Pharmacy Drug Policy

SUBJECT: Systemic Lupus Erythematosus (SLE) and Lupus Nephritis (LN): Benlysta IV (benlimumab), Gazyva (obintuzumab), Lupkynis (voclosporin), and Saphnelo (anifrolumab-fnia)
POLICY NUMBER: PHARMACY-143
EFFECTIVE DATE: 05/2026
LAST REVIEW DATE: 09/11/2026

If the member's subscriber contract excludes coverage for a specific service or prescription drug, it is not covered under that contract. In such cases, medical or drug policy criteria are not applied. This drug policy applies to the following line/s of business:

Policy Application

Category:	☒ Commercial Group (e.g., EPO, HMO, POS, PPO)	☒ Medicare Advantage
	☒ On Exchange Qualified Health Plans (QHP)	☐ Medicare Part D
	☒ Off Exchange Direct Pay	☒ Essential Plan (EP)
	☒ Medicaid & Health and Recovery Plans (MMC/HARP)	☒ Child Health Plus (CHP)
	☐ Federal Employee Program (FEP)	☐ Ancillary Services
	☒ Dual Eligible Special Needs Plan (D-SNP)	

DESCRIPTION:

Systemic lupus erythematosus (SLE) is an autoimmune disease affecting multiple organ systems and is characterized by recurrent courses of relative remission followed by flares.[1] SLE is the most common and serious form of lupus, and the exact cause is unknown; however, it is thought to develop in response to a combination of factors (hormones, genetics, external environmental factors including viruses and ultraviolet light). Women are at significantly higher risk for developing SLE compared to men; the female-to-male ratio is 9 to 1. More serious complications of this disease affect several organ systems including inflammation involving the kidneys (lupus nephritis), brain and nervous system (ranging from headaches/memory problems to strokes), and the cardiovascular system (most severely leading to heart attacks). The goal of therapy for SLE is to ease symptoms, which vary depending on which organ systems are affected.[2]
The American College of Rheumatology (ACR) posted an updated guideline for the treatment of SLE in 2025.[3] Current guidelines focus on a "treat-to-target" strategy with hydroxychloroquine as the mainstay of therapy while glucocorticoids may be used as needed, for the shortest duration possible to manage SLE flares. Early initiation of conventional and biologic immunosuppressants is recommended to reduce disease activity and maintain clinical remission. Selection of immunosuppressive agents depends on the organ system(s) affected and severity of symptoms; treatment options include but are not limited to azathioprine, calcineurin inhibitors, intravenous cyclophosphamide, mycophenolic acid analogs, methotrexate, rituximab, obinutuzumab, anifrolumab, and belimumab.

Lupus Nephritis (LN) occurs in nearly 50% of SLE patients with a mortality rate of up to 30% at 10 years.[4] The 2024 ACR Guidelines provide recommendations regarding diagnosis and management of this condition. A kidney biopsy is performed to confirm LN in patients with SLE for whom it is suspected. Glucocorticoid treatment is recommended for suspected LN to suppress acute inflammation. Depending on severity, triple therapy with a glucocorticoid plus one of the following combinations may be warranted:

- Belimumab plus either a mycophenolic acid analog or cyclophosphamide
- A calcineurin inhibitor plus a mycophenolic acid analog
- Obinutuzumab plus a mycophenolic acid analog

The goal of treatment is to slow disease progression, preserve kidney function, reduce morbidity and mortality associated with chronic kidney disease, and to minimize medication-related toxicities.

Benlysta (belimumab)
Benlysta is a monoclonal antibody that inhibits the binding of soluble human B-lymphocyte stimulator protein (BLyS) to its receptors on B cells with resultant inhibition of B cell survival, including autoreactive B cells.[5] Benlysta is indicated for the treatment of patients at least five years of age with either active SLE and are receiving standard therapy or with active lupus nephritis who are receiving standard therapy. Dosing depends on the indication and patient age. For active SLE, the recommended dose for adults and pediatric patients weighing at least 40 kg is 200 mg once weekly and 200 mg once every 2 weeks for pediatric patients between 15 kg to 40 kg. A diagnosis of active LN requires a loading dose of 400 mg once weekly for 4 doses, followed by 200 mg once weekly in adults and pediatric patients weighing at least 40 kg. The loading dose is reduced to 200 mg once weekly for 4 weeks, followed by 200 mg once every 2 weeks in pediatric patients between 15 kg and 40 kg. Adults may use either the autoinjector or prefilled syringe whereas pediatric patients may only use the autoinjector.

