

Complete Patient and Physician information (PLEASE PRINT)

STEP
1

Member Name:	Physician Name:
Address:	Address:
Member ID:	Phone #:
Member DOB:	Fax #:
	Tax ID or NPI Number:

If Applicable: Pharmacy Name: _____ Pharmacy Phone: _____

Complete the Clinical Assessment:

STEP
2

Diagnosis	<input type="checkbox"/> Systemic Lupus Erythematosus (SLE) <input type="checkbox"/> Autoantibody-positive (documentation required)	<input type="checkbox"/> Other (please state): _____ _____
Clinical Consideration	Autoantibody-positive criteria met if: <input type="checkbox"/> Antinuclear antibody (ANA) titre $\geq 1:80$ OR <input type="checkbox"/> Anti-double stranded DNA antibody ≥ 30 IU/ml	Documentation Required: <input type="checkbox"/> Persistently active disease in spite of treatment with standard therapy OR <input type="checkbox"/> Intolerance, Contraindication, or Failure of standard therapy (see coverage criteria).
	<input type="checkbox"/> Patient <i>does not</i> have severe active lupus nephritis or severe active CNS lupus.	<input type="checkbox"/> Patient is <i>not</i> on other biologics or IV cyclophosphamide.
Physician Specialty	Diagnosis made by: <input type="checkbox"/> Rheumatologist <input type="checkbox"/> Other (please state): _____	
Supporting Documentation	Diagnosis: ICD-9 Code #/ Description / J Code (required):	
	Please attach a copy of the prescription or provide ALL of the information below: Benlysta [®] (belimumab)	
	Strength _____ Sig _____ Qty _____ Refills _____	
<p style="text-align: center;"><i>*Please attach all relevant medical records and test results*</i></p> <p style="text-align: center;">We will not process incomplete forms.</p> <p style="text-align: center;">If we do not receive the completed form & all relevant medical records & test results within 10 calendar days of this request, it will be denied.</p>		

STEP
3

I certify that the above is correct and accurate to the best of my knowledge and that the form is complete. (please sign and date)

Prescriber Signature

Date

STEP
4

Fax completed form to the Rocky Mountain Health Plans Pharmacy Help Desk: 970-248-5034

Name of Person filling out form: _____

Pharmacy Technician initials _____ Date Initiated _____

Confidentiality Notice:

This facsimile transmission (and/or documents accompanying it) may contain confidential information. This information is intended only for the use of the individual(s) named above. If you have received this transmission in error, or cannot identify the recipient for distribution purposes, please notify us immediately at 970-244-7760. Plans underwritten by Rocky Mountain HMO or Rocky Mountain HealthCare Options. 11/10/11

RMHP Formulary Coverage Policy

THIS INFORMATION IS NOT ALL-INCLUSIVE AND IS PROVIDED FOR INFORMATIONAL PURPOSES ONLY

Benlysta (belimumab)

CLASSIFICATION

- Immunosuppressant/B-lymphocyte stimulator (BLyS)-specific inhibitor

DESCRIPTION

- Belimumab is indicated to treat adult patients with active, autoantibody-positive systemic lupus erythematosus (SLE) who are receiving standard therapy.
- Treatment with belimumab is not recommended for patients with severe active lupus nephritis or severe active CNS lupus, or in combination with other biologics or IV cyclophosphamide, as it has not been studied in these situations.
- Belimumab is a human monoclonal antibody that blocks the binding of soluble B-lymphocyte stimulator (BLyS), a B-cell survival factor, to its receptors on B cells. Belimumab does not bind B cells directly, but by binding BLyS, belimumab inhibits the survival of B cells, including autoreactive B cells, and reduces the differentiation of B cells into immunoglobulin-producing plasma cells. Belimumab inhibits the survival of B cells, including autoreactive B cells, and reduces the differentiation of B cells into immunoglobulin-producing plasma cells by inhibiting the binding of BLyS to B cells.
- In a randomized, double-blind, placebo-controlled study (n=449), systemic lupus erythematosus (SLE) outcomes at 24 and 52 weeks were not improved with any of 3 doses of belimumab compared with placebo. Exploratory analysis yielded improvement in a subgroup of patients with autoantibodies at baseline (72%).
- In randomized, double-blind, placebo-controlled trials, a systemic lupus erythematosus response was achieved by a significantly greater proportion of patients with belimumab 10 mg/kg compared with placebo after 52 weeks of treatment (study 1 (n=819) and study 2 (n=865)) but not after 76 weeks of treatment (study 1).
- In the 2 studies combined, there was not a significant difference between the belimumab groups and the placebo group in the proportion of patients who experienced a severe SLE flare and the proportion of patients who were receiving prednisone at doses more than 7.5 mg/day at baseline and who were able to reduce their average prednisone dose during weeks 40 through 52.
- Black Population: Definitive conclusions can not be drawn from the subgroup analysis of 3 clinical trials; however, the manufacturer suggests caution when considering belimumab therapy for SLE in black patients.
 - Black patients (n=106) in the randomized, double-blind, placebo-controlled study of 449 patients, did not differ in response in the belimumab groups and the placebo group.
 - In a combined subgroup analysis of black patients (n=148) in the 2 randomized, double-blind, placebo-controlled studies (study 1, n=819; study 2, n=865), an SRI response was achieved by fewer patients in the belimumab 10 mg/kg group (36%; 18/50) and the belimumab 1 mg/kg group (31%; 15/48) than in the placebo group (44% 22/50).
- Adverse events occurring in $\geq 5\%$ of patients receiving Benlysta include nausea, diarrhea, pyrexia, nasopharyngitis, bronchitis, insomnia, pain in extremity, depression, migraine, and pharyngitis. The most common serious AE was infection which was reported in 6.0% and 5.2% of patients treated with Benlysta and placebo, respectively.
- More deaths were reported with Benlysta compared to placebo in clinical trials. Deaths were due to infection, cardiovascular disease, and suicide; however, no cause of death predominated.
- Psychiatric events, including depression, insomnia, and anxiety, have been reported more frequently in clinical trials with Benlysta (17%) compared to placebo (12%). Most patients reporting serious depression or suicidal behavior had a history of depression or another serious psychiatric disorder and most were taking psychoactive medications.

