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Policy Number: 019.006
Title: Coverage Determination Policy for Systemic Lupus Erythematosus agents: Benlysta (Belimumab); Saphnelo (Anifrolumab-fnia)

Regions: ☒ **Texas** ☒ **New Mexico**

Impacted Areas:

- ☒ Network Management/Provider Services
- ☐ Member services
- ☐ Quality Management
- ☐ Credentialing
- ☐ IT
- ☐ Administration
- ☐ Compliance/delegation
- ☒ Utilization Management
- ☐ Case management
- ☐ Disease management
- ☒ Claims
- ☐ Human resources
- ☐ Finance
- ☒ Pharmacy
- ☐ ALL

Available LCD/NCD/LCA: None

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Doctors helping patients for more than 25 years

Title: Coverage Determination Policy for SLE Agents: Benlysta (Belimumab); Saphnelo (Anifrolumab-fnia)

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Coverage Policy Number: 019.006

Line of Business: Medicare Part B

Policy Type: Prior Authorization

Coverage Determination:

PLEASE NOTE: Benlysta is available for subcutaneous administration via self-injection. First subcutaneous dose should be administered under health care professional supervision per FDA-approved labeling. For Benlysta renewal requests, member should be transitioned from IV to SQ self-administration when possible and clinically appropriate. Benlysta (belimumab) for self-administered subcutaneous injection is obtained under the pharmacy benefit and is indicated for systemic lupus erythematosus and active lupus nephritis.

Medicare rules expect that for self-administered drugs, patients should either self-administer the drug **OR** there should be a clear medical justification to do otherwise; for example, an individual afflicted with paraplegia or advanced dementia would not have the capacity to self-administer any injectable drug.
See the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50.2 Drugs and Biologicals at http://www.cms.hhs.gov/manuals/Downloads/bp102c15.pdf.

Step Therapy Criteria

This policy supplements the Medicare guidelines such as NCDs, LCDs, and other Medicare manuals for the purposes of determining coverage under the Part B medical benefits. This Step Therapy Policy is implemented to enforce a step therapy requirement for new starts only. This policy is not applicable to members continuing therapy within the past 365 days. Coverage is granted if Medicare Coverage requirements PLUS these step criteria are met.

Preferred product(s): Benlysta (Belimumab)

Non-preferred product(s): Saphnelo (anifrolumab-fnia)

Non-Preferred Product Step Therapy Criteria

Coverage of **Saphnelo** when prescribed for **Systemic Lupus Erythematosus** may be covered when **ONE** of the criteria listed below are met:

A. History of use of Benlysta resulting in minimal clinical response to therapy
B. History of contraindication, intolerance or adverse event(s) to Benlysta
C. Continuation of prior therapy within the past 365 days.

Initial/New Requests

Benlysta (belimumab) is **proven and medically necessary** for the treatment of:
Active Systemic lupus erythematosus (SLE) when **ALL** of the following criteria are met:

A. Diagnosis of active systemic lupus erythematosus, without severe active central nervous system lupus
B. Currently receiving at least **one** standard of care treatment for active systemic lupus erythematosus (e.g., antimalarials, corticosteroids, or immunosuppressants) that is not a biologic
C. Patient is not receiving Benlysta in combination with Lupkynis (voclosporin) or Saphnelo (anifrolumab-fnia)
D. Dosing is in accordance with FDA approved dosing for SLE

Active Lupus Nephritis when **ALL** of the following criteria are met:

A. Diagnosis of active lupus nephritis, without severe active central nervous system lupus
B. Currently receiving at least one standard treatment for lupus nephritis (e.g. corticosteroids, cyclophosphamide, immunosuppressants) that is not a biologic
C. Patient is not receiving Benlysta in combination with Lupkynis (voclosporin) or Saphnelo (anifrolumab-fnia)
D. Dosing is in accordance with FDA approved dosing for active lupus nephritis

NOTE: Benlysta is unproven and NOT medically necessary for the conditions below:

- Antineutrophil cytoplasmic antibody-associated vasculitis
- Rheumatoid arthritis
- Severe active central nervous system (CNS) lupus
- Sjögren's syndrome
- Use in combination with other biologics
- Waldenström macroglobulinemia

Saphnelo (anifrolumab-fnia) is proven and medically necessary for the treatment of **moderate to severe systemic lupus erythematosus (SLE)** when **ALL** of the following criteria are met:

