GIG CYMRU NHS WALES
Cyd-bwyllgor Comisiynu
Joint Commissioning Committee

Belumosudil for treating chronic graft-versus-host disease in people aged 12–17 years after 2 or more systemic treatments

Policy Position Statement: PPS301

Document Information	
Document Name	Belumosudil for treating chronic graft-versus-host disease in people aged 12-17 years after 2 or more systemic treatments
Document No	PPS301
Document Purpose	Policy Position Statement
Publication date	December 2025
Version No	1.0
Commissioning Team Author	Cancer and Blood
Target Audience	Chief Executives, Medical Directors, Directors of Finance, Haematology Clinical Leads, Directors of Pharmacy, Lead Paediatric Pharmacists, Paediatric Cancer Centres, Consultant Paediatric Haematologists, children's hospitals, Paediatric Haematology Nurse Specialists, SANOFI, Children with Cancer UK Charity
Description	NHS Wales will routinely commission this specialised service in accordance with the criteria described in this policy

Contents

Policy Statement

NHS Wales Joint Commissioning Committee (NWJCC) will commission belumosudil for people aged 12 to 17 years with chronic graft-versus-host disease 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 Act (1993), 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 and people have access to either a translator or 'Language-line' if requested. 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 belumosudil for people aged 12 to 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 that belumosudil should be made available.

1.1 Background

The bone marrow is responsible for the production of blood cells including red cells, platelets and white cells. Stem cell transplants are used to treat conditions where the bone marrow is damaged and not able to produce healthy blood cells. Conditions that stem cell transplants are used to treat include some lymphomas, leukaemia and myelofibrosis. An allogenic stem cell transplant involves taking healthy cells from a person (donor) and transferring them into the recipient[2]. Before a transplant the recipient and the donor undergo tissue typing. This is a blood tests to check how closely a protein marker on cells called human leuckocyte antigen (HLA) matches[3]. HLA is inherited from our parents[2]. The immune system uses HLA to see which cells belong in our body and which do not. A good HLA match between the person donating the cells and the recipient reduces the risk of graft versus host disease (GvHD). GvHD happens when particular types of white blood cell (T cells) in the donated stem cells or bone marrow attacks the recipient's body cells. This is because the donated cells (the graft) see the recipient's cells (the host) as foreign and attack them[4].

There are 2 main types of GvHD, acute and chronic. Acute GvHD usually occurs within the first 100 days after a stem cell transplant. Chronic GvHD typically occurs more than 100 days after the transplant. GvHD can affect different areas of the body including the skin, eyes, mouth, digestive system and liver. Symptoms depend on which area of the body is affected and can range from mild to severe and life threatening. Symptoms include rash, diarrhoea, abdominal pain, nausea, loss of appetite, low red cells, low platelets and an increased risk of infection. Symptoms of chronic GvHD can last for months, years or even a lifetime[4].

[1] Recommendations | Belumosudil for treating chronic graft-versus-host disease after 2 or more systemic treatments in people 12 years and over | Guidance | NICE
[2] Stem cell transplant - NHS
[3] Tissue typing | Cancer Research UK
[4] What is graft versus host disease (GvHD)? | Coping physically | Cancer Research UK

Belumosudil is a selective rho-associated kinase 2 (ROCK2) inhibitor. The ROCK2 pathway is partially responsible for immune cell signalling and independent or concurrent fibrotic pathways[5]. In chronic GvHD this particular cell pathway has been shown to be too active. Belumosudil works by blocking this pathway, which decreases inflammation and fibrotic symptoms such as scarring[6].

It is estimated that approximately 4 people per year in Wales will be eligible for belumosudil[7]. This figure includes both adult and children. Treatment for chronic GvHD depends on the severity of the condition and the area affected. Current treatment options include steroids, ciclosporin and monoclonal antibodies[4]. Chronic GvHD can be very difficult to cope with, especially when people have already been through such a lot of treatment. Dealing with long term, uncomfortable symptoms can be hard to accept and can lead to depression and anxiety[8].

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).

This policy has been subjected to an 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.

An EIA was carried out by NICE during the evaluation of belumosudil. For further details, please refer to the NICE website at: Equality Impact Assessment

[5] REZUROCK 200 mg film-coated tablets - Summary of Product Characteristics (SmPC) - (emc)
[6] Belumosudil: A Rising Star for the Management of Chronic Graft-Versus-Host Disease and the First FDA-Approved ROCK2 Inhibitor | The Hematologist | American Society of Hematology
[7] Resource impact statement | Belumosudil for treating chronic graft-versus-host disease after 2 or more systemic treatments in people 12 years and over | Guidance | NICE
[8] Coping with chronic GvHD | Cancer Research UK

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

Belumosudil is recommended, within its marketing authorisation, for treating chronic graft-versus-host disease in people 12 years and over after 2 or more systemic treatments. It is recommended only if the company provides it according to the commercial arrangement[1].

