GIG CYMRU NHS WALES
Cyd-bwyllgor Comisiynu
Joint Commissioning Committee

# Ruxolitinib for treating Acute Graft versus Host Disease that responds inadequately to corticosteroids in people 12 years and over

## Policy Position Statement: PPS292

| Document Information | |
|---|---|
| **Document Name** | Ruxolitinib for Acute Graft versus Host Disease that responds inadequately to corticosteroids in people 12 years and over |
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| **Commissioning Team Author** | Cancer and Blood |
| **Target Audience** | Chief Executives, Medical Directors, Directors of Finance, Medicines Manufacturer, patient groups, Consultant Haematologists, Directors of Pharmacy, Haematology Pharmacists |
| **Description** | NHS Wales will routinely commission this specialised service in accordance with the criteria described in this policy |
| **Document Update Information** | This policy has been moved to the new template and reviewed.<br><br>March 2026 University Hospitals Birmingham NHS Foundation Trust added as provider (in line with our service specification) |

# Contents

# Policy Statement

NHS Wales Joint Commissioning Committee (NWJCC) will commission ruxolitinib for treating acute graft versus host disease that responds inadequately to corticosteroids in people 12 years and over 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 judgement, 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.

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

# 1. Introduction

This Policy Position Statement has been developed for the planning and delivery of ruxolitinib for treating acute graft versus host disease (aGvHD) that responds inadequately to corticosteroids in people 12 years and over for people 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 that ruxolitinib should be made available.

## 1.1 Background

Graft versus host disease (GvHD) can occur after treatment with an allogeneic haematopoietic stem cell transplantation (HSCT) which involves taking stem cells from a healthy person (the donor) and putting them into the patient's body (the recipient)[2]. This treatment is used for some patients with blood cancers or other bone marrow diseases. Stem cells are the body's raw materials — cells from which all other cells with specialised functions are generated. The donated stem cells can come from either a related or an unrelated donor.

In some cases, the transplanted stem cells from the donor recognise the recipient's cells as "foreign" and attack them. This is known as GvHD. GvHD can occur within a few months of the transplant or develop several months or occasionally a few years later. The condition varies in severity, but can sometimes be life-threatening. It can also affect different organ systems including the skin, mouth, eyes, lung, liver and gut.

There are two types of GvHD: acute and chronic. Acute GvHD (aGvHD) generally starts within 100 days of transplant, with chronic GvHD 100 days after transplant, however, signs of acute and chronic GVHD may occur outside of these designated periods. Both can present with mild to severe symptoms. This policy position statement covers aGvHD only.

GvHD can be treated with medications that suppress the immune system and stop the transplanted stem cells attacking the rest of the recipients' body. First line treatments include topical therapies, oral corticosteroids or calcineurin inhibitors. For patients with corticosteroid-refractory GvHD, second line or subsequent therapy is guided by grade and clinical presentation of GvHD.

[1] Overview | Ruxolitinib for treating acute graft versus host disease that responds inadequately to corticosteroids in people 12 years and over | Guidance | NICE
[2] Ruxolitinib for treating acute graft versus host disease that responds inadequately to corticosteroids in people 12 years and over

Ruxolitinib is a selective janus associated kinase (JAK) inhibitor (blocker)[3]. The JAK pathway helps regulate the development, proliferation, and activation of immune cells involved in the development of GvHD. By selectively blocking the JAK pathway, ruxolitinib decreases expression of inflammatory makers (such as cytokines) and prevents abnormal cell proliferation.

## 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 EIA was carried out by NICE during the evaluation of ruxolitinib. For further details, please refer to the NICE website at: NICE EQIA

[3] Mechanism of action | Jakafi® (ruxolitinib)

# 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 guidance[1], alongside the individual needs, preferences and values of the patient.

## 2.1 Inclusion Criteria

Ruxolitinib is recommended, within its marketing authorisation, as an option for treating aGvHD that has an inadequate response to corticosteroids in people 12 years and over[1]. Ruxolitinib is only recommended if the company provides it according to the commercial arrangement.

Ruxolitinib is licensed for the treatment of patients aged 2 years and older with acute graft versus host disease who have inadequate response to corticosteroids. As such, people aged between 2-11 years can access this treatment through NWJCC under the medicines for children's policy'.

