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Belimumab for treating active autoantibody- positive systemic lupus erythematosus in people aged 5-17 years

Policy Position Statement: PPS317

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

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Policy Statement

NHS Wales Joint Commissioning Committee (NWJCC) will commission belimumab for people aged 5-17 years with active autoantibody-positive systemic lupus erythematosus in people with high disease activity 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 belimumab for people aged 5-17 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 belimumab should be made available. NWJCC will commission belimumab in people aged 5-17 years.

1.1 Background

Systemic lupus erythematosus (SLE) is an autoimmune condition. The immune system becomes overactive, mistakenly identifying the body's own tissue as foreign and starts making antibodies and attacking its own cells². When the disease is active, this immune response can cause inflammation in cells and can affect one or many tissues within the body. SLE can cause a wide range of symptoms, depending on the areas of the body that are affected³. Areas that can be affected include - skin, joints, muscles, blood vessels, blood cells, brain, nerves and organs such as lungs, heart, kidneys, gastrointestinal tract⁴. This can lead to symptoms of extreme tiredness, joint and muscle pain, feeling generally unwell, high temperatures and skin rashes, which can be painful and itchy. Complications of lupus can also include behavioural changes, seizures, kidney damage, heart attacks and pregnancy related complications⁵. For the majority of patients, the disease can last many years⁴. There are times when the disease flares up and the symptoms become worse and then settles down again⁶.

There is currently no cure for SLE, but there are treatments that can ease the symptoms, control the disease, and help prevent the disease causing further damage to the body. Corticosteroids can be used to reduce inflammation in the body. Immunosuppressants are a type of medicine that suppress your immune system. They can help improve your symptoms of SLE by limiting the damage your immune system causes when it attacks healthy parts of your body. Medications which are commonly used to treat malaria, such as hydroxychloroquine, can be useful when there is skin, joint involvement and fatigue². In more severe cases of SLE cyclophosphamide, a type of chemotherapy drug or rituximab, a biological medicine may be used to help control the immune system⁵. SLE

¹ [Overview | Belimumab for treating active autoantibody-positive systemic lupus erythematosus | Guidance | NICE](#)

² [What is Lupus? | Lupus UK](#)

³ [Lupus | NHS inform](#)

⁴ <https://lupusuk.org.uk/wp-content/uploads/2024/08/A-Short-Guide-to-Lupus-and-Visiting-Your-Doctor.pdf>

⁵ [Lupus \(SLE\): Symptoms, causes and treatment | Bupa UK](#)

⁶ [Lupus - NHS](#)

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in children can be more severe and active than SLE in adults. There is also a higher incidence of renal disease and central nervous system involvement in SLE in children compared to adults⁷. Children often receive more intensive drug therapy and accrue more damage, often related to steroid toxicity⁸.

B lymphocytes (B cells), are a type of white blood cell that play an important role in the immune system through their ability to produce antibodies⁹. B lymphocytes are part of the normal immune response but are also responsible for the over-aggressive response seen in autoimmune diseases like SLE. B-cell activating factor (BAFF) is a protein required for the development and survival of B cells. In people with SLE, BAFF is overexpressed, which may cause increased B cell production and prolonged survival of B cells. Belimumab binds to BAFF and prevents it from binding to B cells. Without BAFF, B cells cannot survive and can no longer contribute to the autoimmune damage of SLE¹⁰.

Childhood-onset SLE (cSLE) is a rare disease with an incidence of 0.3-0.9 per 100,000 children per year and a prevalence of 3.3-8.8 per 100,000 children¹¹.

Based on the Welsh Government mid-year estimates population data 2023, there are around 549,000 children and young people between the ages of 0-15 years living in Wales¹². Based on the figures there would be an incidence of between 1-5 cases of cSLE a year in Wales in children between the ages of 0-15 years. However, most cases of cSLE start around 12 years old. It is rare for cSLE to begin before the age of 5¹³.

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 belimumab. For further details, please refer to the NICE website at: [Equality-impact-assessment](#)

⁷ [Paediatric-onset systemic lupus erythematosus - ScienceDirect](#)

⁸ [Difference in disease features between childhood-onset and adult-onset systemic lupus erythematosus - PubMed](#)

⁹ [B Cells \(B Lymphocytes\) - The Definitive Guide | Biology Dictionary](#)

¹⁰ [Lupus Mechanism of Action | BENLYSTA \(belimumab\) for HCPs](#)

¹¹ [Prevalence and burden of pediatric-onset systemic lupus erythematosus | Nature Reviews Rheumatology](#)

¹² [Mid year estimates of the population: 2023 \[HTML\] | GOV.WALES](#)

¹³ [Lupus \(SLE\) in Children, Pediatric Lupus: Causes & Treatment](#)

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

Belimumab is recommended as an option as add-on treatment for active autoantibody-positive systemic lupus erythematosus in people with high disease activity despite standard treatment, only if:

- high disease activity is defined as at least 1 serological biomarker (positive anti-double-stranded DNA or low complement) and a SELENA-SLEDAI score of greater than or equal to 10
- treatment is continued beyond 24 weeks only if the SELENA-SLEDAI score has improved by 4 points or more
- the company provides belimumab according to the commercial arrangement¹.

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 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

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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.

2.5 Designated Providers

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

Alder Hey Children's Hospital
East Prescott Road
Liverpool
L14 5AB

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

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

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Funding is approved on the basis that belimumab is prescribed and administered in accordance with its marketing authorisation (PLGB 19494/0270 – 120mg, PLGB 19494/0272 – 400mg). Belimumab, is available as 120mg and 400mg powder for concentrate for solution for infusion. The cost is £121.50 for a 120mg vial and £405.00 for a 400mg vial (excluding VAT; company's evidence submission). The company has a commercial arrangement. This makes belimumab 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.

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.
- Providers are to ensure they are purchasing belimumab at the agreed discounted price.
- Providers are to ensure the need to approve belimumab 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.

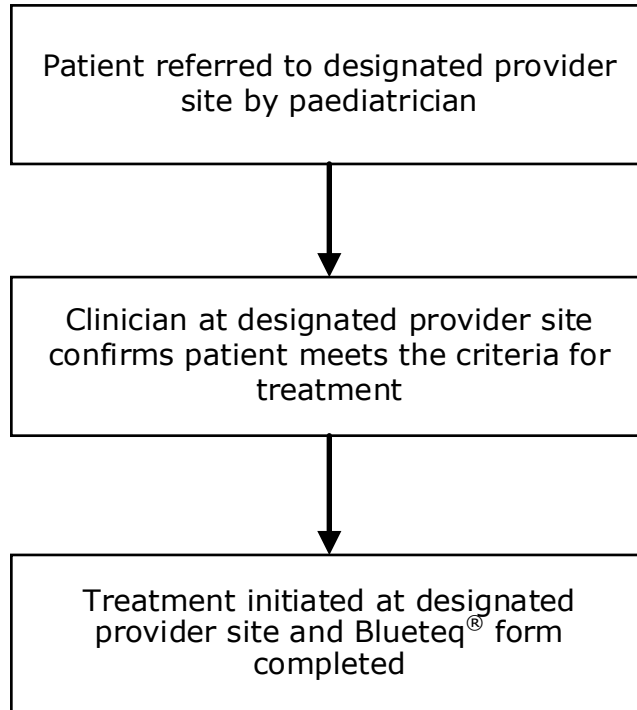
3.2 Individual Patient Funding Request (IPFR)

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, and 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