a factual inaccuracy, the application should not be referred to the National Review Panel but the clinician should pursue a resubmission through the initial NHS Board PACS Tier Two process.

No new evidence will be considered by the National Review Panel.

The National Review Panel refer to the decision making criteria as the local NHS Board PACS Tier two Panel which is laid out in this guidance.

Evidence to be submitted at the time of the request and that will be considered by the National Review Panel includes:

- The original request submitted to the Board's PACS Tier Two Panel (Parts A-D of the paperwork
- Appendix 1 of the paperwork completed by the requesting clinician making the case for procedural impropriety or that the decision could not have been made reasonably on the basis of the evidence presented
- Any additional note of the meeting or evidence relating to the case by the NHS Board and
- The NHS Board's PACS Tier Two process and procedures

Both the NHS Board and the requesting clinician will be invited to attend and present at the National Review Panel.

7.4. Outcome of the Review Process

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

The National review Panel will either make a finding:

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

In the event that the Panel make a finding that the review ground(s) is/are not established then the NHS Board will **not be expected** to revisit the original decision.

If the ground(s) of the review is/are established then the case will be redirected back to the BHS Board who will be expected to convene a new PACS Tier Two Panel in order to revisit their original decision, taking into account the National Review Panel reasoning as the why it considered either the original decision unreasonable in light of the evidence submitted and/or that due process had not been followed.

The National Review Panel will issue its findings and recommendations to the Board Chief Executive, Medical Director and Director of Pharmacy, ideally within one day of the panel meeting.

The NHS Board must inform the requesting clinician as soon as practicable, taking into consideration any clinical urgency, of the National review Panel's decision and recommendations

The final decision is for the NHS Board to determine. The NHS Board should convene a new PACS tier Two panel to consider the request and ensure that the final PACS Tier Two decision is communicated within a timescale that takes into account any associated clinical urgency and/or the patients clinical needs.

It is the responsibility of the requesting clinician to inform the patient or the final decision.

There will be no further right of appeal.

8. RESPONSIBILITIES AND ORGANISATIONAL ARRANGEMENTS

Responsible Person	Responsibility		Organisational Arrangement
Individual Prescriber	To gain peer support for the prescribing decision from Lead Clinician or other consultant in the field if this is not possible before application:		See: *Appendix 3*: 'Request to prescribe a non-formulary medicine' or *Appendix 4:* 'PACS Request Form'
	Unlicensed	*Category 1*: Unlicensed medicines requests, including special formulations	
	Licensed	*Category 2*: 'Off-label' medicines requests, i.e. use out with their licensed indications, or medicines where no submission has been made to SMC *Category 3*: PACS requests *Category 4*: Non-formulary requests out with NHS Tayside Drug and Therapeutics Committee advice. This includes medicines that are accepted by SMC but are not listed in the formulary/specialist list or local protocols.	
Lead/ Principal Clinical Pharmacists	To review the evidence that supports individual requests to prescribe non-formulary medicines and suggest alternatives, approve request or escalate to non-formulary panel. To provide advice and support to clinical group/IJB		Clinical Group/ Joint IJBs
Prescribing Support Unit	To receive requests for PACS (Category 3) following screening by a clinical pharmacist and process these through the PACS panel. To maintain a record of PACS decisions and provide a regular report to MAG		MAG
Clinical Groups and IJBs	To establish and maintain processes to enable the transparent review of significant non-formulary requests		Clinical Group/ Joint IJBs
NHS Tayside Area Drug and Therapeutics Committee	To monitor the implementation of the Policy on the Prescribing of Medicines that are Non-Formulary. To review situations in which medicines are requested by secondary care for use in primary care which require a shared care protocol.		ADTC

9. PATIENTS RECEIVING CONCURRENT TREATMENT FROM NHS AND PRIVATE PROVIDERS

The following guidance was issued from the Scottish Executive (SEHD/CMO(2007)3) in February 2007.

1. Clinicians may receive requests from patients to supplement NHS treatments with drugs or other treatments not currently available from the NHS following SMC and/or NHS Quality Improvement Scotland advice. This guidance sets out the legal position and the process that should be followed in such circumstances.

2. If a patient seeks to pay for one or other part of a possible treatment episode or total package of care not currently available from the NHS whilst at the same time continuing with the rest of that episode or total package of care within the NHS Scotland, NHS Boards will wish to be aware that:

   - There is no legislation that allows NHS Boards to require the patient to pay for all aspects of their treatment if they opt to pay for a particular drug or other treatment not currently available from the NHS
   - There should be protocols and processes already in place within NHS Boards for consideration of such non-NHS Formulary treatment requests. (This policy covers such prescribing for exceptional use).
   - If, in the opinion of the prescribing clinician there is a case to be made, non-NHS formulary protocols and processes should be followed in all such cases in line with local guidance. (This policy covers such exceptional use prescribing).
   - Each request for non-NHS formulary treatments (prescribing for exceptional use) should, therefore, be considered on its individual merit.
   - NHS Consultants cannot treat a patient both as a private patient and as an NHS patient for the treatment of one condition during a single visit to an NHS organisation (section 2.2 of the Consultants Contract).

