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Selpercatinib for advanced thyroid cancer with RET alterations after treatment with a targeted cancer drug in people 12-17 years of age

Policy Position Statement: PPS321

Policy Position Statement:

PPS321, Selpercatinib for advanced thyroid cancer with RET alterations after treatment with a targeted cancer drug in people aged 12-17 years

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Description	NHS Wales will routinely commission this specialised service in accordance with the criteria described in this policy

Contents

Policy Statement.....	4
Welsh Language	4
Decarbonisation.....	4
Disclaimer.....	4
1. Introduction.....	6
1.1 Background.....	6
1.2 Equality Impact Assessment.....	7
2. Recommendations	8
2.1 Inclusion Criteria	8
2.2 Continuation of Treatment	8
2.3 Acceptance Criteria	8
2.4 Transition arrangements.....	9
2.5 Designated Providers.....	9
2.6 Patient Pathway (Annex i).....	10
2.7 Mechanism for funding	10
2.8 Clinical Outcome and Quality Measures.....	10
2.9 Action to be taken.....	11
3. Listening to People	12
3.1 Complaints, Incidents and Redress Process	12
3.2 Individual Patient Funding Request (IPFR).....	12
Annex i Patient Pathway	13
Annex ii - Codes	14
Contact Us	15

Policy Statement

NHS Wales Joint Commissioning Committee (NWJCC) will commission selpercatinib for people with advanced thyroid cancer with RET alterations after treatment with a targeted cancer drug in people 12 years to 17 years in accordance with the criteria outlined in this document.

Welsh Language

NWJCC is committed to treating the English and Welsh languages on the basis of equality, and endeavour to ensure commissioned services meet the requirements of the legislative framework for Welsh Language, including the [Welsh Language \(Wales\) Measure 2011](#) and the [Welsh Language Standards \(No.7\) Regulations](#) 2018.

Where a service is provided in a private facility or in a hospital outside of Wales, the provisions of the Welsh language standards do not directly apply but in recognition of its importance to the patient experience, the referring health board should ensure that wherever possible patients have access to their preferred language.

In order to facilitate this, NWJCC is committed to working closely with providers to ensure that in the absence of a Welsh speaker, written information will be offered. Where possible, links to local teams should be maintained during the period of care.

Decarbonisation

NWJCC is committed to taking assertive action to reducing the carbon footprint through mindful commissioning activities. Where possible and taking into account each individual patient's needs, services are provided closer to home, including via digital and virtual access, with a delivery chain for service provision and associated capital that reflects the NWJCC commitment.

Disclaimer

NWJCC assumes that healthcare professionals will use their clinical judgment, knowledge and expertise when deciding whether it is appropriate to apply this document.

This document may not be clinically appropriate for use in all situations and does not override the responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or their carer or guardian, or Local Authority.

Policy Position Statement:

PPS321, Selpercatinib for advanced thyroid cancer with RET alterations after treatment with a targeted cancer drug in people aged 12-17 years

NWJCC disclaims any responsibility for damages arising out of the use or non-use of this policy.

1. Introduction

This Policy Position has been developed for the planning and delivery of selpercatinib for advanced thyroid cancer with RET alterations after treatment with a targeted cancer drug in people aged 12-17 years resident in Wales. This service will only be commissioned by the NHS Wales Joint Commissioning Committee (NWJCC) and applies to residents of all seven Health Boards in Wales.

In creating this document NWJCC has reviewed the relevant guidance issued by the National Institute of Health and Care Excellence (NICE)¹ and has concluded selpercatinib should be made available. NWJCC will commission selpercatinib in people aged 12-17 years.

1.1 Background

The thyroid is a small butterfly shaped gland found at the front of the neck that makes and releases hormones². Thyroid cancer starts in the cells in the thyroid gland. There are different types of thyroid cancer, the type depends on what type of cell the cancer starts in. The different types of thyroid cancer include: papillary, follicular, oncocytic cell (hurthle cell), medullary thyroid cancer and anaplastic thyroid cancer. Papillary thyroid cancer is the most common type³.