## 2.2 Exclusion Criteria

Chronic GvHD (when symptoms start 100 days after transplant).

## 2.3 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.

## 2.4 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 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.

## 2.5 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.

## 2.6 Designated Providers

All providers of HSCT must be Joint Accreditation Committee-ISCT & EBMT (JACIE) accredited. NWJCC will only commission from specialised HSCT centres, who will provide oversight of diagnosis of GvHD and initiation of Ruxolitinib.

**University Hospital of Wales**
Heath Park
Cardiff
CF14 4XW

**The Christie NHS Foundation Trust**
550 Wilmslow Road
Withington
Manchester
M20 4BX

**University Hospitals Bristol NHS Foundation Trust**
Bristol Royal Hospital for Children
Paul O'Gorman Building
Upper Maudlin Street
Bristol
BS2 8BJ

**Royal Manchester Children's Hospital**
Oxford Road
Manchester
M13 9WL

**University Hospitals Birmingham NHS Foundation Trust**
Queen Elizabeth Hospital
Birmingham
Mindelsohn Way
B15 2GW

## 2.7 Patient Pathway (Annex i)

See annex i for patient pathway.

## 2.8 Mechanism for funding

Ruxolitinib 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.ICP@wales.nhs.uk. They will be asked to demonstrate they have an appropriate MDT in place.

Funding is approved on the basis that ruxolitinib is prescribed and administered in accordance with its marketing authorisation. Ruxolitinib is available as 5mg, 10mg, 15mg and 20mg tablets. The company has a commercial arrangement. This makes ruxolitinib available to the NHS with a discount. The size of the discount is commercial in confidence. Health Boards in Wales should refer to the AWTTC 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.

## 2.9 Clinical Outcome and Quality Measures

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.

## 2.10 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 the technology will be commissioned.
- Providers are to ensure that all providers are purchasing ruxolitinib at the agreed discounted price.
- Providers are to ensure the need to approve ruxolitinib 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.
- The Provider should work to written quality standards and provide monitoring information to NWJCC on request.

# 3. Putting things right

## 3.1 Raising a Concern

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.

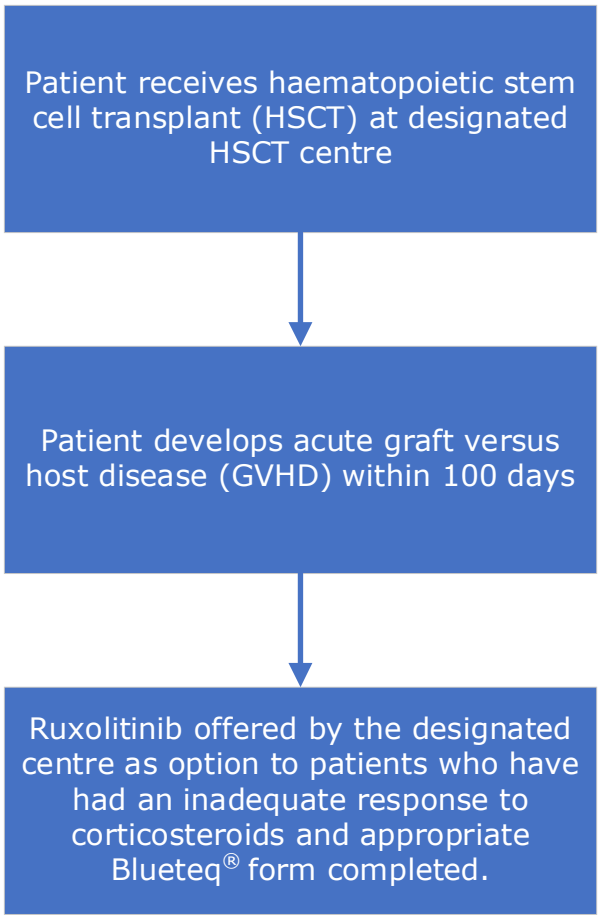
## 3.2 Individual Patient Funding Request (IPFR)

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



# 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 | T86.0 | Bone marrow transplant rejection Graft versus Host disease |

# 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