   If a patient who has been offered a treatment or total package of care from the NHS chooses to reject this in favour of an alternative option not currently available from the NHS (see paragraph 1) and where non-formulary (prescribing for exceptional use) request process(es) have been exercised and exhausted, they should be advised of alternative options that may be available, for example, provision via the independent sector of the treatment in question and/or total package of care as appropriate to the individual case.

3. A patient cannot be both a private and an NHS patient for the treatment of one episode of care (see paragraph 2). For patient safety reasons and good clinical governance, protocols should be in place to ensure safe and effective handover of the patient to the lead independent sector clinician or to ensure the safe provision of concurrent treatment where appropriate. NHS Boards should seek to establish such protocols with independent sector providers.

4. This guidance does not override the individual responsibility of health professionals to make decisions in the exercise of their clinical judgement in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

10. KEY CONTACTS

Category Type 3 (PACS Tier One and Two) Requests

Carol Walkinshaw
Business Manager, Pharmacy Service
E-mail: carol.walkinshaw@nhs.net

Oncology & Haematology Category Type 1, 2 and 4 Requests

Lynn McKenzie
Pharmacy Team Support Officer (Oncology)
E-mail: lynn.mckenzie@nhs.net

All other Category Type 1, 2 and 4 Requests

For other Directorates/Clinical Groups the Principal Pharmacist should be contacted for processing of requests.

11. SOURCES OF INFORMATION

(1) MHRA Guidance Note 14: The supply of unlicensed relevant medicinal products for individual patients. Medicines and Healthcare Products Regulatory Agency, May 2005.

(2) BNF for Children 2005. BMJ Publishing Group Ltd. London 2005.

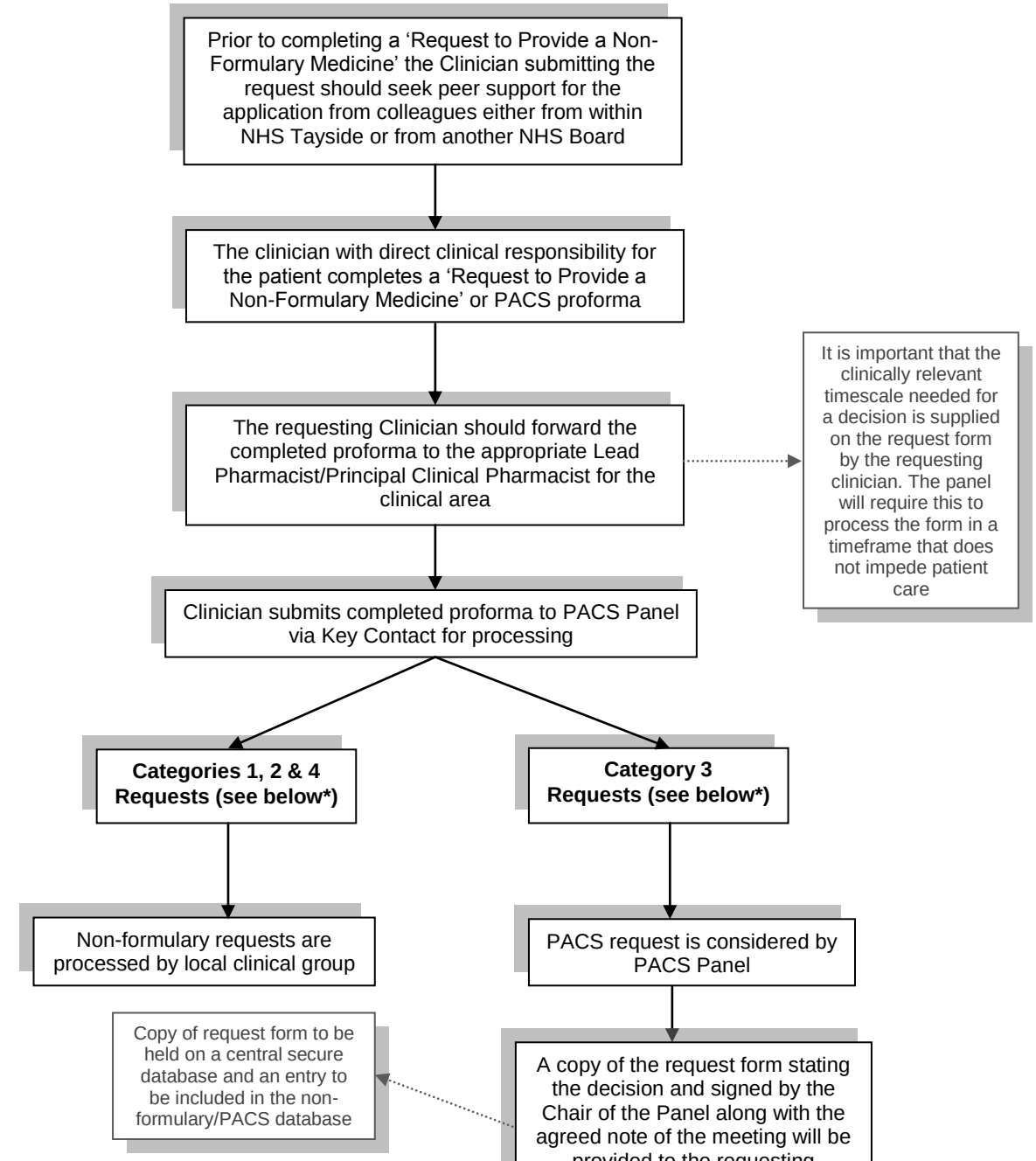
(3) Page D. *Special formulations in primary care: A guide for pharmacists*. Information and Statistics Division, Edinburgh. 2002.