A number of cases of medullary thyroid cancer have been linked to point mutations in the rearranged during transfection (RET) gene⁴. A point mutation is a modification to the cell's genetic material⁵. These mutations can be hereditary (passed down from your parents) or develop spontaneously⁶.

Changes within the RET gene also occur in papillary thyroid cancer. In this case the RET gene fuses together with another gene. These rearrangements lead to disruption of normal gene function⁷.

Faulty versions of the RET gene through point mutation or fusion can cause the RET protein to remain constantly active, causing abnormal cell multiplication and tumour development⁶.

¹ [Overview | Selpercatinib for advanced thyroid cancer with RET alterations after treatment with a targeted cancer drug in people 12 years and over | Guidance | NICE](#)

² [Thyroid cancer | Cancer Research UK](#)

³ [Types of thyroid cancer | Cancer Research UK](#)

⁴ [RET Fusion, Point Mutation, and Signaling](#)

⁵ [Point Mutation: Definition, Types, Examples | Biology Dictionary](#)

⁶ [What Is RET-Mutated Medullary Thyroid Cancer?](#)

⁷ [The importance of the RET gene in thyroid cancer and therapeutic implications - PubMed](#)

Policy Position Statement:

PPS321, Selpercatinib for advanced thyroid cancer with RET alterations after treatment with a targeted cancer drug in people aged 12-17 years

Selpercatinib is a RET kinase inhibitor, meaning it blocks the RET receptor protein. Blocking the RET kinase blocks the main growth signal for cancer cells and thereby prevents them from dividing, this may slow the growth of the cancer or help shrink the cancer⁸.

On average there are 10 cases of thyroid cancer in children and young people each year in the UK⁹. The number of people estimated to be eligible for treatment in the previously treated non-medullary and medullary RET fusion-positive settings is anticipated to be very small and likely to become smaller following the publication of NICE's technology appraisal guidance on selpercatinib for advanced thyroid cancer with RET alterations untreated with a targeted cancer drug in people 12 years and over (TA1039). This is because the treatment will be given at an earlier line of therapy¹⁰.

1.2 Equality Impact Assessment

The Equality Impact Assessment (EIA) process has been developed to help promote fair and equal treatment in the delivery of health services. It aims to enable NHS Wales Joint Commissioning Committee to identify and eliminate detrimental treatment caused by the adverse impact of health service policies upon groups and individuals for reasons of race, gender re-assignment, disability, sex, sexual orientation, age, religion and belief, marriage and civil partnership, pregnancy and maternity and language (Welsh).

An EQIA was also carried out by NICE during the evaluation of selpercatinib. For further details, please refer to the NICE website at: [NICE - equality-impact-assessment](#)

The Assessment demonstrates the policy is robust and there is no potential for discrimination or adverse impact. All opportunities to promote equality have been taken.

⁸ [Selpercatinib | Macmillan Cancer Support](#)

⁹ [Thyroid cancer in children | British Thyroid Foundation](#)

¹⁰ [Resource impact summary report | Tools and resources | Selpercatinib for advanced thyroid cancer with RET alterations after treatment with a targeted cancer drug in people 12 years and over | Guidance | NICE](#)

2. Recommendations

The recommendations below represent the views of NICE arrived at after careful consideration of the evidence available. Health professionals are expected to take into account the relevant NICE guidance¹, alongside the individual needs, preferences and values of the patient.

2.1 Inclusion Criteria

Selpercatinib is recommended as an option in people aged 12-17 years for treating¹¹:

- advanced RET fusion-positive thyroid cancer that is refractory to radioactive iodine (if radioactive iodine is appropriate), only if systemic treatment is needed after sorafenib or lenvatinib
- advanced RET-mutant medullary thyroid cancer, only if systemic treatment is needed after cabozantinib or vandetanib.

