

Benlysta (belimumab)

- Benlysta (belimumab) [120mg, 400mg] Powder for Injection
- Benlysta (belimumab) SC 200 mg/mL Autoinjector Solution for Injection
- Benlysta (belimumab) SC 200 mg/mL Prefilled Syringe Solution for Injection

Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.

Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.

Summary

Systemic lupus erythematosus (SLE) is an autoimmune disease that can impact almost every organ in the body. Common symptoms include fatigue, fever and weight loss, and many will experience joint pain (arthralgias and arthritis), skin lesions, and cardiac, kidney, lung, and gastrointestinal disease, anemia and neurological side effects (cognitive impairment, psychosis, seizures, headaches or neuropathies). It is characterized by periods of remissions and relapses. The first line of therapy for anyone with SLE includes hydroxychloroquine with or without a steroid depending on disease severity. Other therapies include azathioprine, methotrexate, mycophenolate, Saphnelo (anifrolumab), rituximab (Rituxan), and Benlysta (belimumab).

Lupus nephritis can occur in those with SLE with kidney involvement. Lupus nephritis (LN) typically occurs early in the disease course and is diagnosed by an abnormal urinalysis (including elevated protein in the urine, microscopic hematuria). Management of LN includes preventative management by treating SLE

with hydroxychloroquine, supportive care through dietary modifications (low sodium and protein restrictions) and blood pressure control. Immunosuppression should be used in those with focal or diffuse LN who have active lesions on kidney biopsy. Immunosuppressive therapies include steroids, mycophenolate, cyclophosphamide, or Benlysta (belimumab).

Benlysta (belimumab) is a B-lymphocyte stimulator (BLyS)-specific inhibitor indicated for the treatment of:

- Those 5 years of age and older with active systemic lupus erythematosus (SLE) who are receiving standard therapy.
- Those 5 years of age and older with active lupus nephritis who are receiving standard therapy.

Benlysta is available as both an intravenous (IV) infusion and a subcutaneous (SC) injection.

- **Preferred Formulation:** The subcutaneous formulation of Benlysta (belimumab) is preferred over the intravenous formulation.
 - Vials are for intravenous administration only.
 - Autoinjectors and prefilled syringes are for subcutaneous administration only.
 - Vials are not intended for subcutaneous injection or autoinjectors/prefilled syringes for intravenous infusion.

NOTE: For full dosage and administration information, please refer to the current prescribing information.

- Members should use the SC formulation unless specific exception criteria for IV administration are met (see [Additional Exception Criteria for Intravenous Administration](#)).
- Benlysta (belimumab) should be administered by a healthcare profession or trained caregiver for those 10 years of age or younger.

There is a risk of progressive multifocal leukoencephalopathy (PML), an opportunistic viral infection of the brain that can result in severe disability or death. Risk factors include presence of anti-JCV antibodies, duration of therapy, and prior use of immunosuppressants. Concurrent use of immunosuppressants, antineoplastics and immunomodulatory therapies can increase the risk of PML and thus concomitant use is not recommended. If any new or deteriorating neurological signs and symptoms are identified, Benlysta (belimumab) should be stopped immediately and PML should be ruled out before continuing therapy.

Definitions

“Anti-JCV antibodies” are markers for exposure to the John Cunningham (JC) virus. If present, anti-JCV antibodies are associated with a higher risk of progressive multifocal leukoencephalopathy (PML), an opportunistic viral infection of the brain that can result in severe disability or death.

“Antimalarial” is a drug class that is used to treat malaria but also is used in autoimmune diseases such as lupus and rheumatoid arthritis.

"Autoantibody" is an antibody produced by one's own immune system that attacks the body's normal cells, rather than foreign antigens (such as viruses and bacteria).

"B cells" are cells in the body that help activate an immune response.

"B lymphocyte stimulator protein (BLyS)" is a molecule in the body that aids in the development of B cells.

"Central nervous system lupus" is a complication that can be seen in those with lupus and can involve conditions such as seizures, cerebrovascular accidents (strokes), delirium, and nerve pain.

"Corticosteroid" is a drug class that reduces inflammation and suppresses the immune system.