(4) Royal College of Paediatrics and Child Health. The use of unlicensed medicines or licensed medicines for unlicensed applications in paediatric practice. Policy statement produced by the joint RCPCH/NPPG Standing Committee on medicines. www.rcpch.ac.uk [Dec 2013].

(5) Faculty of Family Planning and reproductive health care Clinical Effectiveness Unit Guidance (2005). The use of contraception outside the terms of the product licence. J. Fam Plann Reprod Health care 2005: 31(3); 225-241.

REQUEST TO PRESCRIBE A NON-FORMULARY MEDICINE

FLOWCHART



CATEGORIES*	
Unlicensed	
Category 1	Unlicensed medicines requests, including special formulations
Licensed	
Category 2	'Off-label' medicines requests, i.e. use out with their licensed indications or medicines where no submission has been made to SMC
Category 3	PACS requests - licensed, not recommended by SMC etc.
Category 4	Non-formulary requests out with NHS Tayside Drug and Therapeutics Committee advice. This includes medicines that are accepted by SMC but are not listed in the formulary/specialist list or local protocols.

NHS Tayside

REQUEST TO PRESCRIBE A NON-FORMULARY MEDICINE

GUIDANCE NOTES

Requests to prescribe a non-formulary medicine (Category 1,2 and 4) should be considered by the relevant group as follows:

- Secondary Care – relevant Clinical Group
- Oncology and Haematology requests – Oncology & Haematology Medicines Management Group (OHMMG)
- Mental health, Care of the Elderly, General practice requests – relevant Clinical Group

The Clinical Group/OHMMG must consider whether there are overriding factors that make the decision not to prescribe unreasonable in the particular circumstances.

Please Note:

- Secondary care clinicians who wish a patient to receive a medicine that is unlicensed or has not been submitted to SMC advice should make a case to their Clinical Group, as well as complete the proforma in Appendix 3. Prescribing approved by the Clinical Group and/or non-formulary panel remains the clinical and financial responsibility of secondary care ie such medicines should normally be supplied from hospital. Primary care should only be asked to continue prescribing if: This is the best care delivery method for the patient AND an adequate secondary care trial of medication has established tolerability and benefit of treatment AND a shared care agreement/ Individual Patient Treatment Plan is in place where appropriate AND the arrangement has been agreed by the patient's GP.
- A separate form should be completed for each case, this process is not to be utilised for treatment of groups of patients where it is known at the time a group exists. For groups of patients a submission should be made to the Medicines Advisory Group after approval of the appropriate clinical group if in secondary care.
- Following discussion by the Clinical Group/OHMMG, completed forms should be forwarded to the relevant Principal or IJB Lead Pharmacist . The non-formulary database should also be completed.
- Appeals should be submitted as outlined in section 7 of the policy, seek early advice from the appropriate Principal/Lead Pharmacist if required.

Guidance on specific questions:

Requested medicine (Q.5)

The approved (generic) and brand name should be entered

Anticipated duration of treatment (Q.8)

Length of treatment should the unlicensed/new medicine be approved for use in this patient e.g. one course of 7 days; life-long; or duration of trial period, if that is what is intended.

Cost (Q.9)

The NHS cost for a relevant treatment period e.g. per course or per 28 day treatment period.

Reason for request (Q.11)

If the medicine is continued from another health board then details of that approval would be helpful to the application but NHS Tayside will make an independent decision.

Treatment continuation (Q.12)

If secondary care wishes to transfer the liability of prescribing to primary care on the basis that this is necessary for the patients optimal care, the appropriate approval of primary care must be sought, confirming to Primary Care that a PACS is in place, see notes above.

Previous treatment options and alternatives (Q.13 & 14)

Provide details of previous treatment options the patient has received. State any alternative medicines also licensed for the indication and reasons why they are not being used in this case.

Clinical evidence (Q.15)

Provide details of clinical outcomes associated with this unlicensed/new medicine in this patient group e.g. increase in disease free survival, overall survival and quality of life. Indicate the quality of evidence to support use, attach relevant references. For Category 1, unlicensed medicines, evidence of safety is vital to construct a risk: benefit argument supporting use. If the medicine represents a financial liability then evidence of cost effectiveness will usually be required, such as alterative costs saved, hospital admissions reduced etc.

Treatment outcomes and timescales (Q.16)

In order to ensure financial governance clear timescales for treatment trial, duration and exit strategies will need described. Objective measures of treatment success and failure resulting in treatment stopping will usually need to be described, it is also desirable for this to explained to the patient if clinically appropriate.