A. Diagnosis of moderate to severe systemic lupus erythematosus, without severe active central nervous system lupus or severe active lupus nephritis
B. Currently receiving at least one standard of care treatment for active systemic lupus erythematosus (e.g., antimalarials, corticosteroids, or immunosuppressants) that is not a biologic
C. Patient is not receiving Saphnelo in combination with a biologic agent or Benlysta
D. Dosing is in accordance with FDA approved dosing for SLE

NOTE: Saphnelo is unproven and not medically necessary for the conditions below:

- Severe active lupus nephritis
- Severe active central nervous system (CNS) lupus
- Use in combination with other biologics

Renewal/Continuation of Therapy Requests

Benlysta (belimumab) will be covered for all renewal requests for **Active Lupus Nephritis and Systemic lupus erythematosus (SLE)** when **ALL** of the following criteria are met:

A. Patient has previously received Benlysta injection for intravenous infusion
B. Documentation of positive clinical response
C. Currently receiving at least one standard of care treatment for systemic lupus erythematosus or active lupus nephritis
D. Patient is not receiving Benlysta in combination with Lupkynis (voclosporin) or Saphnelo (anifrolumab-fnia)
E. Dosing is in accordance with FDA approved dosing

Saphnelo (anifrolumab-fnia) will be covered for renewal requests for **Moderate to severe Systemic lupus erythematosus (SLE)** when **ALL** of the following criteria are met:

A. Patient has previously received Saphnelo injection for intravenous infusion
B. Documentation of positive clinical response
C. Patient is without severe active central nervous system lupus or severe active lupus nephritis
D. Currently receiving at least one standard of care treatment for active systemic lupus erythematosus (e.g., antimalarials, corticosteroids, or immunosuppressants) that is not a biologic
E. Patient is not receiving Saphnelo in combination with a biologic agent or Benlysta
F. Dosing is in accordance with FDA approved dosing for SLE

FDA Approved Dose and Indication

Product	FDA Approved Indication	Approved Dosing
Benlysta (belimumab)	**Active Systemic lupus erythematosus (SLE) in patients 5 years and older receiving standard therapy**	• IV: 10 mg/kg IV infusion over 1 hr every 2 weeks for the first 3 doses, then 10mg/kg every 4 weeks thereafter • May transition to subcutaneous administration by administering first SQ dose 1 to 4 weeks after the last IV dose • SQ: 200 mg SQ once weekly
	Active Lupus nephritis in patients 5 years and older receiving standard therapy	• IV: 10 mg/kg IV infusion over 1 hour every 2 weeks for the first 3 doses, then 10mg/kg every 4 weeks thereafter • May transition from IV to subcutaneous administration by administering first subQ dose 1 to 2 weeks after the last IV dose; must complete first 2 IV doses before transitioning • SQ: 400 mg (two 200-mg injections) subQ once weekly for four doses, then 200 mg subQ once weekly thereafter
Saphnelo (anifrolumab-fnia)	**Systemic lupus erythematosus (Moderate to Severe) receiving standard therapy**	• 300 mg IV infusion over 30 minutes every 4 weeks

General Background

Benlysta (belimumab) is a recombinant human IgG1λ monoclonal antibody specific for soluble human B lymphocyte stimulator protein (BLyS, also referred to as BAFF and TNFSF13B). Belimumab blocks the binding of soluble 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.

Benlysta is a B-lymphocyte stimulator (BLyS)-specific inhibitor indicated for the treatment of adult patients with active autoantibody-positive systemic lupus erythematosus and patients with active lupus nephritis who are receiving standard therapy. Benlysta should be administered by healthcare providers prepared to manage anaphylaxis. Benlysta is not recommended in patients with severe active lupus nephritis or severe active central nervous system lupus and Benlysta is not recommended to be used in combination with other biologics or intravenous cyclophosphamide. The efficacy of Benlysta has not been evaluated in patients in these situations.

In 2019, The European League Against Rheumatism (EULAR published updated recommendations for the management of systemic lupus erythematosus (SLE). Their recommendations applicable to belimumab are as follows:

For treatment of SLE; In patients with inadequate response to standard-of-care (combinations of hydroxychloroquine (HCQ) and glucocorticoids (GC) with or without immunosuppressive agents), defined as residual disease activity not allowing tapering of glucocorticoids and/or frequent relapses, add-on treatment with belimumab should be considered (1a/A).

