SHARP Health Plan

Clinical Policy

SUBJECT: CLINICAL POLICIES – INJECTABLE MEDICATIONS - SAPHNELO AND "BENLYSTA FOR TREATMENT OF SYSTEMIC LUPUS ERYTHEMATOSUS (SLE) **POLICY NUMBER: HS-CP-MA _I3s** **EFFECTIVE DATE: 3/25/26** **SERVICE/PRODUCT LINE: MEDICARE – MEDICAL PHARMACY**	Product Line (check all that apply): ☐ All ☐ Group HMO ☐ Individual HMO ☐ PPO ☐ POS ☒ Medicare ☐ FEHB

These guidelines are used in conjunction with the independent judgment of a qualified licensed physician and do not constitute the practice of medicine or medical advice. This Clinical Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care and are solely responsible for the medical advice and treatment of members. This Clinical Policy is not intended to recommend treatment for members. Members should consult with their treating provider in connection with diagnosis and treatment decisions.

When coverage criteria are not fully established by Medicare including but not limited to National Coverage Decisions (NCD), Local Coverage Decisions (LCD), Medicare Manuals and National Coverage Articles, Sharp Health Plan develops Clinical Policies that serve as recommendations for medical necessity decisions. Sharp Health Plan utilizes evidence-based guidelines from nationally recognized professional organizations, peer reviewed medical and scientific literature and evidence-based consensus statements, which are all based on generally accepted standards of care.

I. BENEFIT STATEMENT: Any service reviewed and approved by this Sharp Health Plan Clinical Policy must be a covered benefit according to the member's evidence of coverage (EOC). Since benefit plans vary in coverage and some plans may not provide coverage for certain services discussed in this clinical policy, decisions are subject to all terms and conditions of the applicable benefit plan. Benefit determinations should be based in all cases on the member's contract benefits in effect at the time of service.

A. All reviewers must first identify member eligibility, and all decisions of this clinical policy are subject to current state and/or federal law. This Clinical policy does not constitute plan authorization, nor is it an explanation of benefits. In the event of a conflict, a member's benefit plan, EOC, always supersedes the information in the Clinical Policies.

II. REGULATORY: N/A

III. DESCRIPTION

A. This clinical policy should be utilized referencing the member's specific Member Handbook to confirm the member's coverage benefit(s).

B. This policy defines the Sharp Health Plan (Plan) requirements for determination of medical necessity in order for DRUG NAME to be covered.

C. This policy is to be used when there is no CMS criteria (NCD, LCD, NCA, Medicare Manual) for the drug in question.

D. This policy defines the Sharp Health Plan (Plan) criteria for coverage of medications with a parenteral (IM, SQ, IV, Intrathecal) route of administration. These are also referred to as a "medical benefit" medication. A separate policy governs medications administered through the pharmacy benefit (Sharp Health Plan Pharmacy Procedure for Formulary and Pharmaceutical Management Procedures Development

E. This policy provides information about the use of the following IV drugs for the treatment of systemic lupus erythematosus. This policy does not address the subcutaneous form of Benlysta, which is covered under the pharmacy benefit.

ADULT DOSING		
Drug Name	FDA Indication	Dosage
Anifrolumab (Saphnelo)	Systemic Lupus Erythematosus (SLE)	IV: 300mg every 4 weeks
Belimumab (Benlysta)	Systemic Lupus Erythematosus (SLE)	IV: Initial 10 mg/kg every 2 weeks for 3 doses; Maintenance: 10 mg/kg every 4 weeks Transition from IV to SubQ (adults): Give first SubQ dose 1 to 4 weeks after the last IV dose

IV. DEFINITIONS

A. A Qualified Individual is a Sharp Health Plan (Plan) member.

B. Experimental and Investigational drugs and devices:

0. Considered experimental if the FDA has not issued a specific indication or NDC number for the specific drug or device AND they are currently under investigation in a registered Clinical Trial.

1. The Off-Label Use of an FDA approved prescription drug or device is not considered an experimental/investigational service if this off-label use is not currently being investigated in a registered Clinical Trial.

C. Biosimilars: A biosimilar is a biologic that is highly similar to, and has no clinically meaningful differences from, another biologic that is already approved by the FDA (known as the original biologic or reference product). Biosimilars are made with the same types of natural sources as the original medication they were compared to; they are given the same way, have the same strength and dosage, and have the same potential side effects. A biosimilar provides the same treatment benefits as the original biologic.

D. Injection: The introduction of a medicinal substance into the body; either subcutaneous, intramuscular, intravenous, intra-arterial or into other canals or cavities of the body. For purposes of this medical policy, a medication is provided either by a member (self-injectable) or by a medical provider. It is a "shot" or a dosage of medication given by way of a syringe and needle rather than over a period of time, though not to be given as part of a procedure.

E. Infusion: The slow diagnostic, prophylactic, or therapeutic introduction of fluid or medicinal substance into a vein or tissue given over a period of time.

F. Systemic lupus erythematosus (SLE) is a chronic autoimmune disease that may impact varying bodily organs. This can lead to immunologic defects with the production of antinuclear antibodies (ANA). It may be characterized by mild joint and skin concerns to serious renal, hematologic, or central nervous system involvement which may be life-threatening. Patients may present with limited clinical symptoms which can sometimes appear as other autoimmune, infectious, or hematologic disorders.