Service Implications (Q.17)

Describe any service pressure that will result, such as additional expensive tests/monitoring. Describe any service savings if not previously described.

Exceptionality (Q.18)

In this section you must explain why this patient's clinical circumstances and potential response to treatment with this medicine would be significantly different from the patient group/population considered by SMC/NHS QIS or NHS Tayside. The significant benefit you expect this patient to gain must be clearly explained and how you expect to measure/demonstrate this.

Timelines (Q. 21)

Please describe the timescale within which a decision is needed. It is very difficult to hold frequent panels, NHS Tayside will endeavour to hold in-person panels for these requests. Should an urgent decision be clinically necessary please indicate this and why. A decision will be taken via the most appropriate communication means to meet the clinical deadline.

Declaration (Q.22)

It is important to describe this process to the patient/carer, and to explain that the request may be rejected so as not to raise false hope/expectation if this is clinically appropriate. Ensure also you provide the patient/carer with the described leaflet, the hyperlink to which is on the electronic form (see *Appendices 4 & 5*).

Completed Form for PACS process must be submitted to the appropriate Key Contact detailed below:

Carol Walkinshaw
Business Manager, Pharmacy Service
E-mail: carol.walkinshaw@nhs.net

NHS Tayside

REQUEST TO PRESCRIBE A NON-FORMULARY MEDICINE

This form (guidance on completing this form is available in Appendix 2) should be completed by the clinician* who wishes the patient to receive a non-formulary medicine in any of the following circumstances:

Unlicensed	
Category 1	Unlicensed medicines requests, including special formulations
Licensed	
Category 2	'Off-label' medicines requests, i.e. use out with their licensed indications
Category 3	PACS requests use separate National form at *Appendix 4*
Category 4	Non-formulary requests out with NHS Tayside Drug and Therapeutics Committee advice. This includes medicines that are accepted by SMC but are not listed in the formulary/specialist list or local protocols.

* Note that a Specialist recommending treatment should complete this form and submit to the relevant Clinical Pharmacist.

Guidance on completing this form is available at *Appendix 2*.

1. Clinical Group/IJB:			
2. Clinical Team/Speciality:			
3. Requesting Clinician:			
4. Patient CHI:			
5. Requested Medicine:			
6. Indication the medicine is to be used for:			
7. Dose (including strength, form and frequency):			
8. Anticipated duration of treatment:			
9. Treatment Cost:		**Annual Cost:**	

10. Exception Category: (*please tick*)

☐ Category 1: Unlicensed medicines requests, including special formulations **(NB: Read Policy Section 3)**

I have read and understood Section 3 – Signed: ……

☐ Category 2: 'Off-label' medicines requests, i.e. use out with their licensed indications and/or medicines not submitted to SMC

☐ Category 3: Use separate form at *Appendix 4 (PACS)*

☐ Category 4: Non-formulary requests out with NHS Tayside Drug and Therapeutics Committee advice. This includes medicines that are accepted by SMC but are not listed in the formulary/specialist list or local protocols.

11. Reason for Request:

Continuation of medicine initiated in primary care: ☐ **Go to Section 22**
(If previous authorisation not granted: supply may be refused)

Continuation of previous hospital supply: ☐ **Go to Section 22**
(If previous authorisation not granted: supply may be refused)

Continuation of medicine approved in other health board: ☐

New treatment decision: ☐

12. Will treatment continue:

Only in hospital ☐ **Hospital, then in primary care** ☐

If to be continued in primary care:

Individual Patient Treatment Plan written* ☐

***Seek advice from Principal Pharmacist.**

13. Previous treatments that the patient has received:

14. Explain why available licensed and formulary medicines are not appropriate in this case:

15. Summary of peer reviewed evidence for use in this indication in terms of safety, clinical and cost effectiveness if available (attach relevant references)**:**

NB: If for Category 1 or 2 then safety evidence is necessary to enable a risk/benefit assessment.

Evidence Quality (*Please tick)*

	I	RCTs
	II	Case control or cohort studies
	III	Non-analytic studies e.g. case reports, case series
	IV	Expert opinion

16. Treatment Outcomes and Timescales:

Please note that treatment will only be authorised if agreed outcomes and timescales are clear. If approved, circumstances in which treatment may cease should be explained to the patient or carer by the prescriber. Please indicate clearly circumstances in which treatment will be stopped.

17. Service Implications (if any):

18. Approval Rationale

Example: Explain how the patient is expected to gain significantly greater benefit from this drug than the normal treatment group considered by SMC or NHS Tayside policy for this drug.

19. Monitoring requirements for treatment:
If required of primary care, an individual patient treatment plan is needed (seek advice from pharmacy)

20. Details of all discussions relevant to this case:
Example: Advised by national experts, second opinions, colleagues etc.

21. Timeliness (Please indicate timeframe, if relevant, in which decision is needed - this must be realistic and clinically relevant):

22. Declaration:

I declare I have completed a conflict of interest form that I have explained this process to the patient or carer and that approval is not guaranteed.

