DRUG DETERMINATION POLICY

Title: DDP-19 Benlysta

Effective Date: 8/23/23

Physicians Health Plan
PHP Insurance Company
PHP Service Company

Important Information - Please Read Before Using This Policy

The following policy applies to health benefit plans administered by PHP and may not be covered by all PHP plans. Please refer to the member's benefit document for specific coverage information. If there is a difference between this general information and the member's benefit document, the member's benefit document will be used to determine coverage. For example, a member's benefit document may contain a specific exclusion related to a topic addressed in a coverage policy.

Benefit determinations for individual requests require consideration of:

1. The terms of the applicable benefit document in effect on the date of service.
2. Any applicable laws and regulations.
3. Any relevant collateral source materials including coverage policies.
4. The specific facts of the situation.

Contact PHP Customer Service to discuss plan benefits more specifically.

1.0 Policy:

This policy describes the determination process for coverage of specific drugs.

This policy does not guarantee or approve benefits. Coverage depends on the specific benefit plan. Drug Determination Policies are not recommendations for treatment and should not be used as treatment guidelines.

2.0 Background or Purpose:

Benlysta is a specialty drug indicated for Systemic Lupus Erythematosus (SLE) and Lupus Nephritis and is useful for specific organ system symptoms. These criteria were developed and implemented to ensure appropriate use for the specific symptoms detailed below.

3.0 Clinical Determination Guidelines:

Document the following with chart notes.

I. General Considerations:

A. Required site-of-care as determined by the Health Plan (see DDP-08 Site of Care for Administration of Parenteral Specialty Medications).

B. Dose Rounding: Medication requests may be automatically rounded up or down by 10% of the requested dose in order to fit the nearest manufacturer's strength of the requested medication for patients weighing above 10 kg (see DDP-21 Dose Rounding and Wastage).

C. Exclusions:

1. Concurrent Disease: central nervous system lupus.

2. Concurrent Medications: other biologics or intravenous cyclophosphamide.

3. Pharmaceutical sample use: The Plan does not recognize samples as a medication trial or for continuation of therapy.

D. Approval.

1. Initial: six months.

2. Re-approval: one year [must meet both listed below]:

a. Decrease signs and symptoms and/or laboratory values of disease.

b. Adherence [must meet one listed below]:

i. Medications processed under the pharmacy benefit: consistent (at least 80% of days covered) fill history electronically or verbally from pharmacy.

ii. Medications processed under the medical benefit: consistent utilization (at least 80% of days covered) based on medical claims history or chart notes.

II. Systemic Lupus Erythematosus [must meet all listed below]:

A. Age: at least five years.

B. Diagnosis and severity [must meet both listed below]:

1. Active moderate to severe systemic lupus erythematosus refractory or intolerant to other immunosuppressive drugs.

2. Autoantibody positive: ANA at or above 1:80 and/or anti-dsDNA at or above 30 units per ml.

C. Other therapies: A trial of the appropriate regimen (based on severity see Appendix I) listed below is required unless all are contraindicated. Trial must result in an inadequate response after four consecutive months of use per medication or a severe adverse reaction.

1. Moderate disease: prednisolone (at least 7.5mg per day); hydroxychloroquine; and azathioprine, methotrexate, mycophenolate mofetil, OR cyclosporine.

2. Severe disease: prednisolone (at least 7.5mg per day); hydroxychloroquine; and mycophenolate OR cyclosporine.

D. Dosage regimen:

1. Adults: Benlysta intravenous (belimumab IV): 10 mg per kg every two weeks for three doses, then every four weeks; or Benlysta subcutaneous (belimumab SQ): 200mg every week.

2. Pediatrics: Benlysta intravenous 10 mg per kg every two weeks for three doses, then 10 mg per kg every four weeks.

III. Lupus Nephritis [must meet all listed below]:

A. Age: at least five years.

B. Diagnosis and severity [must meet both listed below]:

1. Urinalysis: proteinuria, microscopic hematuria, kidney impairment, and/or hypertension.

2. Biopsy results in focal (class III), diffuse (class IV), or membranous nephropathy (class V LN).

C. Other therapies in combination with systemic glucocorticoids: Trials of one disease-modifying anti-rheumatic drug (DMARD) and one calcineurin inhibitor below are required unless all are contraindicated. Trials must result in an inadequate response after four consecutive months of use per medication or severe adverse reactions.

1. Disease-modifying anti-rheumatic drugs: mycophenolate or cyclophosphamide intravenous.

2. Calcineurin inhibitor triple therapy: tacrolimus added to one above.

D. Benlysta intravenous or subcutaneous (belimumab IV or SQ):

1. Adults:

a. Benlysta intravenous (belimumab IV): 10 mg per kg every two weeks for three doses, then every four weeks

b. Benlysta subcutaneous (belimumab SQ): 400 mg every week for four doses, then 200 mg every week thereafter.

2. Pediatrics:

a. Benlysta intravenous (belimumab IV): 10 mg per kg every two weeks for three doses, then 10 mg per kg every four weeks.