"Human monoclonal antibody" is a protein made from human cells that is designed to bind to a specific molecule in the body and can be used to treat a variety of diseases including lupus, rheumatoid arthritis, and cancers.

"Immunosuppressives" are medications that prevent the actions of the immune system, used in diseases such as lupus, rheumatoid arthritis, psoriasis, and Crohn's disease.

"JCV" or "John Cunningham virus" refers to a virus associated with the development of progressive multifocal leukoencephalopathy (PML), a side effect of certain immunosuppressive medications. Those who use Benlysta should be tested for JCV before starting treatment and while on treatment to help identify if they are at a higher risk for PML.

"Lupus nephritis" is inflammation of the kidney in those with lupus.

Medical Necessity Criteria for Initial Authorization

The Plan considers Benlysta (belimumab) medically necessary when recent (within the last 6 months) clinical chart documentation is provided indicating the ALL the following criteria are met for the applicable indication listed below:

For active systemic lupus erythematosus

1. The medication is being prescribed by a rheumatologist; *AND*
2. The member is 5 years of age or older; *AND*
3. The member has a diagnosis of active systemic lupus erythematosus and meets BOTH of the following conditions:
 - a. Positive for autoantibodies (e.g., antinuclear antibody [ANA], anti-double-stranded DNA [anti-dsDNA], anti-Smith, anti-RNP, anti-Ro, anti-La, or anti-cardiolipin); *and*

- b. Receiving standard therapy, which includes at least ONE (1) of the following, alone or in combination:
 - i. antimalarials (such as hydroxychloroquine); *or*
 - ii. corticosteroids (such as prednisone, methylprednisolone, dexamethasone); *or*
 - iii. immunosuppressives (such as azathioprine, methotrexate, mycophenolate); *AND*
- 4. The member does not have severe active central nervous system lupus (such as altered mental function or confusion, vision problems, or seizures); *AND*
- 5. The member is not using Benlysta (belimumab) in combination with ANY of the following:
 - a. other biologic therapies (such as Actemra [toilizumab], Enbrel [etanercept], Humira [adalimumab], Stelara [ustekinumab]); *or*
 - b. intravenous cyclophosphamide; *AND*
- 6. If the member is prescribed intravenous Benlysta (belimumab), meets the below [Additional Exception Criteria for Intravenous Administration](#).

For active lupus nephritis

- 1. The medication is being prescribed by a rheumatologist or nephrologist; *AND*
- 2. The member is 5 years of age or older; *AND*
- 3. The member has a diagnosis of active lupus nephritis and meets BOTH of the following conditions:
 - a. Positive for autoantibodies (e.g., antinuclear antibody [ANA], and/or anti-double-stranded DNA [anti-dsDNA], anti-Smith, anti-RNP, anti-Ro, anti-La, or anti-cardiolipin); *and*
 - b. Receiving standard therapy, which includes at least ONE (1) of the following, alone or in combination:
 - i. calcineurin inhibitors (such as cyclosporine, tacrolimus); *or*
 - ii. corticosteroids (such as prednisone, methylprednisolone, dexamethasone); *or*
 - iii. immunosuppressives (such as azathioprine, mycophenolate); *AND*
- 4. The member does not have severe active central nervous system lupus (such as altered mental function or confusion, vision problems, or seizures); *AND*
- 5. The member is not using Benlysta in combination with other biologic therapies (such as Actemra [toilizumab], Enbrel [etanercept], Humira [adalimumab], Stelara [ustekinumab]); *AND*
- 6. If the member is prescribed intravenous Benlysta (belimumab), meets the below [Additional Exception Criteria for Intravenous Administration](#).