Signed: …… Name (BLOCK CAPITALS): ……..

E-Mail Address: …… Page: ……..……

Any request needs to be supported by the relevant Clinical Lead or Associate Medical Director

By signing you are confirming that you have discussed this with the requesting Clinician and support the application.

<u>Clinician in support of application</u>:

Signature:

Name (BLOCK CAPITALS): **Date:**

<u>Clinician in support of application</u>:

Signature:

Name (BLOCK CAPITALS): **Date:**

<u>Pharmacist in support of application</u>:

Signature:

Name (BLOCK CAPITALS): **Date:**

AUTHORISATION:

To be completed by the Principal Clinical Pharmacist/Lead Pharmacist

I have reviewed the request and the evidence for safety, clinical and cost effectiveness.

Request Approved ☐ Clinical Service Manager notified Yes N/A

Request referred to Clinical Group/IJB level ☐

Request referred to non-formulary panel ☐

Request rejected ☐

Name: Signature: Date:

NB: Ensure original is returned to medical notes and a copy forwarded to patients GP.

Rationale behind decision:

AUTHORISATION:

To be completed by Chair of the decision-making panel

Decision and supporting statement:

(Including any conditions such as duration, evidence of outcomes, etc.)

NB: Ensure original is returned to medical notes and a copy forwarded to patients GP.

Name: *Signature:* *Date:*

PEER APPROVED CLINICAL SYSTEM (PACS) TIER TWO REQUEST FORM AND DECISION RECORD

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

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

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

Notes for electronic completion:

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

The form is partitioned into 4 parts and 2 appendices:

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

Before submitting:

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

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

How to submit the request:

Completed Form for PACS process must be submitted to the appropriate Key Contact detailed below:

Carol Walkinshaw
Business Manager, Pharmacy Service
E-mail: carol.walkinshaw@nhs.net

On reaching a decision:

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

PART A: PACS TIER TWO REQUEST DETAILS

To be completed for all requests made by the requesting clinician

Patient's CHI Number:	**Patient Postcode:**
NHS board conducting PACS Tier Two: *(Please select from the drop-down list)*	
Patient's NHS board (if different from above): *(Please select from the drop-down list)*	
Hospital/site where treatment is to be delivered/initiated:	
Requesting Clinician:	
Position held:	
Email address:	
Telephone/pager:	
Acute Services Division:	
Medicine and formulation: *(Include strength and dosage, refrain from using abbreviations. Please also include the SMC ID where known)*	
Intended indication: *(Also include any relevant positioning)*	
Clinical urgency: *(Please select from the drop-down list)*	
Please give an explanation for your response regarding clinical urgency:	
How does this request relate to the SMC status of this medicine: *(Has the medicine not been recommended by SMC or is it awaiting/undergoing evaluation by the SMC, or is the intention to use the medicine outside of the restrictions on use imposed by SMC advice? Please select from the drop-down list)*	
Under which process(es) was medicine considered by SMC *(This is the status of the medicine according to the SMC classification. Tick all options which apply)*	☐ Orphan ☐ End-of-life ☐ None

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

☐ Tick here to confirm

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

☐ Tick here to confirm

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

Declaration of interests:
(Please select from the drop-down list)

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

Details of any declared interests:
(Where applicable)

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

PART B: PACS TIER TWO CASE FOR PRESCRIBING

To be completed for all requests

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

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

2. The clinician can present an evidence-based case to demonstrate the potential that the patient will achieve a measurable clinical benefit at least comparable to if not better than that experienced by the population considered by SMC.

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

Information directly relating to referral criteria:

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

Considering any existing SMC advice (if available), please demonstrate the likelihood that the patient will achieve measurable clinical benefit
(You should include all relevant factors such as performance status, previous response to other medicines and individual clinical characteristics that suggest that the patient will derive increased benefit. Please provide full citations for any clinical papers referred to)

Further information relating to patient:

Previous treatment received by patient for this indication where available and why this is not being continued
(Including approximate durations)

Are there any supportive treatments, diagnostic tests or monitoring needed for this treatment?
(provide detail, including whether the tests etc are routinely available)

What are the potential adverse effects of the medicine requested?

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

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

Information directly relating to the medicine:

Relevant NICE advice (available from www.nice.org.uk) If the medicine has been accepted for use by NICE, please provide a reference (e.g. NICE TA number) and brief summary of guidance on use	
Relevant All Wales Medicines Strategy Group (AWMSG) (available from www.awmsg.org) If the medicine has been accepted for use by AWMSG, please provide the reference number and brief summary of guidance on use	
Any other information:	

PART C: PEER REVIEW

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

Name and position:	
NHS board/ Employing authority	
Peer review statement: The clinician should state his/her opinion relating to the request for this medicine for this condition, indicating whether they are supportive of the request and why.	