Gazyva (obintuzumab)
Gazyva is a CD20-directed monoclonal antibody approved for the treatment of multiple oncology indications and also for the treatment of adult patients with active LN.[6] Due to the risk for infusion related reactions and tumor lysis syndrome, pre-medication is required to infusion. Recommended dosing of Gazvya for adults with active LN is intravenous infusion of 1,000 mg initially, then again on Weeks 2, 24, 26, and every 6 months thereafter.

Lupkynis (voclosporin)
Voclosporin is a calcineurin inhibitor that was created by making a small structural change to cyclosporine, incorporating a single carbon extension with a double bond which is being reported to result in a predictable dose response, and potentially eliminating the need for blood level monitoring.[7] By inhibiting calcineurin, voclosporin blocks IL-2 expression and T-cell mediated immune responses and stabilizes the podocyte in the kidney, protecting against proteinuria. It is indicated for the treatment of adult patients with active LN, in combination with a background immunosuppressive therapy regimen. It is noted in the prescribing information that safety and efficacy of Lupkynis in combination with cyclophosphamide has not been established. The recommended dose is 23.7 mg orally, twice a day. Renal function should be regularly assessed based on eGFR to adjust dose accordingly. The use of Lupkynis is not recommended when a patient's baseline eGFR is less than or equal to 45 mL/min/1.73 m^2.

Saphnelo (anifrolumab-fnia)
Saphnelo (anifrolumab-fnia) is a type I interferon (IFN) receptor antagonist indicated for the treatment of adult patients with moderate to severe SLE who are receiving standard therapy.[8] The prescribing information importantly indicates that the efficacy of Saphnelo has not been evaluated in those with severe active lupus nephritis or severe active central nervous system lupus, and therefore use is not recommended in either situation. Saphnelo may be administered either intravenously or via subcutaneous injection. Dosing depends on the route of administration - intravenous infusion dosing is 300 mg over a 30-minute period every 4 weeks and subcutaneous injection dosing is 120 mg once every week.

POLICY:

Benlysta IV (benlimumab) - Medical
1. Must be 5 years of age or older **AND** 2. Must meet for ONE of the following (a **OR** b): a. Must have a confirmed diagnosis of active Systemic Lupus Erythematosus (SLE) i. A diagnosis of SLE is confirmed by the presence of autoantibodies (such as antinuclear antibodies [ANA], anti-double-stranded DNA [anti-dsDNA] antibodies, and anti-Smith [anti-Sm] antibodies) 1. Due to lab variability in standards for positive values, values reported as "positive" from that lab are acceptable **AND** ii. Must be prescribed by or in consultation with a Rheumatologist **OR** b. Must have a diagnosis lupus nephritis (LN) confirmed by a kidney biopsy i. Must be prescribed by or in consultation with a Rheumatologist or Nephrologist **AND** ii. Biopsy must reveal lupus nephritis class III, IV, or V, alone or in combination **AND** iii. Must have a urine protein to creatinine ratio (UPCR) of ≥1 **AND** iv. Must have a baseline eGFR ≥ 30 mL/min/1.73m2 **AND** 3. Must be used in combination with standard-of-care therapy (i.e.., prednisone, hydroxychloroquine, azathioprine, mycophenolate mofetil, methotrexate) **AND** 4. The patient must not have severe active central nervous system (CNS) lupus **AND** 5. For the Commercial, Exchange, Essential and Child Health Plus Plans, the following criteria applies to New Starts **AND** Recertification requests (including new to plan). For Medicare Advantage, D-SNP, and Medicaid (MMC/HARP, FFS), the following criteria applies to New Starts Only: a. All requests for Benlysta IV will require clinical justification why Benlysta SQ cannot be used (i.e. inability to self-inject). i. Documentation must be submitted that confirms the patient is unable to safely self-administer injectable medications and does not have a caregiver who can reliably administer the medication on their behalf. Clinical justification may include but is not limited to history of significant tremor, dexterity limitations, or cognitive impairment. 6. The use of Benlysta IV in combination with Lupkynis, Saphnelo or Gazyva will not be approved as these medications have not been studied for use together. 7. For SLE, initial approval will be provided for 6 months. Recertification for 1 year requires documentation of a decrease in disease signs and symptoms (including reduction in disease flares) and continued compliance with standard of care therapies. a. Subsequent reauthorizations for 1 year at a time require documentation of maintenance of improvement in disease signs and symptoms (including reduction in disease flares) from baseline and continued compliance with standard of care therapies. 8. For LN, initial approval will be provided for 1 year. Recertification for 1 year requires the following documentation: a. Therapeutic benefit defined as a reduction in urine protein to creatinine ratio (UPCR) AND/OR increase in eGFR compared to baseline; **AND** b. Continued compliance with standard of care therapies. i. Subsequent recertifications for 1 year at a time will require documentation of continued therapeutic benefit compared to baseline and continued compliance with standard of care therapies. 9. The approved dose is 10 mg/kg intravenous (IV) once every 2 weeks for the first 3 doses, then once every 4 weeks thereafter. **HCPCS:** J0490