[Additional Exception Criteria for Intravenous Administration](#)

- 7. *The Plan requires all members to use Benlysta (belimumab) subcutaneous (SC) formulation for initial therapy and maintenance treatment. Benlysta (belimumab) for intravenous (IV) infusion will be authorized only when the member meets ONE of the following:*
 - a. The member has a documented contraindication to the subcutaneous (SC) formulation that would NOT be expected to occur with the IV formulation; *OR*

- b. The member has demonstrated a clinical response to Benlysta SC but is unable to continue due to severe injection site reactions that are not manageable with standard interventions (e.g., persistent severe pain, recurrent large areas of erythema, severe pruritus unresponsive to treatment); *OR*
- c. The member experienced a documented intolerable adverse event to the SC formulation of Benlysta that would NOT be expected to occur with the IV formulation; *OR*
- d. The member has physical or cognitive limitations that prevent SC self-administration or administration by a caregiver, including but not limited to visual impairment, limited manual dexterity, or impaired cognitive function (documentation required); *OR*
- e. The member has a documented medical condition that significantly impairs subcutaneous absorption, making IV administration necessary for effective treatment (e.g., severe lipodystrophy, extensive scarring over injection sites, scleroderma with significant skin thickening); *OR*
- f. The member requires a dose that is NOT available or feasible for SC administration; *OR*
- g. The prescriber provides a clear clinical rationale, supported by documentation, for why Benlysta IV is expected to be beneficial despite failure or intolerance of Benlysta SC.

If the above prior authorization criteria are met, Benlysta (belimumab) will be approved for up to 12-months.

- *Subcutaneous administration is the preferred route and should be used for initial therapy and maintenance treatment unless exception criteria for IV administration are met.*

Medical Necessity Criteria for Reauthorization

Reauthorization for up to 12 months will be granted if BOTH of the following are met:

1. The member still meets the applicable [Initial Authorization](#) criteria; *and*
2. Recent chart documentation (within the last 6 months) shows ONE of the following:
 - a. The member has shown a clinical improvement (e.g., sustained improvement in disease activity and reductions in disease flares) in symptoms since starting the requested medication; *or*
 - b. The member has experienced disease stability (e.g., complete remission, low disease activity state, no new lupus disease activity compared with the previous assessment) since starting the requested medication.

Experimental or Investigational / Not Medically Necessary

Benlysta (belimumab) for any other indication is considered not medically necessary by the Plan, as it is deemed to be experimental, investigational, or unproven. Non-covered indications include, but are not limited to, the following:

- Immunoglobulin G4 Related Sclerosing Disease. There have only been case reports of the use of Benlysta (belimumab) for the management of Immunoglobulin G4 Related Sclerosing Disease in those who already have SLE. There are currently no high quality published data to support the safety and efficacy of Benlysta (belimumab) for the management of Immunoglobulin G4 Related Sclerosing Disease, outside of the management of SLE
- Immune Thrombocytopenia (ITP). Benlysta (belimumab) has been studied in small cohort studies, case reports, and case series in those with ITP and SLE. While there has been promising results in these published studies, there are no high quality, large controlled trials with published results to support the safety and efficacy of Benlysta (belimumab) for the management of ITP, outside of the management of SLE.
- Anti-Neutrophil Cytoplasmic Antibody-Associated Vasculitis / Granulomatosis With Polyangiitis. One multicentre double-blind randomized controlled study did not find a significant benefit in reducing vasculitis relapse in those treated with Benlysta (belimumab) plus azathioprine and glucocorticoids compared to placebo. There are no high quality, large controlled trials with published results to support the safety and efficacy of Benlysta (belimumab) for the management of Granulomatosis With Polyangiitis.
- Chronic Obstructive Pulmonary Disease (COPD) / Emphysema. There are no high quality, large controlled trials with published results to support the safety and efficacy of Benlysta (belimumab) for the management of COPD/emphysema. One small (n=17) "proof-of-concept" study (NCT03244059) did not assess clinical outcomes, only surrogate markers of disease (circulating B-cells, pneumococcal polysaccharide-binding antibodies, and circulating anti-GRP78 immunoglobulin-G levels).
- Myasthenia Gravis. One small (n=40), phase II randomized controlled trial assessed Benlysta (belimumab) versus placebo and did not find a significant improvement in the primary outcome of change from baseline in the quantitative myasthenia gravis scale at week 24. There are no high quality, large controlled trials with published results to support the safety and efficacy of Benlysta (belimumab) for the management of myasthenia gravis.
- Rheumatoid Arthritis. In one phase II randomized controlled trial (n=238), Benlysta (belimumab) showed inconsistent benefit amongst those with moderate rheumatoid arthritis who had failed at least one (1) disease-modifying antirheumatic drug (DMARD) compared to placebo. An extension study was terminated, and did not publish results assessing long-term benefits (NCT00583557).
- Sjogren's Syndrome (SS). In a small (n=86) double-blind randomized multicentre clinical study (NCT02631538) there were inconsistent and non-significant improvements in Sjogren's Syndrome disease activity scores in both the Benlysta (belimumab) and Benlysta (belimumab) and Rituximab (Rituxan) combined arms versus placebo. All other studies showing positive and/or promising responses were of low quality and included a very small number of participants. There are no high quality, large controlled trials with published results to support the safety and efficacy of Benlysta (belimumab) for the management of Sjogren's Syndrome (SS).
- Cryoglobulinemia. Small studies and case reports find some promising results with Benlysta (belimumab), however there are currently no high quality published data to support the safety and efficacy of Benlysta (belimumab) for the management of cryoglobulinemia.