FORMULARY COVERAGE

Prior authorization: YES

Good Health Formulary: Medical (Tier 6)

Commercial Formulary: Medical (Tier 6)

Medicare Part D coverage: Specialty (Tier 5); Part D if obtained at a pharmacy; Part B if incident to a physician's service

COVERAGE CRITERIA

Benlysta (belimumab) meets the definition of **medical necessity** for the following:

- Adult patients with ***persistently*** active, ***autoantibody-positive*** systemic lupus erythematosus (SLE) even with the use of standard therapy.
- Autoantibody-positive criteria to be met:
 - Antinuclear antibody (ANA) titre $\geq 1:80$; OR
 - Anti-double stranded DNA antibody ≥ 30 IU/ml
- Failure of standard of care is defined as any SLE patient who gets a flare of their disease and cannot be tapered to less than 7.5mg/day of prednisone even with use of an antimalarial (hydroxychloroquine or chloroquine) and at least one immunosuppressant (azathioprine, methotrexate, *or* cellcept). Documentation required.
- Documentation required if patient has a contraindication, intolerance, or allergy to standard therapy.
- Benlysta has not been studied in patients with severe active lupus nephritis or severe active CNS lupus, or in combination with other biologics or IV cyclophosphamide. Therefore, Benlysta ***is not*** a benefit for these patients.

Benlysta (belimumab) is considered **experimental** for the following:

- Any indication that is not FDA approved or Compendia supported

Required Provider Specialty:

- Rheumatologist

DOSAGE/ADMINISTRATION:

Adult dosing:

- 10 mg/kg IV infusion over 1 hour every 2 weeks for the first 3 doses, then every 4 weeks thereafter
- Consider premedication for prophylaxis against infusion reactions and hypersensitivity reactions

Safety and efficacy has not been established in pediatric patients.

PRECAUTIONS:

- Anaphylaxis has been reported; monitoring recommended
- Use of concomitant IV cyclophosphamide or other biologic therapies not recommended
- Hypersensitivity reactions (e.g. pruritus, hypotension, angioedema, urticaria, and other rash) have been reported; premedication may mask hypersensitivity reactions; monitoring recommended
- Chronic infection increases risk for developing a serious infection; use not recommended
- Infection, serious or possibly fatal has been reported
- Infusion reactions (e.g. bradycardia, myalgia, skin reactions, headache or hypotension) have been reported; premedication may mask infusion reactions; monitoring recommended
- Live vaccine administration not recommended within 30 days of belimumab therapy
- Malignancy may occur
- Mortality greater compared with placebo groups
- Suicidal ideation and behavior or worsening of depression may occur

Billing/Coding information:

Associated HCPCS Codes:

Q2044	Injectable belimumab
J0490	Injection, belimumab, 10mg

Associated ICD-9 Coding:

710.0	Systemic lupus erythematosus
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COST

AWP (October 2011):

- \$4.43/mg
- \$531.82/ 120mg vial
- \$1772.71/ 400mg vial

COMMITTEE APPROVAL:

- November 2011

GUIDELINE UPDATE INFORMATION:

10/ 30/11	Policy creation

REFERENCES:

- DRUGDEX®, accessed 10/30/2011
- Product Information: Benlysta™, (belimumab) for IV injection. Human Genome Sciences, Inc., Rockville, MD and GlaxoSmithKline, Research Triangle Park, NC 2011.