

Pharmacy Policy

Benlysta (belimumab)

Policy Number: 9.115

Version Number: 2.0

Version Effective Date: 1/1/2022

<p>Product Applicability <input type="checkbox"/> All Plan+ Products</p>	
<p>Well Sense Health Plan</p> <p><input type="checkbox"/> New Hampshire Medicaid</p>	<p>Boston Medical Center HealthNet Plan</p> <p><input type="checkbox"/> MassHealth ACO</p> <p><input type="checkbox"/> MassHealth MCO</p> <p><input checked="" type="checkbox"/> Qualified Health Plans/ConnectorCare/Employer Choice Direct</p> <p><input type="checkbox"/> Senior Care Options</p>

Note: Disclaimer and audit information is located at the end of this document.

Prior Authorization Policy

Products Affected:

- Benlysta (belimumab)

The Plan may authorize coverage of the above products for members meeting the following criteria:

Covered Use	All FDA approved indications not otherwise excluded
Exclusion Criteria	Coverage of Benlysta will not be approved in the following instances: 1. Diagnosis of severe active central nervous system (CNS) lupus; OR 2. Use of Benlysta in combination with other biologics
Required Medical Information	1. A diagnosis of active autoantibody-positive (e.g. ANA, anti-ds-DNA, anti-Sm) systemic lupus erythematosus (SLE); AND a. Benlysta will be used in combination with at least one formulary standard therapy for

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	<p>active SLE such as: antimalarials (e.g. hydroxychloroquine), systemic glucocorticoids (e.g. prednisone), or immunosuppressive agents (e.g. cyclophosphamide, methotrexate, azathioprine, and mycophenolate); OR</p> <p>2. Diagnosis of active lupus nephritis (LN); AND</p> <p>a. Member has confirmed diagnosis of systemic lupus erythematosus; AND</p> <p>b. Kidney biopsy confirms class III, IV, or V lupus nephritis; AND</p> <p>c. Benlysta will be used in combination with at least one formulary standard therapy for SLE such as: antimalarials (e.g. hydroxychloroquine), systemic glucocorticoids (e.g. prednisone), or immunosuppressive agents (e.g. cyclophosphamide, methotrexate, azathioprine, and mycophenolate)</p>
Age Restrictions	SLE: 5 years of age or older (IV only) or 18 years of age or older (SC) LN: 18 years of age or older
Prescriber Restriction	SLE: Prescribed by or in consultation with a rheumatologist LN: Prescribed by or in consultation with a rheumatologist or nephrologist
Coverage Duration	12 months

Applicable Coding:

Code	Medication
J0490	Benlysta® (belimumab injection)

*Medical billing codes may not be used for Benlysta injection for subcutaneous use. The subcutaneous formulation must be obtained via the pharmacy benefit

Clinical Background Information and References

1. American College of Rheumatology. Systemic Lupus Erythematosus (Lupus). URL: rheumatology.org/practice/clinical/patients/diseases_and_conditions/lupus.asp. Available from Internet. Accessed 2017 February 20.
2. Benlysta drug information. UpToDate. Waltham, MA: UpToDate Inc. <https://www.uptodate.com> (Accessed on April 4, 2019).
3. Bertsias G, Ioannidis JP, Boletis J et al. EULAR recommendations for the management of systemic lupus erythematosus. Report of a task force of the EULAR Standing Committee for international clinical studies including therapeutics. Ann Rheum Dis. 2008; 67(2):195-205.
4. Bertsias GK, Ioannidis JP, Aringer M, et al. EULAR recommendations for the management of systemic lupus erythematosus with neuropsychiatric manifestations: report of a task force of the EULAR standing committee for clinical affairs. Ann Rheum Dis. 2010 Dec;69(12):2074-82.