V. MEDICAL NECESSITY

A. To be eligible for coverage under this policy, the member must be a Qualified Individual with active Plan membership.

B. Additionally, the provision of physician samples does not guarantee coverage.

C. Member is treated by or in consultation with a contracted rheumatologist, immunologist, neurologist, or dermatologist; and

D. Belimumab (Benlysta):

0. Initial Criteria:

a) Member is 5 years old and older; AND

b) Member has Systemic Lupus Erythematosus (SLE) as indicated by ALL of the following:

(1) Documentation of one of the following positive autoantibody tests:

i. ANA (anti-nuclear antibody) ≥ 1:80, or

ii. Anti-dsDNA (anti-double-stranded DNA) ≥ 30 IU/mL, or

iii. Anti-Sm (anti-Smith) antibodies; AND

(2) Diagnosis of moderate to severe SLE confirmed by SELENA-SLEDAI score ≥ 6; AND

(3) Patient is receiving at least one of the following standard therapies for active SLE for at least 30 days with inadequate response (unless all are contraindicated or not tolerated):

i. Antimalarial (e.g., hydroxychloroquine), or

ii. Systemic corticosteroid (e.g., prednisone), or

iii. Non-biologic immunosuppressant (e.g., azathioprine, methotrexate, mycophenolate); AND

c) Patient does not have severe active central nervous system lupus (with psychosis or seizures); AND

d) Patient is not receiving in combination with another biologic therapy, IV cyclophosphamide (excluding use in induction therapy), or Anifrolumab (Saphnelo); AND

e) Patient does not have HIV, hepatitis B, or hepatitis C infection; AND

f) Belimumab (Benlysta) is dosed according to FDA labelled dosing for SLE; AND

g) Initial authorization is not to exceed 6 months.

1. Reauthorization with ALL of the following:
    a) All initial medical necessity criteria were met at the start of treatment; AND
    b) Documented evidence of clinical response (e.g., reduction in flares, corticosteroid dose, anti-dsDNA titer, improvement in labs (i.e., C3, C4), improvement in organ dysfunction (e.g., musculoskeletal, blood, hematologic, vascular, etc.); AND
    c) Reauthorization does not exceed 12 months; AND
    d) Patient is not receiving in combination with another biologic therapy, cyclophosphamide, or anifrolumab (Saphnelo).

E. Anifrolumab (Saphnelo):

0. Initial Criteria:
    a) Member is 18 years and older; AND
    b) Member has Systemic Lupus Erythematosus (SLE) as indicated by ALL of the following:
        (1) Documentation of one of the following positive autoantibody tests:
            i. ANA (anti-nuclear antibody) ≥ 1:80, or
            ii. Anti-dsDNA (anti-double-stranded DNA) ≥ 30 IU/mL, or
            iii. Anti-Sm (anti-Smith) antibodies; AND
        (2) Diagnosis of moderate to severe SLE confirmed by SLEDAI-2K Score ≥ 6; AND
        (3) Patient is receiving at least one of the following standard therapies for active SLE for at least 30 days with inadequate response (unless all are contraindicated or not tolerated):
            i. Antimalarial (e.g., hydroxychloroquine), or
            ii. Systemic corticosteroid (e.g., prednisone), or
            iii. Non-biologic immunosuppressant (e.g., azathioprine, methotrexate, mycophenolate); AND
    c) Member has tried, failed, or is contraindicated for belimumab (Benlysta) therapy
    d) Patient does not have severe active central nervous system lupus (with psychosis or seizure) or severe active lupus nephritis (proteinuria > 6mg/day, SCr > 2.5mg/dL, requiring dialysis); AND
    e) Patient is not receiving in combination with another biologic therapy, cyclophosphamide, or belimumab (Benlysta); AND
    f) Patient does not have HIV, hepatitis B, or hepatitis C infection; AND
    g) Anifrolumab (Saphnelo) is dosed according to FDA labelled dosing for SLE; AND
    h) Initial authorization is not to exceed 6 months.

1. Reauthorization with ALL of the following:
    a) All initial medical necessity criteria were met at the start of treatment; AND

b) Documented evidence of clinical response (e.g., reduction in flares, corticosteroid dose, anti- dsDNA titer, improvement in labs (i.e., C3, C4), improvement in organ dysfunction (e.g., musculoskeletal, blood, hematologic, vascular, etc.); AND

c) Reauthorization does not exceed 12 months; AND

d) Patient is not receiving in combination with another biologic therapy, cyclophosphamide, or belimumab (Benlysta.)

VI. NOT MEDICALLY NECESSARY

A. The Plan is not required to cover services or benefits that are not otherwise covered under the terms and conditions of the Plan contract.

VII. PROCEDURE/ATTACHMENTS

A. Review and confirm the member's coverage benefit for the member's specific member

VIII. CODES: N/A

IX. REFERENCES

A. Fanouriakis A, Kostopoulou M, Andersen J, et al. EULAR recommendations for the management of systemic lupus erythematosus: 2023 update. Annals of the Rheumatic Diseases. Published Online First: 12 October 2023.

B. Saphnelo® [prescribing information]. Wilmington, DE; AstraZeneca Pharmaceuticals LP; 2024.

C. Benlysta® [prescribing information]. Philadelphia, PA; GlaxoSmithKline LLC; 2025.

D. UptoDate, 2025. Wallace D. Systemic lupus erythematosus in adults: Overview of the management and prognosis. Retrieved online from: https://www.uptodate.com/contents/systemic-lupus-erythematosus-in-adults-overview-of-the-management-and-prognosis

X. REVISION HISTORY

Date	Modification (Original, Reviewed or Revised)
3/25/26	ORIGINAL

Approved by: (Signature of VP /CMO)	**Approval date:**
	3/25/26