Precautions and Warnings:

Cases of JC virus-associated Progressive Multifocal Leukoencephalopathy (PML) resulting in neurological deficits, including fatal cases, have been reported in patients with SLE receiving immunosuppressants, including Benlysta. Risk factors for PML include:

- Testing positive for anti-JC virus (JCV) antibodies
- Longer duration of treatment with immunosuppressant therapies, including Benlysta
- Impairment of immune function.

The risks and benefits of continuing treatment with Benlysta should be carefully considered in those patients who are found to be anti-JCV antibody positive and have one or more of these risk factors for PML. Consider the diagnosis of PML in any patient presenting with new-onset or deteriorating neurological signs and symptoms and consult with a neurologist or other appropriate specialist as clinically indicated. In patients with confirmed PML, consider stopping immunosuppressant therapy, including Benlysta.

A patient's anti-JCV antibody status may be determined using an anti-JCV antibody detection test that has been analytically and clinically validated, and has been ordered by a healthcare professional. The Stratify JCV® DxSelectTM Antibody ELISA test was cleared by FDA on January 20, 2012.

Benlysta should be administered by healthcare providers prepared to manage anaphylaxis.

Saphnelo (anifrolumab-fnia) is a type I interferon (IFN) receptor antagonist**.** It is a human IgG1κ monoclonal antibody that binds to subunit 1 of the type I interferon receptor (IFNAR) with high specificity and affinity. This binding inhibits type I IFN signaling, thereby blocking the biologic activity of type I IFNs. Saphnelo also induces the internalization of IFNAR1, thereby reducing the levels of cell surface IFNAR1 available for receptor assembly. Blockade of receptor mediated type I IFN signaling inhibits IFN responsive gene expression as well as downstream inflammatory and immunological processes. Inhibition of type I IFN blocks plasma cell differentiation and normalizes peripheral T-cell subsets. Type I IFNs play a role in the pathogenesis of SLE. Approximately 60-80% of adult patients with active SLE express elevated levels of type I IFN inducible genes. Update immunization according to current immunization guidelines prior to initiating Saphnelo therapy. Avoid concurrent use of live or live-attenuated vaccines in patients treated with Saphnelo.

Clinical Evidence

For Systemic Lupus Erythematosus:

Belimumab

Ginzler et al evaluated the efficacy/safety of belimumab plus standard therapy in patients (n = 449) with active SLE treated up to 7 years (n = 177, currently ongoing).14 Patients (n = 345) who completed a double-blind, placebo-controlled, 52-week study of belimumab 1, 4, or 10 mg/kg and 24-week extension of belimumab (placebo switched to 10 mg/kg; belimumab same dose or switched to 10 mg/kg) could receive belimumab 10 mg/kg in an open-label continuation study (n = 296). Disease activity was analyzed in patients with active SLE at baseline of the initial study. Efficacy endpoints measured included percentage change in the Safety of Estrogen in Lupus Erythematosus National Assessment-SLE Disease Activity Index (SELENA-SLEDAI), frequency of 1 new British Isles Lupus Assessment Group (BILAG) A or 2 new BILAG B scores, frequencies of mild-moderate and severe flares as defined by SELENA-SLEDAI Flair Index (SFI), and change in corticosteroid use. Total belimumab exposure over 7 years (double-blind5 and open-label periods14) was 1746 patient-years. SLE Responder Index (SRI) response rates reported at Week 52 in autoantibody-positive patients was placebo, 29%; belimumab, 46% ($p < 0.05$). Researchers reported the following in the continuation study: 57% of auto-antibody-positive patients had an SRI response by Year 2 and 65% by Year 7; severe flares occurred in 19% with placebo and 17% with belimumab during the first year, with the annual rate declining to 2%-9% during years 2-7. Anti-dsDNA autoantibodies in patients positive for them at baseline had a progressive decline of 40%-60% from baseline over 2-7 years with belimumab. Corticosteroid use decreased over time with ≥ 50-55% reduction in median dose during years 5-7. Serious and overall annual AE rates, including infections, were generally stable or decreased during 7-year treatment. Researchers concluded that the data showed that belimumab administered over the long term with standard therapy was generally well tolerated, and sustained disease control was maintained for up to 7 years in patients with active SLE at baseline.

In phase 3 trials, response rates for the primary endpoint was less for African-American subjects in the Benlysta group relative to African-American subjects in the placebo group. However, the treatment difference was not statistically significant. Therefore, Benlysta should be used with caution in African-American patients.