4.0 Coding:

COVERED CODES				
HCPCS Code	**Brand Name**	**Generic Name**	**Billing Units (1 unit)**	**Prior Approval**
J0490	Benlysta	belimumab	10mg	Y

Medication	**Process through pharmacy benefit**	**Process through medical benefit**
Benlysta	Autoinjector - Subcutaneous Prefilled syringe - Subcutaneous	Vial - Intravenous

5.0 References, Citations & Resources:

1. Lexi comp Online®, Lexi-Drugs®, Hudson, Ohio: Lexi-Comp, Inc.; Benlysta, accessed July 2022.
2. The British Society for Rheumatology guideline for the management of SLE in adults: Executive Summary. Rheumatology 2018;57.
3. DDP-08 Site of Care for Administration of Parenteral Specialty Medications.

6.0 Appendices:

See page 4.

7.0 Revision History:

Original Effective Date: 12/1/2011

Next Review Date: 09/01/2024

Revision Date	Reason for Revision
7/19	Annual review; replaced abbreviations
6/20	Annual review: removed mild disease other therapies replaced abbreviations, approved by P&T Committee 8/26/20.
6/21	Annual review, reformatted, added indication Lupus nephritis, revised SLE age
7/22	Annual review, no changes
6/23	Annual review; added general considerations section (no sample use, adherence requirement for re-approval, dose rounding), update other therapies language

Appendix I: SLE Treatment Strategies for Mild, Moderate and Sever Non-renal Lupus[2]

Item	Mild activity/flare BILAG C scores or single B score; SLEDAI <6	Moderate activity/flare BILAG 2 or more systems with B scores, SLEDAI 6–12	Severe activity/flare (non-renal) BILAG 1 or more A scores; SLEDAI >12
Typical manifestations attributed to lupus	Fatigue, malar rash, diffuse alopecia, mouth ulcers, arthralgia, myalgia, platelets 50–149 × 10^9/l	Fever, lupus-related rash up to 2/9 body surface area, cutaneous vasculitis, alopecia with scalp inflammation, arthritis, pleurisy, pericarditis, hepatitis, platelets 25–49 × 10^9/l	Rash involving >2/9 body surface area, myositis, severe pleurisy and/or pericarditis with effusion, ascites, enteritis, myelopathy, psychosis, acute confusion, optic neuritis, platelets <25 × 10^9/l
Initial typical drugs and target doses if no contra-indications	CSs[a]: topical preferred or oral prednisolone ⩽20 mg daily for 1–2 weeks or I.m. or IA methyl-prednisolone 80–120 mg and HCQ ⩽6.5 mg/kg/day and/or MTX 7.5–15 mg/week and/or NSAIDs (for days to few weeks only)	Prednisolone[a] ⩽0.5 mg/day or i.v. methyl- prednisolone ⩽250 mg × 1–3 or i.m. methyl-prednisolone 80–120 mg and AZA 1.5–2.0 mg/kg/day or MTX (10–25 mg/week) or MMF (2–3 g/day) or ciclosporin ⩽2.0 mg/kg/day and HCQ ⩽6.5 mg/kg/day	Prednisolone[a] ⩽0.5 mg/day and/or i.v. methyl-prednisolone 500 mg × 1–3 or prednisolone ⩽0.75–1 mg/kg/day and AZA 2–3 mg/kg/day or MMF 2–3 g/day or CYC i.v. or ciclosporin ⩽2.5 mg/kg/day and HCQ ⩽6.5mg/kg/day
Aiming for typical maintenance drugs/doses providing no contra-indications	Prednisolone[a] ⩽ 7.5 mg/day and HCQ 200 mg/day and/or MTX 10 mg/week	Prednisolone[a] ⩽7.5 mg/day and AZA 50–100 mg/day or MTX 10 mg/week or MMF 1 g/day or ciclosporin 50–100 mg/day and HCQ 200 mg/day;	Prednisolone[a] ⩽7.5 mg/day and MMF 1.0–1.5 g/day or AZA 50–100 mg/day or ciclosporin 50–100 mg/day and HCQ 200 mg/day;
	Aim to reduce and stop drugs except HCQ eventually when in stable remission	Aim to reduce and stop drugs except HCQ eventually when in stable remission	Aim to reduce and stop drugs except HCQ eventually when in stable remission

[a]The lowest effective dose of prednisolone or other CSs should be used at all times.

Appendix II: Monitoring & Patient Safety

Drug	Adverse Reactions	Monitoring	REMS
Benlysta belimumab	• Gastrointestinal: nausea (15%), diarrhea (12%) • Miscellaneous: infusion related reaction (17%), hypersensitivity (13%) • Pregnancy: IgG molecules cross placenta with increased amount through pregnancy (use contraception during and 4 mos. post use)	• Central Nervous System: worsening depression, mood changes, suicidal thought • Hypersensitivity, infusion reactions • Infections	None needed