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5. Bertsias GK, Ioannidis JP, Boletis J, et al. EULAR points to consider for conducting clinical trials in systemic lupus erythematosus: literature based evidence for the selection of endpoints. *Ann Rheum Dis*. 2009; 68(4):477-83.
6. Bezalel S, Asher I, Elbirt D, Sthoeger ZM. Novel biological treatments for systemic lupus erythematosus: current and future modalities. *Isr Med Assoc J*. 2012 Aug;14(8):508-14.
7. Dooley MA, Houssiau F, Aranow C, et al. Effect of belimumab treatment on renal outcomes: results from the phase 3 belimumab clinical trials in patients with SLE. *Lupus*. 2013 Jan;22(1):63-72.
8. FDA Briefing Information, Belimumab (Benlysta), for the November 16, 2010 Meeting of the Arthritis Advisory Committee.
9. Furie R, Petri M, Zamani O, et al. A phase III, randomized, placebo-controlled study of belimumab, a monoclonal antibody that inhibits B lymphocyte stimulator, in patients with systemic lupus erythematosus. *Arthritis Rheum*. 2011 Dec;63(12):3918-30.
10. Ginzler EM, Wallace DJ, Merrill JT, et al. Disease control and safety of belimumab plus standard therapy over 7 years in patients with systemic lupus erythematosus. *J Rheumatol*. 2014 Feb;41(2):300-9.
11. Gurevitz SL, Snyder JA, Wessel EK, et al. Systemic lupus erythematosus: a review of the disease and treatment options. *Consult Pharm*. 2013 Feb;28(2):110-21.
12. Manzi S, Sánchez-Guerrero J, Merrill JT, et al. Effects of belimumab, a B lymphocyte stimulatorspecific inhibitor, on disease activity across multiple organ domains in patients with systemic lupus erythematosus: combined results from two phase III trials. *Ann Rheum Dis*. 2012 Nov;71(11):1833-8.
13. Merrill JT, Ginzler EM, Wallace DJ, et al. Long-term safety profile of belimumab plus standard therapy in patients with systemic lupus erythematosus. *Arthritis Rheum*. 2012 Oct;64(10):3364- 73.
14. Mosca M, Tani C, Aringer M, et al. European League Against Rheumatism recommendations for monitoring patients with systemic lupus erythematosus in clinical practice and in observational studies. *Ann Rheum Dis*. 2010 Jul;69(7):1269-74.
15. Navarra SV, Guzman RM, Gallacher AE, et al. Efficacy and safety of belimumab in patients with active systemic lupus erythematosus: a randomized, placebo-controlled, phase 3 trial. *Lancet*. 2011; 377(9767):721-31.
16. Product information. Benlysta[®], belimumab. Human Genome Sciences, Inc. (a subsidiary of GlaxoSmithKline). Rockville, Maryland. July 2017.
17. van Vollenhoven RF, Petri MA, Cervera R, et al. Belimumab in the treatment of systemic lupus erythematosus: high disease activity predictors of response. *Ann Rheum Dis*. 2012 Aug;71(8):1343-9.
18. Wallace DJ, Navarra S, Petri MA, et al. Safety profile of belimumab: pooled data from placebocontrolled phase 2 and 3 studies in patients with systemic lupus erythematosus. *Lupus*. 2013 Feb;22(2):144-54.
19. Wallace DJ. Advances in drug therapy for systemic lupus erythematosus. *BMC Med*. 2010;8:77.

Original Approval Date	Original Effective Date	Policy Owner	Approved by
12/1/2020	1/1/2021	Pharmacy Services	Pharmacy & Therapeutics (P&T) Committee

Policy Revisions History

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Policy Revisions History

Review Date	Summary of Revisions	Revision Effective Date	Approved by
12/1/2020	9.178 Benlysta Policy retired, new policy created	1/1/2021	P&T Committee
8/12/2021	P&T Annual Review. Added diagnosis of lupus nephritis and removed some exclusions and reauthorization criteria.	1/1/2022	P&T Committee

Next Review Date

8/2022

Other Applicable Policies

Reference to Applicable Laws and Regulations, If Any

Disclaimer Information

Medical Policies are the Plan's guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member's benefit document, and when appropriate, coordinates with the Member's health care Providers to consider the individual Member's health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan's service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member's benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.

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