Gazyva (obintuzumab) - Medical

1. For oncology indications, refer to the Oncology Clinical Review Prior Authorization (CRPA) Medical Drugs Policy (Pharmacy-64).
2. For the diagnosis of Lupus Nephritis (LN):
    a. Must be 18 years of age or older **AND**
    b. Must be prescribed by, or in consultation with, a rheumatologist or nephrologist **AND**
    c. Must have a diagnosis of lupus nephritis confirmed by a kidney biopsy
        i. Biopsy must reveal Class III or IV disease, with or without concomitant Class V
    d. Must have a urine protein to creatinine ration (UPCR) of ≥ 1 **AND**
    e. Must have a baseline eGFR ≥ 30 mL/min/1.73 m2 **AND**
    f. Must be used in combination with mycophenolate and corticosteroids as Gazyva is not approved to be used as monotherapy
        i. Gazyva has not been studied in combination with any other immunosuppressants (such as cyclophosphamide or azathioprine) and will not be approved for use with other immunosuppressants
    g. All requests for Gazyva for the treatment of lupus nephritis require clinical justification why Benlysta SQ cannot be used.
        i. Clinical justification may include documentation of the following:
            1. Severe side effects (e.g., serious infections, Progressive Multifocal Leukoencephalopathy [PML], hypersensitivity reactions including anaphylaxis, hypotension, angioedema, urticaria, pruritic and dyspnea) OR
            2. Drug failure (e.g., Early treatment failure [≤ 3 months] with worsening proteinuria, declining eGFR, or worsening serologies [rising anti-dsDNA, falling complement] or Inadequate response [6-12 month] with failure to achieve at least a partial renal response — typically defined as ≥50% reduction in proteinuria from baseline with stabilization of renal function).
    h. The use of Gazyva in combination with Benlysta or Lupkynis will not be approved as these medications have not been studied for use together.
    i. Initial approval will be for 1 year.
    j. Recertification for 1 year at a time requires the following:
        i. For Initial Recertification:
            1. Documentation of therapeutic benefit defined as a reduction in urine protein to creatinine ratio (UPCR) and/or increase in eGFR compared to baseline **AND**
            2. Continued compliance with mycophenolate and corticosteroids
        ii. For subsequent recertifications:
            1. Documentation of continued therapeutic benefit compared to baseline and continued compliance with mycophenolate and corticosteroids.
    k. The approved dosage of Gazyva is 1,000 mg IV administered at Weeks 0, 2, 24, and 26, and every 6 months thereafter.

HCPCS: J9301

Lupkynis (voclosporin) - Rx

1. Must be 18 years of age or older **AND**
2. Must be prescribed by or in consultation with a rheumatologist **OR** nephrologist
3. Must have a diagnosis of lupus nephritis confirmed by a kidney biopsy
    a. Biopsy must reveal lupus nephritis class III, IV, or V, alone or in combination
        i. Class III or IV lupus nephritis (alone or in combination with class V) will also require a urine protein to creatinine ratio (UPCR) of ≥1.5 mg/mg
        ii. Class V lupus nephritis alone will require a urine protein to creatinine ratio (UPCR) of ≥2 mg/mg