Selpercatinib is only recommended if the company provides it according to the commercial arrangement.

This recommendation is not intended to affect treatment with selpercatinib that was started in the NHS before this guidance was published. People having treatment outside these recommendations may continue without change to the funding arrangements in place for them before this guidance was published, until they and their NHS healthcare professional consider it appropriate to stop. For children or young people, this decision should be made jointly by the healthcare professional, the child or young person, and their parents or carers.

2.2 Continuation of Treatment

Healthcare professionals are expected to review a patient's health at regular intervals to ensure they are demonstrating an improvement to their health due to the treatment being given.

If no improvement to a patient's health has been recorded then clinical judgement on the continuation of treatment must be made by the treating healthcare professional.

2.3 Acceptance Criteria

The service outlined in this specification is for patients ordinarily resident in Wales, or otherwise the commissioning responsibility of the NHS in Wales. This excludes patients

¹¹ [1 Recommendations | Selpercatinib for advanced thyroid cancer with RET alterations after treatment with a targeted cancer drug in people 12 years and over | Guidance | NICE](#)

Policy Position Statement:

PPS321, Selpercatinib for advanced thyroid cancer with RET alterations after treatment with a targeted cancer drug in people aged 12-17 years

who whilst resident in Wales, are registered with a GP practice in England, but includes patients resident in England who are registered with a GP Practice in Wales.

2.4 Transition arrangements

Transition arrangements should be in line with [Transition from children's to adults' services for young people using health or social care services, NICE guidance NG43](#) and the [Welsh Government Transition and Handover Guidance](#)

Transition involves a process of preparation for young people and their families for their transition to adulthood and their transition to adult services. This preparation should start from early adolescence 12-13 year olds. The exact timing of this will ideally be dependent on the wishes of the young person but will need to comply with local resources and arrangements.

The transition process should be a flexible and collaborative process involving the young person and their family as appropriate and the service.

The manner in which this process is managed will vary on an individual case basis with multidisciplinary input often required and patient and family choice taken into account together with individual health board and environmental circumstances factored in.

For the specialised paediatric services it commissions, the JCC will routinely commission treatment up until a patient is 16 years old. The JCC does not commission specialised paediatric services for patients aged 18 years and older. For patients aged 16 or 17 years of age, the JCC will continue to commission ongoing specialised treatment initiated before the patient's 16th birthday and under the ongoing care of a specialised paediatric team.

2.5 Designated Providers

- Children's Hospital for Wales
University Hospital of Wales
Heath Park Way
Cardiff
CF14 4XW
- Alder Hey Children's hospital
Eaton Road
Liverpool
L12 2AP

Policy Position Statement:

PPS321, Selpercatinib for advanced thyroid cancer with RET alterations after treatment with a targeted cancer drug in people aged 12-17 years

2.6 Patient Pathway (Annex i)

Patients should be referred to one of the designated providers listed in section 2.5 for assessment of eligibility for treatment included in this policy. See annex i for the patient pathway.

2.7 Mechanism for funding

Selpercatinib will only be funded for patients registered via the Blueteq[®] system and where an appropriately constructed MDT has approved its use within highly specialised centres.

Where the patient meets the criteria in this policy and the referral is received by an agreed centre, a Blueteq[®] form should be completed for approval.

For further information on accessing and completing the Blueteq[®] form please contact NWJCC using the following email address: NWJCC.Blueteq@wales.nhs.uk

If a non-contracted provider wishes to treat a patient that meets the criteria they should contact NWJCC at NWJCC.IPC@wales.nhs.uk They will be asked to demonstrate they have an appropriate MDT in place.

