# DRUG DETERMINATION POLICY

**Title:** DDP-19 Benlysta

**Effective Date**: 09/05/2019

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 particular 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 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

A. Systemic Lupus Erythematosus (SLE).

   1. Age: at least 18 years.

   2. Prescriber: Rheumatologist.

   3. Diagnosis and severity.

      a. Active moderate to severe SLE refractory or intolerant to other immunosuppressive drugs.

      b. Autoantibody positive: ANA $\geq$1:80 &/or anti-dsDNA $\geq$30 Units/mL.

   4. Chronic other therapies: failed or had significant adverse effects (see appendix I).

      a. Mild disease (4 months): both below

         i. Prednisolone ($\leq$7.5mg per day) **plus;**

ii. Hydroxychloroquine or methotrexate .

b. Moderate disease (4 months): all below:

i. Prednisolone (≤7.5mg per day) **plus;**

ii. Hydroxychloroquine **plus**;

iii. Azathioprine, Methotrexate, mycophenolate mofetil or cyclosporine.

c. Severe disease (4 months): all below

i. Prednisolone (≥7.5mg per day) **plus;**

ii. Hydroxychloroquine **plus;**

iii. Mycophenidate or cyclosporine.

5. Dosage regimen:

a. Adults: Benlysta IV (belimumab): 10mg/Kg every two weeks times three, then every four weeks or Benlysta SC (belimumab): 200mg every week.

b. Pediatrics: Benlysta IV 10mg/Kg every two weeks, then 10mg/kg every four weeks.

6. Approval.

a. Initial: six months.

b. Re-approval: one year (decrease signs and symptoms of disease).

c. Administration: Medication falls under site of care policy

7. Exclusions:

a. Concurrent Disease: severe active lupus nephritis or Central Nervous System (CNS) lupus.

b. Concurrent Medications: other biologics or IV cyclophosphamide.

**4.0 Coding:**

| **AFFECTED CODES** | | | | |
|---|---|---|---|---|
| **HCPCS Code** | **Brand Name** | **Generic Name** | **Billing Units (1U)** | **Prior Approval** |
| J0490 | Benlysta | belimumab | 10mg | Y |

**5.0 References, Citations & Resources:**

1. Lexicomp Online®, Lexi-Drugs®, Hudson, Ohio: Lexi-Comp, Inc.; Benlysta, accessed July 2019.

2. The British Society for Rheumatology guideline for the management of SLE in adults: Executive Summary. Rheumatology 2018;57.

## 6.0 Appendices:

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 contraindications | CSs[a]: topical preferred or oral prednisolone ⩽20 mg daily for 1–2 weeks or I.m. or IA methyl-prednisolone 80–120 mg<br>and HCQ ⩽6.5 mg/kg/day<br>and/or MTX 7.5–15 mg/week<br>and/or NSAIDs (for days to few weeks only) | Prednisolone[a] ⩽0.5 mg/day<br>or i.v. methyl- prednisolone ⩽250 mg × 1–3<br>or i.m. methyl-prednisolone 80–120 mg<br>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<br>and HCQ ⩽6.5 mg/kg/day | Prednisolone[a] ⩽0.5 mg/day<br>and/or i.v. methyl-prednisolone 500 mg × 1–3<br>or prednisolone ⩽0.75–1 mg/kg/day<br>and AZA 2–3 mg/kg/day or MMF 2–3 g/day or CYC i.v. or ciclosporin ⩽2.5 mg/kg/day<br>and HCQ ⩽6.5mg/kg/day |
| Aiming for typical maintenance drugs/doses providing no contraindications | Prednisolone[a] ⩽ 7.5 mg/day<br>and HCQ 200 mg/day<br>and/or MTX 10 mg/week | Prednisolone[a] ⩽7.5 mg/day<br>and AZA 50–100 mg/day<br>or MTX 10 mg/week<br>or MMF 1 g/day<br>or ciclosporin 50–100 mg/day<br>and HCQ 200 mg/day; | Prednisolone[a] ⩽7.5 mg/day<br>and MMF 1.0–1.5 g/day<br>or AZA 50–100 mg/day<br>or ciclosporin 50–100 mg/day<br>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 | • GI: nausea (15%), diarrhea (12%)<br>• Misc: infusion related rx (17%), hypersensitivity (13%)<br>• Pregnancy.: IgG molecules cross placenta w ↑ amt. thru pregnancy (use contraception during and 4 mons. post use) | • CNS: worsening depression, mood changes, suicidal thought<br>• Hypersensitivity, infusion reactions<br>• Infections | None needed |

## 7.0 Revision History:

Original Effective Date: 12/1/2011

Last Approval Date: 09/05/2019

Next Review Date: 09/05/2020

| Revision Date | Reason for Revision |
|---|---|
| 7/19 | Annual review; replaced abbreviations |
| | |