4. Must be used in combination with mycophenolate and corticosteroids as Lupkynis is not approved to be used as monotherapy
    a. Lupkynis has not been studied in combination with any other immunosuppressants (such as cyclophosphamide or azathioprine) and will not be approved for use with other immunosuppressants except hydroxychloroquine, which is permitted to be used in combination with mycophenolate, corticosteroids and Lupkynis
5. Must have a baseline eGFR ≥ 45 mL/min/1.73m^2
6. All requests for Lupkynis will require clinical justification why Benlysta SQ cannot be used.
    a. Clinical justification may include documentation of the following:
        i. Severe side effects (e.g., serious infections, Progressive Multifocal Leukoencephalopathy [PML], hypersensitivity reactions including anaphylaxis, hypotension, angioedema, urticaria, pruritic and dyspnea) OR
        ii. Drug failure (e.g., Early treatment failure [≤ 3 months] with worsening proteinuria, declining eGFR, or worsening serologies [rising anti-dsDNA, falling complement] or Inadequate response [6-12 month] with failure to achieve at least a partial renal response — typically defined as ≥50% reduction in proteinuria from baseline with stabilization of renal function)
7. Use of Lupkynis in combination with Benlysta or Gazyva will not be approved as these medications have not been studied for use together
8. Initial approval will be for 6 months.
9. Initial recertification after 6 months of therapy will require:
    a. Documentation of therapeutic benefit defined as a reduction in urine protein to creatinine ratio (UPCR) and/or increase in eGFR compared to baseline **AND**
    b. Continued compliance with mycophenolate and corticosteroids
    c. Approval will be for an additional 6 months of therapy
10. Recertification after 1 year of therapy and all subsequent reauthorizations will require documentation of complete response defined as:
    a. UPCR ≤ 0.5 mg/mg **AND**
    b. eGFR ≥ 60 mL/min/1.73 m^2 **OR** no decrease ≥20% from baseline eGFR **AND**
    c. Continued compliance with mycophenolate and corticosteroids
    d. Approval will be granted for 1 year at a time
11. Quantity limit: 180 capsules/30 days

Saphnelo (anifrolumab-fnia) – Medical and Rx

1. Must be 18 years of age or older **AND**
2. Must be prescribed by or in consultation with a rheumatologist **AND**
3. Must have a confirmed diagnosis of active Systemic Lupus Erythematosus (SLE)
    a. A diagnosis of SLE is confirmed by the presence of autoantibodies (such as antinuclear antibodies [ANA], anti-double-stranded DNA [anti-dsDNA] antibodies, and anti-Smith [anti-Sm] antibodies)
        i. Due to lab variability in standards for positive values, values reported as “positive” from that lab are acceptable **AND**
4. Must be used in combination with standard-of-care therapy (i.e., prednisone, hydroxychloroquine, azathioprine, mycophenolate mofetil, methotrexate) **AND**
5. The patient must not have severe active lupus nephritis or severe active central nervous system (CNS) lupus.
6. For New starts only, all requests for Saphnelo will require clinical justification why Benlysta SQ cannot be used.
    a. Clinical justification may include documentation of the following:

i. Severe side effects (e.g., serious infections, Progressive Multifocal Leukoencephalopathy [PML], hypersensitivity reactions including anaphylaxis, hypotension, angioedema, urticaria, pruritic and dyspnea) OR
ii. Drug failure (e.g., inability to reduce corticosteroids, occurrence of severe flares while on Benlysta SQ, worsening serologies [anti-dsDNA, falling complement])

7. The use of Saphnelo in combination with Benlysta will not be approved as these medications have not been studied for use together.
8. Initial approval will be for 6 months. Recertification for 1 year will require documentation of a decrease in disease signs and symptoms (including reduction in disease flares) and continued compliance with standard of care therapy.
9. Subsequent reauthorizations for 1 year at a time require documentation of maintenance of improvement in disease signs and symptoms (including reduction in disease flares) from baseline and continued compliance with standard of care therapy.
10. Saphnelo subcutaneous injection is self-administered and will be covered under the pharmacy benefit.
    a. The recommended dosage is 120 mg administered as a subcutaneous injection once every week.
11. Saphnelo intravenous infusion is administered by a healthcare provider and will be covered under the medical benefit.
    a. The recommended dosage is 300 mg administered as an intravenous infusion once every 4 weeks.