Funding is approved on the basis that selpercatinib is prescribed and administered in accordance with its marketing authorisation (PLGB 14895/0311 PLGB 14895/0312)¹². Selpercatinib, is available as 40mg and 80mg hard capsules. The cost £2,184 for 56 capsules of 40 mg selpercatinib and £4,368 for 56 capsules of 80 mg (excluding VAT; company's evidence submission)¹³. The company has a commercial arrangement. This makes selpercatinib available to the NHS with a discount. The size of the discount is commercial in confidence. Health Boards in Wales should refer to the AWTTTC Commercial Medicines Access References Tool (CMART) for further information on the Patient Access Scheme (PAS) price.

If treatment is discontinued, it is the responsibility of the prescribing team to discontinue the Blueteq[®] form.

2.8 Clinical Outcome and Quality Measures

The Provider must work to written quality standards and provide monitoring information to the lead commissioner.

¹² [Retsevmo 40 mg hard capsules - Summary of Product Characteristics \(SmPC\) - \(emc\) | 12195](#)

¹³ [Medicinal forms | Selpercatinib \[Specialist drug\] | Drugs | BNF | NICE](#)

Policy Position Statement:

PPS321, Selpercatinib for advanced thyroid cancer with RET alterations after treatment with a targeted cancer drug in people aged 12-17 years

The centre must enable the patient's, carer's and advocate's informed participation and to be able to demonstrate this. Provision should be made for patients with communication difficulties and for children, teenagers and young adults.

2.9 Action to be taken

- Health Boards and NWJCC are to circulate this Policy Position Statement to all Hospitals/MDTs to inform them of the conditions under which this drug will be commissioned.
- NWJCC are to ensure that all providers are purchasing selpercatinib at the agreed discounted price.
- Providers are to ensure the need to approve selpercatinib at the appropriate MDT and are registering use on the Blueteq[®] system, and the treatment will only be funded where the Blueteq[®] minimum dataset is fully and accurately populated.
- Providers are to determine estimated patients numbers and the current dose of any patient(s) who will transfer from any company compassionate use scheme EAMS.
- The Provider should work to written quality standards and provide monitoring information to NWJCC on request.

3. Listening to People

3.1 Complaints, Incidents and Redress Process

Whilst every effort has been made to ensure that decisions made under this policy are robust and appropriate for the patient group, it is acknowledged that there may be occasions when the patient or their representative are not happy with decisions made or the treatment provided.

The patient or their representative should be guided by the clinician, or the member of NHS staff with whom the concern is raised, to the appropriate arrangements for management of their concern.

If a patient or their representative is unhappy with the care provided during the treatment or the clinical decision to withdraw treatment provided under this policy, the patient and/or their representative should be guided to [Listening to People, The NHS Wales Complaints, Incidents and Redress Process – People’s Guidance 2026](#). For services provided outside NHS Wales the patient or their representative should be guided to the [NHS Trust Concerns Procedure](#), with a copy of the concern being sent to NWJCC.

