Policy Title:	Benlysta (belimumab) (Intravenous)		
		Department:	PHA
Effective Date:	01/01/2020		
Review Date:	10/02/2019, 12/18/19		
Revision Date:	10/02/2019		

Purpose: To support safe, effective and appropriate use of Benlysta (belimumab).

Scope: Medicaid, Exchange, Medicare-Medicaid Plan (MMP)

Policy Statement:

Benlysta (belimumab) is covered under the Medical Benefit when used within the following guidelines. Use outside of these guidelines may result in non-payment unless approved under an exception process.

Procedure:

Coverage of Benlysta (belimumab) will be reviewed prospectively via the prior authorization process based on criteria below.

Initial Criteria:

Systemic Lupus Erythematosus (SLE)

- Patient is 5 years of age or older; AND
- Patient has a confirmed diagnosis of SLE with at least 4 diagnostic features (see list of diagnostic SLE criteria below) one of which must include a positive autoantibody test (e.g., anti-nuclear antibody [ANA] greater than laboratory reference range and/or anti-doublestranded DNA [anti-dsDNA] greater than 2 fold the laboratory reference range if tested by ELISA); AND
- Patient has failed to respond adequately to at least two (2) standard therapies such as antimalarials, corticosteroids, non-steroidal anti-inflammatory drugs, or immunosuppressives (excluding intravenous cyclophosphamide); AND
- Patient has one of the following:
    - Safety of Estrogen in Lupus National Assessment -Systemic Lupus Erythematosus Disease Activity Index (SELENA-SLEDAI) score of 6-12; OR
    - British Isles Lupus Assessment Group (BILAG) B organ domain score ≥2; AND
- Patient must not have an active infection; AND
- Patient has not received a live vaccine within 30 days before starting or concurrently with Benlysta; AND
- Used in combination with standard therapy (e.g. anti-malarials, corticosteroids, nonsteroidal anti-inflammatory drugs, immunosuppressives); AND

- Patient does not have any of the following exclusion criteria:
    - Severe active central nervous system lupus
    - Severe active lupus nephritis
    - Individuals who are on other biologics or IV cyclophosphamide

Systemic Lupus Erythematosus Diagnostic Criteria
Patient must have at least 4 out of 11 diagnostic SLE features: 1. Malar rash 2. Discoid rash 3. Photosensitivity 4. Oral ulcers 5. Nonerosive arthritis (involving 2 or more peripheral joints) 6. Pleuritis/pericarditis a. Pleuritis - history of pleuritic pain or rubbing heard by a physician or evidence of pleural effusion b. Pericarditis - documented by electrocardiogram or rubbing heard by a physician or evidence of pericardial effusion 7. Renal disorder a. Persistent proteinuria > 0.5 grams/day or > 3+ on urine dipstick b. Cellular casts (red cell, hemoglobin, granular, tubular, or mixed) 8. Seizures/psychosis 9. Hematologic disorder: a. Hemolytic anemia with reticulocytosis b. Leukopenia < 4,000/mm^3 on ≥ 2 occasions c. Lymphopenia < 1,500/mm^3 on ≥ 2 occasions d. Thrombocytopenia < 100,000/mm^3 in the absence of offending drugs 10. Immunologic disorder: a. Presence of anti-Sm or antiphospholipid antibodies b. Presence of anti-double-stranded DNA [anti-dsDNA] greater than 2 fold the laboratory reference range if tested by ELISA 11. Positive anti-nuclear antibody [ANA] greater than laboratory reference range

Continuation of Therapy Criteria:

- Meets all initial criteria and is tolerating treatment; AND
- Adequate documentation of disease stability and/or improvement as indicated by one or more of the following when compared to pre-treatment baseline:
    - Improvement in the SELENA-SLEDAI score of ≥4 points; OR
    - No new BILAG-A organ domain score or 2 new BILAG-B organ domain scores; OR
    - No worsening (<30-point point increase) in Physician's Global Assessment (PGA) score; OR
    - Seroconverted (negative) or had a 20% reduction in autoantibody level; AND
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: depression, suicidal thoughts, serious infections, signs or symptoms of

progressive multifocal leukoencephalopathy (PML), malignancy, severe hypersensitivity reactions, etc

Coverage durations:

- Initial coverage: 6 months
- Continuation of therapy coverage: 6 months

*** Requests will also be reviewed to National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) if applicable.***

Dosage/Administration:

Indication	Dose	Maximum dose (1 billable unit = 10 mg)
SLE	Loading Dose: 10 mg/kg intravenously (by a healthcare provider) every 2 weeks x 3 doses (days 1, 15 and 29) Maintenance Dose: 10 mg/kg intravenously (by a healthcare provider) every 4 weeks	Loading Dose (on days 1, 15 and 29): 360 billable units per 29 days Maintenance Dose: 120 billable units per 28 days

Investigational use: All therapies are considered investigational when used at a dose or for a condition other than those that are recognized as medically accepted indications as defined in any one of the following standard reference compendia: American Hospital Formulary Service Drug information (AHFS-DI), Thomson Micromedex DrugDex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs, or Peer-reviewed published medical literature indicating that sufficient evidence exists to support use. Neighborhood does not provide coverage for drugs when used for investigational purposes.

Applicable Codes:
Below is a list of billing codes applicable for covered treatment options. The below tables are provided for reference purposes and may not be all inclusive. Requests received with codes from tables below do not guarantee coverage. Requests must meet all criteria provided in the procedure section.

The following HCPCS/CPT codes are:

HCPCS/CPT Code	Description
J0490	Injection, belimumab, 10mg

References:

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11. American College of Rheumatology Ad Hoc Committee on Systemic Lupus Erythematosus Guidelines. Guidelines for referral and management of systemic lupus erythematosus in adults. Arthritis Rheum. 1999;42(9):1785–1796.
12. Lam NC, Ghetu MV, Bieniek ML. Systemic Lupus Erythematosus: Primary Care Approach to Diagnosis and Management. Am Fam Physician. 2016 Aug 15;94(4):284-94.
13. Wisconsin Physician Service Insurance Corp. Local Coverage Determination (LCD): Drugs and Biologics (Non-chemotherapy) (L34741). Centers for Medicare & Medicare Services. Updated on 05/24/2018 with effective dates 06/01/2018. Accessed March 2019.