- Vasculitis. Vasculitis can be a manifestation of SLE, and small studies have shown some benefit in vasculitis resolution in those with SLE. However, a multicentre double-blind randomized controlled study did not find a significant benefit in reducing vasculitis relapse in those treated with Benlysta (belimumab) plus azathioprine and glucocorticoids compared to placebo. There are currently no other high quality published data to support the safety and efficacy of Benlysta (belimumab) for the management of vasculitis, outside of the management of SLE.
- Relapsed Chronic Lymphocytic Leukemia (CLL). There is currently no high quality published data to support the safety and efficacy of Benlysta (belimumab) for the management of relapsed CLL.
- Anti-Phospholipids Syndrome (APS). There is currently no high quality published data to support the safety and efficacy of Benlysta (belimumab) for the management of APS.
- Graft-versus-host Disease (GVHD). There is currently no high quality published data to support the safety and efficacy of Benlysta (belimumab) for the prevention or management of GVHD.
- Idiopathic CD4 Lymphocytopenia. There is currently no high quality published data to support the safety and efficacy of Benlysta (belimumab) for the management of idiopathic CD4 lymphocytopenia.
- Neuromyelitis Optica Spectrum Disorders. There is currently no high quality published data to support the safety and efficacy of Benlysta (belimumab) for the prevention or management of neuromyelitis optica spectrum disorders.
- Discoid Lupus Erythematosus (DLE). There is currently no high quality published data to support the safety and efficacy of Benlysta (belimumab) for the management of DLE.

Additionally, the Plan requires all members to use the subcutaneous formulation of Benlysta for initial therapy and maintenance treatment, unless specific exception criteria for intravenous administration are met and documented (see [Additional Exception Criteria for Intravenous Administration](#)). Use of the intravenous formulation without meeting these criteria or continuing intravenous administration when transition to subcutaneous administration is feasible is considered not medically necessary.

Applicable Billing Codes (HCPCS/CPT Codes)

CPT/HCPCS Codes for Applicable Medications	
<i>Code</i>	<i>Description</i>
J0490	Benlysta IV Injection, belimumab, 10 mg
J3590	Benlysta SC (belimumab) Unclassified biologics
ICD-10-CM Codes for Clinical Indications	
<i>Codes</i>	<i>Description</i>
<i>Systemic Lupus Erythematosus</i>	

M32.0	Drug-induced systemic lupus erythematosus
M32.10	Systemic lupus erythematosus, organ or system involvement unspecified
M32.11	Endocarditis in systemic lupus erythematosus
M32.12	Pericarditis in systemic lupus erythematosus
M32.13	Lung involvement in systemic lupus erythematosus
M32.15	Tubulo-interstitial nephropathy in systemic lupus erythematosus
M32.19	Other organ or system involvement in systemic lupus erythematosus
M32.8	Other forms of systemic lupus erythematosus
M32.9	Systemic lupus erythematosus, unspecified
<i>Lupus Nephritis</i>	
M32.14	Glomerular disease in systemic lupus erythematosus

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Clinical Guideline Revision / History Information

Original Date: 08/06/2020

Reviewed/Revised: 06/24/2021, 12/01/2021, 06/23/2022, 9/15/2022, 9/21/2023, 8/29/2024, 12/01/2025