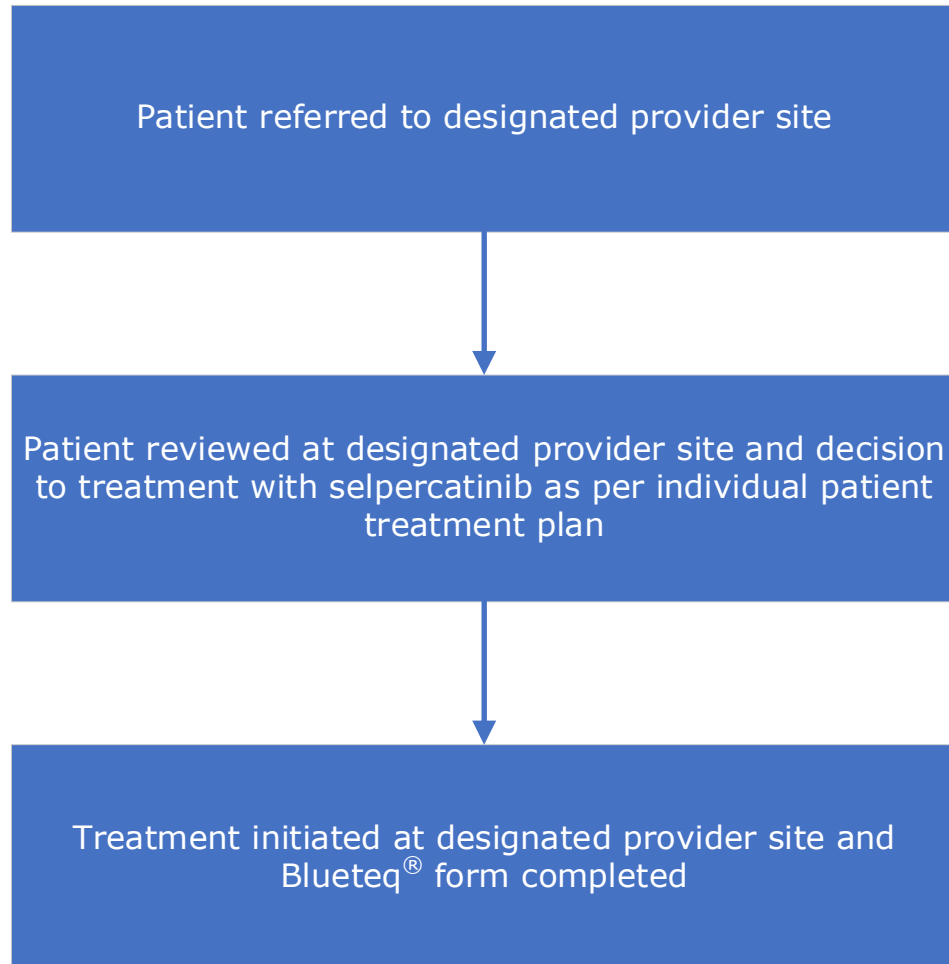
3.2 Individual Patient Funding Request (IPFR)

If the patient does not meet the criteria for treatment as outlined in this policy, an Individual Patient Funding Request (IPFR) can be submitted for consideration in line with the All Wales Policy: Making Decisions on Individual Patient Funding Requests. The request will then be considered by the All Wales IPFR Panel.

If the patient wishes to be referred to a provider outside of the agreed pathway, and IPFR should be submitted.

Further information on making IPFR requests can be found at: [Individual Patient Funding Requests](#)

Annex i Patient Pathway



Policy Position Statement:

PPS321, Selpercatinib for advanced thyroid cancer with RET alterations after treatment with a targeted cancer drug in people aged 12-17 years

Annex ii - Codes

The list of ICD codes below is indicative and is not exhaustive. The ICD10 codes have been provided and verified by the Information Standards Team at Digital Health and Care Wales (DCHW). Additional codes may be used for contract monitoring purposes, furthermore some codes may cover indications not included within this policy.

Code Category	Code	Description
ICD-10	C73.X	Malignant neoplasm of thyroid gland

Policy Position Statement:

PPS321, Selpercatinib for advanced thyroid cancer with RET alterations after treatment with a targeted cancer drug in people aged 12-17 years

Contact Us

If you have a question related to this document you can contact us using one of the methods outlined below.

If you would like this document in an alternative format and/or language, please contact us for assistance.

Email:

NWJCC consultation mailbox – NWJCC.Consultation@wales.nhs.uk

Telephone:

General Enquiries – 01443 433112

Website:

[Contact us - NHS Wales Joint Commissioning Committee](#)

Writing:

If you wish to contact the NHS Wales Joint Commissioning Committee, you can write to us at one of our locations below, we welcome correspondence in Welsh or English:

South Wales Offices

Unit 1, Charnwood Court, Heol Billingsley, Nantgarw, CF15 7QZ

Unit G1 The Willowford, Main Avenue, Treforest Industrial Estate, Pontypridd, CF37 5YL

North Wales Offices

Unit 3, Media Point - Unit 3, Mold Business Park, Mold, CH7 1XY

Preswylfa, Hendy Road, Mold, CH7 1PZ