Dear Oregon Drug Use Research and Management Staff,

Thank you for the opportunity to provide additional comments on the *Drug Class Literature Scan for Newer Drugs for Heart Failure* scheduled for review in August 2026. Specifically, I would like to offer feedback on the draft Prior Authorization Criteria for Finerenone (Appendix 6), where the criteria may benefit from updates to reflect the most current clinical evidence, prescribing information, guideline recommendations, and real-world implementation of therapy.

Proposed criteria #6 for finerenone

- "Is the patient currently on standard of care for heart failure including a maximally tolerated angiotensin converting enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB), or angiotensin receptor-neprilysin inhibitor (ARNI) OR have a documented contraindication to these medications?"

Recommendation:
Split this question into 2, with one focusing on CKD and T2D and another on HF.

Heart Failure: "Is the patient currently on standard of care for heart failure (e.g., RAAS inhibitors/ARNIs, beta-blockers, MRAs, SGLT2 inhibitors), as clinically appropriate?"
Chronic Kidney Disease associated with Type-2 Diabetes: "Is the patient currently on standard of care therapy for CKD associated with type 2 diabetes (e.g., ACE inhibitor or ARB and other evidence-based agents) as clinically appropriate?"

Rationale:
According to the current FDA-approved prescribing information, finerenone (Kerendia) is indicated in adults for two distinct populations: (1) reducing the risk of sustained estimated glomerular filtration rate (eGFR) decline, end-stage kidney disease, cardiovascular death, nonfatal myocardial infarction, and hospitalization for heart failure in patients with chronic kidney disease associated with type 2 diabetes; and (2) reducing the risk of cardiovascular death, hospitalization for heart failure, and urgent heart failure visits in patients with heart failure and left ventricular ejection fraction (LVEF) ≥40%.[1]

Given these distinct indications, the patient populations and standards of care differ between chronic kidney disease and heart failure management. Including indication-specific questions would help ensure that the appropriate criteria are applied to the correct patient population and better align utilization management with current clinical practice.

Additionally, guideline-directed medical therapy (GDMT) for heart failure includes multiple foundational medication classes, including RAAS inhibitors/ARNIs, beta-blockers, MRAs, and SGLT2 inhibitors. Current guidelines emphasize implementation of

these therapies based on clinical appropriateness, tolerability, and individual patient factors. They do not require all therapies to be titrated to maximally tolerated doses before initiating additional evidence-based treatments.[2] In clinical practice, therapies are often introduced in parallel and subsequently titrated over time, allowing patients to benefit from multiple evidence-based therapies without unnecessary delays in treatment optimization.

1. Kerendia (finerenone) [prescribing information]. Bayer HealthCare Pharmaceuticals Inc; 2025.
2. Heidenreich PA, Bozkurt B, Aguilar D, et al. 2022 AHA/ACC/HFSA guideline for the management of heart failure. *Circulation*. 2022;145(18):e895-e1032.

Thank you again for the opportunity to provide this feedback.

Freundliche Grüße / Best regards,

Bashir Kalayeh, PharmD, RPh
National Director, Health Economics & Outcomes Research
UW/Bayer HEOR Fellowship Program Director

US Medical - HEOR Field Medical Affairs

Genentech
A Member of the Roche Group

Submitted by:
Aileen Le, PharmD, BCPS
Medical Information, US Medical Affairs
Genentech, Inc.
1 DNA Way
South San Francisco, CA 94080
Phone: (408) 835-4768
Email: le.aileen@gene.com
Date of request: July 15, 2026

Dear Clinical Team:

This evidence submission pertains to Oregon Health Authority's public comment request on the draft *Drug Class Update with New Drug Evaluation: Monoclonal Antibodies for Lupus* for obinutuzumab. Please consider the enclosed information on use of obinutuzumab for active lupus nephritis (LN) for your policy updating needs.

Specific Request & Supporting Scientific Evidence:

Request: Consider expanding proposed criteria for obinutuzumab (Gazyva) requiring concurrent use or documented contraindication to hydroxychloroquine (HCQ) (approval criteria #9) or an angiotensin-converting enzyme inhibitor (ACEi) or an angiotensin II receptor blocker (ARB) (approval criteria #11) to also allow for documented intolerances, inadequate responses, or clinical reasons for withholding these therapies.

Scientific Evidence:

Clinical Practice Guidelines

While the European Alliance of Associations for Rheumatology (EULAR), the American College of Rheumatology (ACR), and the Kidney Disease Improving Global Outcomes (KDIGO) clinical practice guidelines universally recommend HCQ and renin-angiotensin-aldosterone system (RAAS) blockade as components of LN management, all guidelines explicitly detail clinical scenarios where these therapies must be withheld, dose-adjusted, or substituted.[1-3]

- **EULAR** explicitly notes that alternative antihypertensives must be used if RAAS blockade is **not tolerated, insufficient, or strictly contraindicated** - specifically during episodes of **hyperkalemia** or **worsening azotemia** (acute kidney injury/worsening estimated glomerular filtration rate [eGFR]).[1]
- **ACR** similarly highlights that the clinical deployment of RAAS inhibitors **"may be limited by blood pressure or eGFR".**[2]
- **KDIGO** also states that renoprotective medications such as RAAS blockade be used to minimize risk of complications related to LN in **stable patients without acute kidney injury.**[3]