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

Declaration of interests: *(Please select from the drop-down list)*	

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

Details of any declared interests: *(Where applicable)*	

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

PART D: PACS TIER TWO DECISION RECORD

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

PACS TIER TWO PANEL MEMBERSHIP:

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

	Name and position:	Declaration of interests:
Panel Chair (Typically a senior clinician)		
Panel member and position held:		
Panel member and position held:		
Panel member and position held:		
Panel member and position held:		

PACS TIER TWO PANEL DISCUSSION:

Date request received:		**Date of discussion:**	
How panel discussion was conducted: *(Please select from the drop-down list)*			
Main discussion points of panel: *(Include how evidence and peer perspective were weighted)*			

DECISION OF REQUEST AND RATIONALE:

PACS TIER TWO PANEL DECISION: *(Please select from the drop-down list)*	
Terms and conditions of acceptance (optional): *E.g. duration of treatment after which efficacy must be reviewed, monitoring schedule or stopping criteria. Where applicable, these terms should be clearly conveyed to the patient prior to commencing treatment.*	
Rationale for submission not supported: *Where a request has been rejected, the reasoning MUST be clearly stipulated in this section to allow the patient and clinician to be able to understand the rationale for the decision made.*	

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

☐ Please provide further detail and resubmit as new request
☐ Other (provide additional comment in text box below)

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

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

APPENDIX 1: APPLICATION TO NATIONAL REVIEW PANEL

Date of original application:		**Date of PACS TIER TWO Panel advice:**	

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

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

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

APPENDIX 2: NATIONAL REVIEW PANEL ADVICE

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

NATIONAL REVIEW PANEL MEMBERSHIP:

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

	Name:	Declaration of interests:
Panel Chair and position held		
Panel Member and position held:		
Panel Member and position held:		
Panel Member and position held:		

NATIONAL REVIEW PANEL DISCUSSION:

Date request received:		**Date of discussion:**	
How review panel discussion was conducted: *(Please select from the drop-down list)*			
Basis for review request: *(NOTE: a review will not be accepted on the grounds that the patient or clinician does not agree with the views or conclusions reached)*			
Main discussion points of review panel:			

OUTCOME AND RATIONALE:

NATIONAL REVIEW PANEL FINDING *(Please select from the drop-down list)*	
Rationale: *(state why the panel feels a review is or is not necessary based on original evidence submitted)*	

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

NHS Tayside

STANDARD EXPLANATION OF DECLARATIONS OF INTEREST

Personal Interests

A personal interest involves personal payment to the individual personally. The main examples are:

(i) Consultancies: any consultancy, directorship, position in or work for the pharmaceutical industry which attracts regular or occasional payments in cash or kind.

(ii) Fee-Paid Work: any work commissioned by the pharmaceutical industry for which the individual is paid in cash or kind.

(iii) Shareholdings: any shareholding in or other beneficial interest in shares of the pharmaceutical industry. This does not include shareholdings through unit trusts or similar arrangements where the individual has no influence or financial management.

Non-Personal Interests

A non-personal interest involves payment which benefits a department for which an individual is responsible, but is not received by the individual personally. The main examples are:

(i) Fellowships: the holding of a fellowship endowed by the pharmaceutical industry.

(ii) Support by the pharmaceutical industry: any payment, other support or sponsorship by the pharmaceutical industry which does not convey any pecuniary or material benefit to an individual personally but which does benefit his/her position or department e.g.

- A grant from a company for the running of a unit or department for which an individual is responsible;
- A grant or fellowship or other payment to sponsor a post or a member of staff in the unit for which the individual is responsible. This does not include financial assistance for students;
- The commissioning of research or other work by, or advice from, staff who work in a unit for which the individual is responsible.

Interests are considered to have lapsed after 2 years.

DECLARATION OF INTERESTS

It is important that any interests in pharmaceutical companies that may be relevant to this submission are declared. Please complete this section regardless of whether you have any declared interests or not (see *Appendix 5*).

Clinician Declaration of Interest
I have an interest in the following pharmaceutical companies that are relevant to this application:
Current Personal Interests (consultancy fees, fee-paid work, shareholdings, etc.):
Non-Personal Interests (Fellowships, Department grants/fellowships, sponsorship etc):
Clinician's Full Name (BLOCK CAPITALS):
Clinician's Signature:
Date:

NHS TAYSIDE – POLICY APPROVAL CHECKLIST

This form must be completed by the Policy Manager and this checklist must be completed and forwarded with the policy to the Executive Team, Clinical Quality Forum or Area Partnership Forum for approval and to the appropriate Committee for adoption.