Saphnelo

Furie et al evaluated the efficacy and safety of anifrolumab, a type I interferon (IFN) receptor antagonist, in a phase IIb, randomized, double-blind, placebo-controlled study of adults with moderate-to-severe systemic lupus erythematosus (SLE). Patients (N = 305) were randomized to receive intravenous anifrolumab (300 mg or 1,000 mg) or placebo, in addition to standard therapy, every 4 weeks for 48 weeks. Randomization was stratified by SLE Disease Activity Index 2000 score (< 10 or ≥ 10), oral corticosteroid dosage (< 10 or ≥ 10 mg/day), and type I IFN gene signature test status (high or low) based on a 4-gene expression assay. The primary end point was the percentage of patients achieving an SLE Responder Index (SRI[4]) response at week 24 with sustained reduction of oral corticosteroids (< 10 mg/day and less than or equal to the dose at week 1 from week 12 through 24). Other end points (including SRI[4], British Isles Lupus Assessment Group [BILAG]-based Composite Lupus Assessment [BICLA], modified SRI[6], and major clinical response) were assessed at week 52. The primary end point was analyzed in the modified intent-to-treat (ITT) population and type I IFN-high subpopulation. The study result was considered positive if the primary end point was met in either of the 2 study populations. The Type I error rate was controlled at 0.10 (2sided), within each of the 2 study populations for the primary end point analysis. The primary end point was met by more patients treated with anifrolumab (34.3% of 99 for 300 mg and 28.8% of 104 for 1,000 mg) than placebo (17.6% of 102) (P = 0.014 for 300 mg and P = 0.063 for 1,000 mg, versus placebo), with greater effect size in patients with a high IFN signature at baseline (13.2% in placebo-treated patients versus 36.0% [P = 0.004] and 28.2% [P = 0.029]) in patients treated with anifrolumab 300

mg and 1,000 mg, respectively. At week 52, patients treated with anifrolumab achieved greater responses in SRI(4) (40.2% versus 62.6% [P < 0.001] and 53.8% [P = 0.043] with placebo, anifrolumab 300 mg, and anifrolumab 1,000 mg, respectively), BICLA (25.7% versus 53.5% [P < 0.001] and 41.2% [P = 0.018], respectively), modified SRI(6) (28.4% versus 49.5% [P = 0.002] and 44.7% [P = 0.015], respectively), major clinical response (BILAG 2004 C or better in all organ domains from week 24 through week 52) (6.9% versus 19.2% [P = 0.012] and 17.3% [P = 0.025], respectively), and several other global and organ-specific end points. Herpes zoster was more frequent in the anifrolumab-treated patients (2.0% with placebo treatment versus 5.1% and 9.5% with anifrolumab 300 mg and 1,000 mg, respectively), as were cases reported as influenza (2.0% versus 6.1% and 7.6%, respectively), in the anifrolumab treatment groups. Incidence of serious adverse events was similar between groups (18.8% versus 16.2% and 17.1%, respectively).
Researchers concluded that anifrolumab substantially reduced disease activity compared with placebo across multiple clinical end points in the patients with moderate-to-severe SLE.

Pooled data from the phase 3 TULIP-1 and TULIP-2 trials in patients with moderate to severe SLE were analyzed by Furie et al to determine anifrolumab's effect on flares, including those arising with glucocorticoid taper. TULIP-1 and TULIP-2 were randomized, placebo-controlled, 52-week trials of intravenous anifrolumab (300 mg every 4 weeks for 48 weeks). For patients receiving baseline glucocorticoid ≥ 10 mg/day, attempted taper to ≤ 7.5 mg/day prednisone or equivalent from Weeks 8-40 was required and defined as sustained reduction when maintained through Week 52. Flares were defined as ≥ 1 new BILAG-2004 A or ≥ 2 new BILAG-2004 B scores versus the previous visit. Flare assessments were compared for patients receiving anifrolumab (N = 360) versus placebo (N = 366).
The authors concluded that analyses of pooled TULIP-1 and TULIP-2 data support that anifrolumab reduces flares while permitting glucocorticoid taper in patients with SLE.