Eligibility for REGENCY

- The safety and efficacy of obinutuzumab plus standard therapy was evaluated in the Phase 3, randomized, double-blind, placebo-controlled, multicenter REGENCY study in patients with International Society of Nephrology (ISN)/Renal Pathology Society (RPS) 2003 Class III or IV LN with or without concomitant Class V LN.[4]
- While HCQ and ACEi/ARBs are guideline-directed therapies, the Phase 3 REGENCY trial allowed for the omission of HCQ and ACEi/ARBs based on investigator discretion.[4]

Dosing and Cost of Obinutuzumab for Active Lupus Nephritis

- The recommended dose of obinutuzumab for active lupus nephritis is 1,000 mg IV at the initial infusion on Day 1, Week 2, 24, 26, and every 6 months thereafter.[5]

- Obinutuzumab has the lowest estimated annual medication cost among FDA-approved advanced therapies for lupus nephritis (belimumab and voclosporin) with an annual WAC of $37,801 in Year 1 and $18,901 in Year 2 and beyond.[6-8]

FDA Approval: Gazyva® (obinutuzumab) injection, for intravenous use, is FDA-approved for the treatment of adult patients with active lupus nephritis receiving standard therapy. Please refer to the product prescribing information for the full FDA-approved indications and safety information, available at: https://www.gene.com/download/pdf/gazyva_prescribing.pdf.

Thank you for your consideration of this request. If you have any questions, please contact your Medical Affairs Executive Director, Lisa Carman, PharmD, at carman.lisa@gene.com.

Respectfully submitted,
Aileen Le, PharmD, BCPS

References

1. Fanouriakis A, Kostopoulou M, Anders HJ, et al. EULAR recommendations for the management of systemic lupus erythematosus with kidney involvement: 2025 update. Ann Rheum Dis. Published online October 16, 2025. doi:10.1016/j.ard.2025.09.007
2. Sammaritano LR, Askanase A, Bermas BL, et al. 2024 American College of Rheumatology (ACR) Guideline for the Screening, Treatment, and Management of Lupus Nephritis. Arthritis Care & Research. 2025; Accessed Online June 30, 2026. DOI 10.1002/acr.25528.
3. Kidney Disease Improving Global Outcomes. KDIGO 2024 Clinical Practice Guideline for the Management of Lupus Nephritis. Kidney International (2024) 105 (Suppl 1S), S1–S69. Accessed online June 30, 2026.
4. Furie RA, Rovin BH, Garg JP, et al. Efficacy and Safety of Obinutuzumab in Active Lupus Nephritis. N Engl J Med. 2025;392(15):1471-1483. doi:10.1056/NEJMoa2410965.
5. Gazyva® [Package Insert]. Genentech, Inc.; South San Francisco, CA.
6. Micromedex. RED BOOK search results: obinutuzumab. Accessed January 3, 2026. https://www.micromedexsolutions.com/micromedex2/librarian/
7. Micromedex. RED BOOK search results: Benlysta. Accessed January 3, 2026. https://www.micromedexsolutions.com/micromedex2/librarian/
8. Micromedex. RED BOOK search results: Lupkynis. Accessed January 3, 2026. https://www.micromedexsolutions.com/micromedex2/librarian/

AVLAYAH™ (tividenofusp alfa-eknm) Overview

Please consult complete Prescribing Information

INDICATIONS & USAGE

AVLAYAH is indicated for the treatment of neurologic manifestations of Hunter syndrome (Mucopolysaccharidosis type II, MPS II) when initiated in presymptomatic or symptomatic pediatric patients weighing at least 5 kg prior to advanced neurologic impairment. This indication is approved under accelerated approval based on the reduction of cerebrospinal fluid heparan sulfate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

Limitation of Use:

AVLAYAH is not recommended for use in combination with other enzyme replacement therapies for the treatment of Hunter syndrome.

IMPORTANT SAFETY INFORMATION

BOXED WARNING: HYPERSENSITIVITY REACTIONS INCLUDING ANAPHYLAXIS

Patients treated with enzyme replacement therapies, including AVLAYAH, have experienced life-threatening hypersensitivity reactions, including anaphylaxis. Anaphylaxis has occurred during the early course of enzyme replacement therapy and after extended duration of therapy.

Initiate AVLAYAH in a healthcare setting with appropriate medical monitoring and support measures, including access to cardiopulmonary resuscitation equipment. If a severe hypersensitivity reaction (e.g., anaphylaxis) occurs, discontinue AVLAYAH and immediately initiate appropriate medical treatment, including use of epinephrine. Inform patients of the symptoms of life-threatening hypersensitivity reactions, including anaphylaxis and to seek immediate medical care should symptoms occur.

Please see pages 11 and 12 for additional Important Safety Information.

The AVLAYAH Medicaid Testimony begins on the following page.