POLICY AREA: Clinical

POLICY TITLE: Policy on the Prescribing of Medicines that are Non-Formulary including Individual Patient Treatment Requests

POLICY MANAGER:Jill Nowell, Head of Prescribing Support Unit

Why has this policy been developed?		This policy is an update of the previous various so not a new development	
Has the policy been developed in accordance with or related to legislation? – Please give details of applicable legislation.		Yes	
Has a risk control plan been developed and who is the owner of the risk? If not, why not?		N/A	
Who has been involved/consulted in the development of the policy?		First version of the policy had wide stakeholder engagement through a short-life working group	
Has the policy been Equality Impact Assessed in relation to:-		Has the policy been Equality Impact Assessed not to disadvantage the following groups:- YES	
	Please indicate Yes/No for the following:		Please indicate Yes/No for the following:
Age	No	People with Mental Health	No
Disability	No	Problems	No
Gender Reassignment	No	Homeless People	No
Pregnancy/Maternity	No	People involved in the Criminal	No
Race/Ethnicity	No	Justice System	No
Religion/Belief	No	Staff	No
Sex (men and women)	No	Socio Economic Deprivation	No
Sexual Orientation	No	Groups	No
		Carers	No
		Literacy	No
		Rural	No
		Language/Social Origins	No
Does the policy contain evidence of the Equality Impact Assessment Process?		YES	
Is there an implementation plan?		YES	
Which officers are responsible for implementation?		Medical Director, Pharmacy Director	
When will the policy take effect?		May 2018	
Who must comply with the policy/strategy?		All prescribers within NHS Tayside	
How will they be informed of their responsibilities?		Information to be disseminated via a Tayside Prescriber and the Principal Clinical Pharmacists.	
Is any training required?		No	
If yes, attach a template		N/A	
Are there any cost implications?		No	
If yes, please detail costs and note source of funding		N/A	
Who is responsible for auditing the implementation of the policy?		Prescribing Support Unit	
What is the audit interval?		Annual	
Who will receive the audit reports?		Medicines Advisory Group	
When will the policy be reviewed and provide details of policy review period (up to 5 years)		Every two years	

POLICY MANAGER: Jill Nowell DATE: May 2018
APPROVAL COMMITTEE TO CONFIRM: Clinical Quality Forum
ADOPTION COMMITTEE TO CONFIRM: Clinical and Care Governance Committee

EQUALITY IMPACT ASSESSMENT

Name of Policy, Service Improvement, Redesign or Strategy:

Prescribing of Medicines that are Non-Formulary (including Peer Approved Clinical System (PACS) Tier One & Two)

Lead Director of Manager:

Medical Director

What are the main aims of the Policy, Service Improvement, Redesign or Strategy?

To provide a local framework for the Prescribing of Medicines that are Non-Formulary including Peer Approved Clinical System (PACS) Requests.

Description of the Policy, Service Improvement, Redesign or Strategy – What is it? What does it do? Who does it? And who is it for?

The NHS Tayside Drug and Therapeutics Committee have the responsibility to define local policies to guide the prescribing of unlicensed medicines within NHS Tayside. Where a licensed medicine is available, it should be prescribed in preference to any unlicensed equivalent alternative.

The clinical liability associated with the prescribing of unlicensed medicines or medicines prescribed out with their marketing authorisation may be accepted by Tayside Health Board, provided that its employees have followed this policy for the prescribing of such medicines.

This policy is applicable to all prescribers within NHS Tayside.

What are the intended outcomes from the proposed Policy, Service Improvement, Redesign or strategy? – What will happen as a result of it? Who benefits from it and how?

To ensure a revised local framework is in place for the Prescribing of Medicines that are Non-Formulary including Peer Approved Clinical System Requests (PACS).

Name of the group responsible for assessing or considering the equality impact assessment? This should be the Policy Working Group or the Project team for Service Improvement, Redesign or Strategy.

Peer Approved Clinical System Panel

SECTION 1 Part B – Equality and Diversity Impacts
Which equality group or Protected Characteristics do you think will be affected

Item	Considerations of impact	Explain the answer and if applicable detail the impact	Document any Evidence/Research/Data to support the consideration of impact	Further actions required
1.1	Will it impact on the whole population? Yes or No. If yes will it have a differential impact on any of the groups identified in 1.2. If no go to 1.2 to identify which groups	No		
1.2	Which of the protected characteristic(s) or groups will be affected? • Minority ethnic population (including refugees, asylum seekers & gypsies/travellers) • Women and men • People in religious/faith groups • Disabled people • Older people, children and young people • Lesbian, gay, bisexual and transgender people • People with mental health problems • Homeless people • People involved in criminal justice system • Staff • Socio- economically deprived groups	None		
Item	**Considerations of impact**	**Explain the answer and if applicable detail the impact**	**Document any Evidence/Research/Data to support the consideration of impact**	**Further actions required**
1.3	Will the development of the policy, strategy or service improvement/redesign lead to • Discrimination • Unequal opportunities • Poor relations between equality groups and other groups • Other	No		

SECTION 2 – Human Rights and Health Impact.
Which Human Rights could be affected in relation to article 2, 3, 5, 6, 9 and 11. (ECHR: European Convention on Human Rights)