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 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 Designated Providers

Sheffield Children's Hospital*
Clarkson Street
Broomhall
Sheffield
S10 2TH

Leeds Children's Hospital*
Clarendon Wing
Leeds
LS1 3EX

Great North Children's Hospital
Victoria Wing, Royal Victoria Infirmary
Newcastle upon Tyne
NE1 4LP

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

Birmingham Children's Hospital
Steelhouse Lane
Birmingham
B4 6NH

Imperial College Healthcare NHS Trust
St Mary's Hospital
Praed Street
London
W2 1NY

Great Ormond Street Hospital
Great Ormond Street
London
WC1N 3JH

Bristol Royal Hospital for Children
Upper Maudlin Street
Bristol
BS2 8BJ

Children's Hospital for Wales**
University Hospital of Wales
Heath Park Way
Cardiff
CF14 4XW

*These centres are providing allograft BMT for Welsh patients on an interim basis until the service is re-instated in Bristol.

**This centre will provide continuation of belumosudil on the advice of the specialist centres.

2.5 Patient Pathway (Annex i)

Patients should be referred to one of the designated providers listed in section 2.4 for assessment of eligibility for treatment included in this policy. See annex i for the patient pathway.

2.6 Mechanism for funding

Belumosudil 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: NWJCCblueteq@wales.nhs.uk.

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

Funding is approved on the basis that belumosudil is prescribed and administered in accordance with its marketing authorisation (reference number PLGB 04425/0902). Belumosidil is available as belumosudil mesylate 200mg tablets. The cost is £6,708.00 (excluding VAT; company's evidence submission) for 30, 200mg tablets. The company has a commercial arrangement. This makes belumosudil 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.

2.7 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.

2.8 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.
- Providers are to ensure that they are purchasing belumosudil at the agreed discounted price.
- Providers are to ensure the need to approve belumosudil 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 the LHB for NHS Putting Things Right. 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.

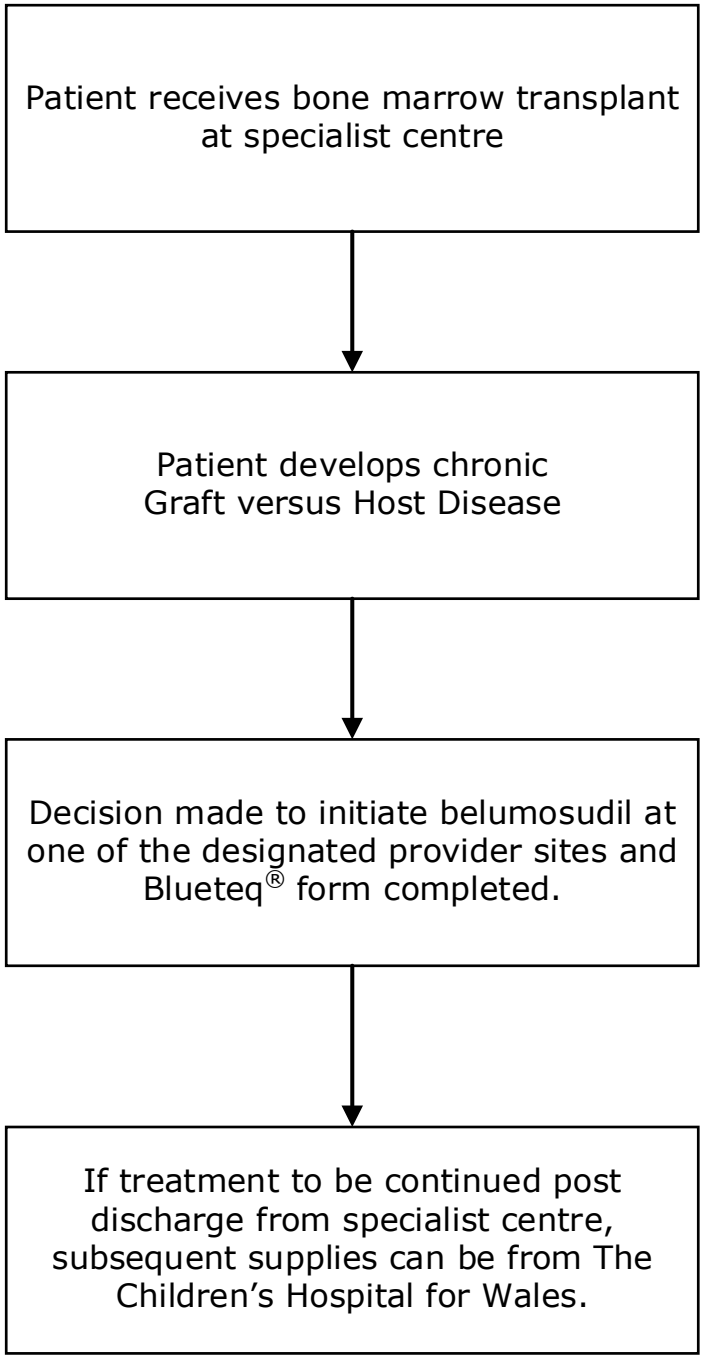
3.2 Individual Patient Funding Request (IPFR)

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, an IPFR should be submitted.

Further information on making IPFR requests can be found at: Individual Patient Funding Requests

Annex i Patient Pathway



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 – nwjccconsultation@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