The TULIP-2 trial (current phase 3 trial) used a secondary endpoint from the TULIP-1 trial (previous phase 3 trial) as its primary endpoint to evaluate the efficacy of anifrolumab in moderate to severe SLE. Morand et al randomly assigned patients in a 1:1 ratio to receive intravenous anifrolumab (300 mg) or placebo every 4 weeks for 48 weeks. The primary end point of this trial was a response at week 52 defined with the use of the British Isles Lupus Assessment Group (BILAG)-based Composite Lupus Assessment (BICLA). A BICLA response requires reduction in any moderate-to-severe baseline disease activity and no worsening in any of nine organ systems in the BILAG index, no worsening on the Systemic Lupus Erythematosus Disease Activity Index, no increase of 0.3 points or more in the score on the Physician Global Assessment of disease activity (on a scale from 0 [no disease activity] to 3 [severe disease]), no discontinuation of the trial intervention, and no use of medications restricted by the protocol. Secondary end points included a BICLA response in patients with a high interferon gene signature at baseline; reductions in the glucocorticoid dose, in the severity of skin disease, and in counts of swollen and tender joints; and the annualized flare rate. A total of 362 patients received the randomized intervention: 180 received anifrolumab and 182 received placebo. The percentage of patients who had a BICLA response was 47.8% in the anifrolumab group and 31.5% in the placebo group (difference, 16.3 percentage points; 95% confidence interval, 6.3 to 26.3; P = 0.001). Among patients with a high interferon gene signature, the percentage with a response was 48.0% in the anifrolumab group and 30.7% in the placebo group; among patients with a low interferon gene signature, the percentage was 46.7% and 35.5%, respectively. Secondary end points with respect to the glucocorticoid dose and the severity of skin disease, but not counts of swollen and tender joints and the annualized flare rate, also showed a significant benefit with anifrolumab. Herpes zoster and bronchitis occurred in 7.2% and 12.2% of the patients, respectively, who received anifrolumab. There was one death from pneumonia in the anifrolumab group.
Researchers concluded that administration of anifrolumab resulted in a higher percentage of patients with a response (as defined by a composite end point) at week 52 than did placebo, in contrast to the findings

of a similar phase 3 trial involving patients with SLE that had a different primary end point. The frequency of herpes zoster was higher with anifrolumab than with placebo.

For Active Lupus Nephritis:

Belimumab is indicated to treat patients aged 5 years of age and older with **Active Lupus nephritis** who are receiving standard therapy.

The safety and effectiveness of belimumab 10 mg/kg administered intravenously over 1 hour on Days 0, 14, 28, and then every 28 days plus standard therapy was evaluated randomized, double-blind, placebo-controlled trial in 448 adult patients with active proliferative and/or membranous lupus nephritis. The patients had a clinical diagnosis of SLE according to American College of Rheumatology classification criteria; biopsy-proven lupus nephritis Class III, IV, and/or V; and had active renal disease at screening requiring standard therapy: corticosteroids with 1) mycophenolate for induction followed by mycophenolate for maintenance, or 2) cyclophosphamide for induction followed by azathioprine for maintenance. The primary efficacy endpoint was Primary Efficacy Renal Response (PERR) at Week 104, defined as a response at Week 100 confirmed by a repeat measurement at Week 104 of the following parameters: urine protein: creatinine ratio (uPCR) ≤ 0.7 g/g and estimated glomerular filtration rate (eGFR) ≥ 60 mL/min/1.73 m2 or no decrease in eGFR of > 20% from pre-flare value.

The proportion of patients achieving Primary Efficacy Renal Response (PERR) at Week 104 was significantly higher in patients receiving belimumab plus standard therapy compared with placebo plus standard therapy. (N=448)

HCPCS Code

HCPCS Code	Available Dosage Form (s)	Route of Administration
J0490- Benlysta (belimumab)	• 120 mg or 400 mg of belimumab lyophilized powder in single-dose vial for IV infusion • 200 mg/mL of belimumab in single-dose prefilled autoinjector or single-dose prefilled syringe	IV infusion or Subcutaneous injection
J0491- Saphnelo (anifrolumab-fnia)	• 300 mg/2 mL (150 mg/mL) in a single-dose vial	IV infusion

Acronyms

NCDs = National Coverage Determinations

LCDs = Local Coverage Determinations

SLE = Systemic lupus erythematosus

ANA = Anti-nuclear antibody

anti-dsDNA = Anti-double-stranded DNA

CNS = Central nervous system

BLyS = B-lymphocyte stimulator

PML = Progressive Multifocal Leukoencephalopathy

SELENA-SLEDAI = Safety of Estrogens in Lupus Erythematosus National Assessment Systemic Lupus Erythematosus Disease Activity Index

SRI = SLE Responder Index

BILAG = British Isles Lupus Assessment Group

PERR = Primary Efficacy Renal Response

Upcr = Urine protein: creatinine ratio

BICLA = (BILAG)-based Composite Lupus Assessment

Anti-Sm = anti-Smith antibody

IFN = Interferons

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