Item	Considerations of impact	Explain the answer and if applicable detail the impact	Document any Evidence/Research/Data to support the consideration of impact	Further actions required
2.1	**On Life (Article 2, ECHR)** • Basic necessities such as adequate nutrition, and safe drinking water • Suicide • Risk to life of / from others • Duties to protect life from risks by self / others • End of life questions	No		
2.2	**On Freedom from ill-treatment (Article 3, ECHR)** • Fear, humiliation • Intense physical or mental suffering or anguish • Prevention of ill-treatment, • Investigation of reasonably substantiated allegations of serious ill-treatment • Dignified living conditions	No		
2.3	**On Liberty (Article 5, ECHR)** • Detention under mental health law • Review of continued justification of detention • Informing reasons for detention	No		
2.4	**On a Fair Hearing (Article 6, ECHR)** • Staff disciplinary proceedings • Malpractice • Right to be heard • Procedural fairness • Effective participation in proceedings that determine rights such as employment, damages / compensation	No		
2.5	**On Private and family life (Article 6, ECHR)** • Private and Family life • Physical and moral integrity (e.g. freedom from	No		

	non-consensual treatment, harassment or abuse • Personal data, privacy and confidentiality • Sexual identity • Autonomy and self-determination • Relations with family, community • Participation in decisions that affect rights • Legal capacity in decision making supported participation and decision making, accessible information and communication to support decision making • Clean and healthy environment			
2.6	**On Freedom of thought, conscience and religion (Article 9, ECHR)** • To express opinions and receive and impart information and ideas without interference	No		
2.7	**On Freedom of assembly and association (Article 11, ECHR)** • Choosing whether to belong to a trade union	No		
2.8	**On Marriage and founding a family** • Capacity • Age	No		
2.9	**Protocol 1 (Article 1, 2, 3 ECHR)** • Peaceful enjoyment of possessions	No		

SECTION 3 – Health Inequalities Impact
Which health and lifestyle changes will be affected?

Item	Considerations of impact	Explain the answer and if applicable detail the impact	Document any Evidence/Research/Data to support the consideration of impact	Further actions required
3.1	What impact will the function, policy/strategy or service change have on lifestyles? For example will the changes affect: • Diet & nutrition • Exercise & physical activity • Substance use: tobacco, alcohol or drugs • Risk taking behaviours • Education & learning or skills • Other	None		
3.2.	Does your function, policy or service change consider the impact on the communities? Things that might be affected include: • Social status • Employment (paid/unpaid) • Social/family support • Stress • Income	No		
3.3	Will the function, policy or service change have an impact on the physical environment? For example will there be impacts on: • Living conditions • Working conditions • Pollution or climate change • Accidental injuries/public safety • Transmission of infectious diseases • Other	No		

3.4	Will the function, policy or service change affect access to and experience of services? For example • Healthcare • Social services • Education • Transport • Housing	No		
3.5	In relation to the protected characteristics and groups identified: • What are the potential impacts on health? • Will the function, policy or service change impact on access to health care? If yes - in what way? • Will the function or policy or service change impact on the experience of health care? If yes – in what way?	No		

SECTION 4 – Financial Decisions Impact
How will it affect the financial decision or proposal?

Item	Considerations of impact	Explain the answer and if applicable detail the impact	Document any Evidence/Research/Data to support the consideration of impact	Further actions required
4.1	• Is the purpose of the financial decision for service improvement/redesign clearly set out • Has the impact of your financial proposals on equality groups been thoroughly considered before any decisions are arrived at	N/A		
4.2	• Is there sufficient information to show that "due regard" has been paid to the equality duties in the financial decision making • Have you identified methods for mitigating or avoiding any adverse impacts on equality groups • Have those likely to be affected by the financial proposal been consulted and involved	N/A		

Item	Considerations of impact	Explain the answer and if applicable detail the impact	Document any Evidence/Research/Data to support the consideration of impact	Further actions required
5.	Involvement, Consultation and Engagement (IEC) 1) What existing IEC data do we have? • Existing IEC sources • Original IEC • Key learning 2) What further IEC, if any, do you need to undertake?	None		

Item	Considerations of impact	Explain the answer and if applicable detail the impact	Document any Evidence/Research/Data to support the consideration of impact	Further actions required
6.	Have any potential negative impacts been identified? • If so, what action has been proposed to counteract the negative impacts? (if yes state how) For example: • Is there any unlawful discrimination? • Could any community get an adverse outcome? • Could any group be excluded from the benefits of the function/policy? (consider groups outlined in 1.2) • Does it reinforce negative stereotypes? (For example, are any of the groups identified in 1.2 being disadvantaged due to perception rather than factual information?)	None		

Item	Considerations of impact	Explain the answer and if applicable detail the impact	Document any Evidence/Research/ Data to support the consideration of impact	Further actions required
7.	Data & Research • Is there need to gather further evidence/data? • Are there any apparent gaps in knowledge/skills?	No		
8.	Monitoring of outcomes • How will the outcomes be monitored? • Who will monitor?	PACS Database in place – monitored by		

	• What criteria will you use to measure progress towards the outcomes?	PSU, reported to Scottish Government quarterly.		
9.	Recommendations State the conclusion of the Impact Assessment	No Further Action Needed		
10.	Completed function/policy • Who will sign this off? • When?	CQF		
11.	Publication	Post to Staffnet		

CONCLUSION SHEET FOR EQUALITY IMPACT ASSESSMENT

Positive Impacts (Note the groups affected)	Negative Impacts (Note the groups affected)

What if any additional information and evidence is required

From the outcome of the Equality Impact Assessment what are your recommendations? (refer to questions 5 - 10)