HCPCS: J0491 (Saphnelo IV only)

POLICY GUIDELINES:

1. Utilization Management is contract dependent. Refer to specific contract/benefit language for exclusions.
    a. Coverage criteria may be dependent on the contract renewal date.
    b. Coverage of drugs listed in this policy are contract dependent.
    c. Not all contracts/benefits allow coverage of healthcare professional administered drugs as part of their pharmacy benefit
    d. Not all contracts/benefits cover all medical infusible drugs.
2. Clinical documentation must be submitted for each request (initial and recertification) unless otherwise specified (e.g., provider attestation required). Supporting documentation includes, but is not limited to, progress notes documenting previous treatments and treatment history, diagnostic testing, laboratory test results, genetic testing or biomarker results, imaging, and other objective or subjective measures of clinical benefit. For recertification, continued approval requires documentation demonstrating that the requested product is providing ongoing benefit to the patient, evidenced by improvement or stability in the disease state or condition, and that continued use remains medically necessary. Ongoing use of the requested product must continue to align with the current policy's preferred formulary. Recertification reviews may result in a requirement to trial more cost-effective treatment alternatives as they become available (e.g., generics, biosimilars, or other guideline-supported treatment options). Requested dosing must remain consistent with FDA-approved or off-label/guideline-supported dosing recommendations.
3. This policy does not apply to Medicare Part D and D-SNP pharmacy benefits. The drugs in this policy may apply to all other lines of business including Medicare Advantage.
4. This policy is applicable to drugs that are included on a specific drug formulary (Pharmacy benefit only). If a drug referenced in this policy is non-formulary, please refer to the Non-Formulary Medication Exception Review Policy (Pharmacy-69) for review guidelines.
5. For members with Medicare Advantage, medications with a National Coverage Determination

(NCD) and/or Local Coverage Determination (LCD) will be covered pursuant to the criteria outlined by the NCD and/or LCD. NCDs/LCDs for applicable medications can be found on the CMS website at https://www.cms.gov/medicare-coverage-database/search.aspx. In the absence of a Medicare National Coverage Determination (NCD), Local Coverage Determination (LCD), or other Medicare coverage guidance, CMS permits a Medicare Advantage Organization (MAO) to establish its own coverage determinations in accordance with 42 CFR § 422.101(b)(6). Indications that have not been addressed by the applicable medication's LCD/NCD will be covered in accordance with criteria determined by the Health Plan (which may include review per the Health Plan's Off Label Use of FDA Approved Drugs policy). Step therapy requirements may be imposed in addition to LCD/NCD requirements.

6. All requests will be reviewed to ensure they are being used for an appropriate indication and may be subject to an off-label review in accordance with our Off-Label Use of FDA Approved Drugs Policy (Pharmacy-32).
7. Dose and frequency should be in accordance with the FDA label or recognized compendia (for off-label uses). When services are performed in excess of established parameters, they may be subject to review for medical necessity.
8. All utilization management requirements outlined in this policy are compliant with applicable New York State insurance laws and regulations. Policies will be reviewed and updated as necessary to ensure ongoing compliance with all state and federally mandated coverage requirements.
9. For commercial contracts, medical necessity determinations align with the Certificate of Coverage issued by the Health Plan, which states that covered services must be clinically appropriate and not primarily for the convenience of the member, the member's family, or the provider.
10. This policy is based on available evidence as of the last review date. Coverage determinations are subject to applicable plan documents, state and federal regulations, and individual patient circumstances. This policy does not constitute medical advice.
11. This policy is subject to ongoing revision. Newly marketed drugs and existing drugs with new indications may be subject to prior authorization requirements until formal coverage criteria are established within this policy.
12. Manufacturers may either discontinue participation in, or may not participate in, the Medicaid Drug Rebate Program (MDRP). Under New York State Medicaid requirements, physician-administered drugs must be produced by manufacturers that participate in the MDRP. Products made by manufacturers that do not participate in the MDRP will not be covered under Medicaid Managed Care/HARP lines of business. Drug coverage will not be available for any product from a non-participating manufacturer. For a complete list of New/Reinstated & Terminated Labelers please visit: https://www.medicaid.gov/medicaid/prescriptiondrugs/medicaid-drug-rebate-program/newreinstated-terminated-labeler-information/index.html
13. The requested site of care may impact approval timeframe and subject to review.

CODES:

Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract. CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.
Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.

Code Key:
Experimental/Investigational = (E/I),
Not medically necessary/ appropriate = (NMN).
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HCPCS:

J0490 – Benlysta IV
J9301 – Gazyva
J0491 – Saphnelo IV

UPDATES:

Date	Revision
09/11/2026	Revised
08/13/2026	Reviewed & Approved P&T Committee
06/01/2026	Revised
05/22/2026	Reviewed and Implemented
05/2026	Created

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6. Gazyva [package insert]. South San Francisco, CA: Genentech, Inc.; Revised December 2025
7. Lupkynis [package insert]. Rockville, MD: Aurinia Pharma U.S., Inc.; Revised October 2025
8. Saphnelo [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; Revised April 2026