Pharmacy Benefit Determination Policy

Policy Subject: Benlysta	**Dates:**
Policy Number: SHS PBD31	**Effective Date:** December 1, 2011
Category: Rheumatology	**Revision Date** July 10, 2018
Policy Type: ☒ **Medical** ☐ **Pharmacy**	**Approval Date:** August 22, 2018
Department: Pharmacy	**Next Review Date:** August 2019
Product (check all that apply):	**Clinical Approval By:**
☒ Group HMO/POS	**Medical Directors**
☒ Individual HMO/POS	PHP: Peter Graham, MD
☒ PPO	**Pharmacy and Therapeutics Committee**
☒ ASO	PHP: Peter Graham, MD

Policy Statement:

Physicians Health Plan, PHP Insurance & Service Company, and Sparrow PHP will cover Benlysta through the Medical Benefit based on approval by the Clinical Pharmacist or Medical Director using the following determination guidelines

Drugs and Applicable Coding:

J-code: J0490 (1u = 10mg)

Clinical Determination Guidelines:

Document the following with chart notes

A. Systemic Lupus Erythematosus (SLE)
   1. Age: ≥18yrs
   2. Prescriber: Rheumatologist
   3. Diagnosis & severity
      a. Active mod-severe SLE refractory or intolerant to other immunosuppressive drugs
      b. Autoantibody +: ANA ≥1:80 &/or anti-dsDNA ≥ 30 Units/mL.
   4. Chronic other therapies: Failed or had significant adverse effects (see appendix I)
      a. Mild disease (4 mons.): Both below
         - Prednisolone (≤7.5mg/day) **plus**
         - Hydroxychloroquine (HCQ) or methotrexate (MTX)
      b. Moderate disease (4 mons): All below
         - Prednisolone (≤7.5mg/day) **plus**
         - HCQ **plus**
         - Azathioprine (AZA), MTX, mycophenolate mofetil (MMF) or cyclosporine
      c. Severe disease (4 mons): All below
         - Prednisolone (≥7.5mg/day) **plus**
         - HCQ **plus**
         - MMF or cyclosporine

5. Dosage regimen:
   a. Benlysta IV (belimumab): 10mg/Kg/2wks x 3, then q 4wk
   b. Benlysta SC (belimumab): 200mg q wk.
6. Approval
   a. Initial: 6 mons.
   b. Re-approval: 1 yr. (↓SLE flares)
7. Exclusions:
   a. Concurrent Disease: Severe active lupus nephritis or CNS lupus
   b. Concurrent Medications: Other biologics or IV cyclophosphamide

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 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 contraindications	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	• GI: Nausea (15%), diarrhea (12%) • Misc: infusion related rx (17%), hypersensitivity (13%) • Preg.: IgG molecules cross placenta w ↑ amt. thru pregnancy (use contraception during and 4 mons. post use)	• CNS: Worsening depression, mood changes, suicidal thought • Hypersensitivity, infusion reactions • Infections	None needed

References and Resources:

1. Lexicomp Online®, Lexi-Drugs®, Hudson, Ohio: Lexi-Comp, Inc.; Benlysta, accessed July 2018
2. The British Society for Rheumatology guideline for the management of SLE in adults: Executive Summary. Rheumatology 2018;57:e1

Approved By:

	8/22/18
Peter Graham, MD – PHP Executive Medical Director	Date
	8/22/18
Kurt Batteen - Human Resources	Date