July 20, 2026
Dear Oregon Drug Use Review / Pharmacy & Therapeutics Committee

Mucopolysaccharidosis Type II Overview
Mucopolysaccharidosis type II, or Hunter syndrome, is an inherited lysosomal disorder caused by deficiency of the enzyme iduronate-2-sulfatase, or IDS. IDS is responsible for breaking down glycosaminoglycans, or GAGs, within lysosomes, particularly heparan sulfate (HS) and dermatan sulfate (DS). This IDS deficiency leads to accumulation of glycosaminoglycans, or GAGs, throughout the body, including in the brain, resulting in progressive multi-organ disease.[1]

MPS II manifests across a spectrum of severity, which cannot always be identified by genetic testing. Patients across the disease spectrum may experience a broad range of neurologic manifestations that impact communication, socialization, and behavior.[2-6] MPS II is a rare disorder, with approximately one pediatric patient per one million covered lives.[2,7]

Insufficient clearance leads to continuing GAG accumulation in both the brain and body, and prolonged exposure to GAGs can contribute to the continued development and worsening of MPS II manifestations over time. Existing enzyme replacement therapy does not cross the blood-brain barrier and therefore does not address neurologic disease, representing a significant unmet need.[8,9]

AVLAYAH Overview
AVLAYAH is a novel fusion protein designed to deliver IDS to both the central nervous system and periphery via Denali's novel TransportVehicle™ platform. It is the first and only FDA-approved enzyme replacement therapy that crosses the blood-brain barrier to reach the CNS in addition to the periphery.[1]

AVLAYAH is indicated for the treatment of neurologic manifestations of Hunter syndrome (Mucopolysaccharidosis type II, MPS II) when initiated in presymptomatic or symptomatic pediatric patients weighing at least 5 kg prior to advanced neurologic impairment and was granted accelerated approval based on reduction of cerebrospinal fluid heparan sulfate.[1]

AVLAYAH was studied in a Phase 1/2 trial of 47 pediatric patients across the MPS II disease spectrum assessing CNS and peripheral biomarkers. Study participants ranged in age from 3 months to 13 years. Approximately 2/3 of patients had prior ERT exposure. In the trial, 93% achieved normal CSF heparan sulfate levels at Week 24 compared to 0% at baseline, with sustained normalization at Week 104. Additionally, 68% achieved normal urine GAG levels at Week 24 and 84% achieved normal urine GAG levels at Week 104.[1,7,9-12]

In this study, "normal" was defined as the percentage of participants whose values fell within the age-based upper limit seen in people without MPS II. A link between biomarker levels and clinical benefit has not been established. The Week 104 results are exploratory and based on fewer participants, so they should be interpreted with caution.

AVLAYAH has a boxed warning for hypersensitivity reactions, including anaphylaxis, and should be administered in an appropriate healthcare setting. Additional warnings include Infusion-associated reactions, anemia, and membranous nephropathy.[1]

Please see the full **Prescribing Information**, including BOXED WARNING, for additional Important Safety Information.

AVLAYAH is given as a weekly intravenous infusion, with dosage based on the patient's actual body weight. For patients who have reached and tolerated the maintenance dosage, AVLAYAH can be administered at home under the supervision of a healthcare professional, based on their discretion. AVLAYAH is available as a sterile white to off-white lyophilized powder for reconstitution in a single-dose 150-mg vial.[1]

In conclusion, AVLAYAH represents a meaningful advance as the first therapy to address the neurologic manifestations of MPS II. We respectfully request coverage for AVLAYAH consistent with the FDA label.

Please see the full **Prescribing Information**, including BOXED WARNING, for additional Important Safety Information.

INDICATIONS & USAGE

AVLAYAH is indicated for the treatment of neurologic manifestations of Hunter syndrome (Mucopolysaccharidosis type II, MPS II) when initiated in presymptomatic or symptomatic pediatric patients weighing at least 5 kg prior to advanced neurologic impairment. This indication is approved under accelerated approval based on the reduction of cerebrospinal fluid heparan sulfate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

Limitation of Use:

AVLAYAH is not recommended for use in combination with other enzyme replacement therapies for the treatment of Hunter syndrome.

IMPORTANT SAFETY INFORMATION

BOXED WARNING: HYPERSENSITIVITY REACTIONS INCLUDING ANAPHYLAXIS

Patients treated with enzyme replacement therapies, including AVLAYAH, have experienced life-threatening hypersensitivity reactions, including anaphylaxis. Anaphylaxis has occurred during the early course of enzyme replacement therapy and after extended duration of therapy.

Initiate AVLAYAH in a healthcare setting with appropriate medical monitoring and support measures, including access to cardiopulmonary resuscitation equipment. If a severe hypersensitivity reaction (e.g., anaphylaxis) occurs, discontinue AVLAYAH and immediately initiate appropriate medical treatment, including use of epinephrine. Inform patients of the symptoms of life-threatening hypersensitivity reactions, including anaphylaxis and to seek immediate medical care should symptoms occur.

Warnings and Precautions

- **Hypersensitivity Reactions Including Anaphylaxis:**
  Life-threatening hypersensitivity reactions, including anaphylaxis, have been reported in patients treated with enzyme replacement therapies (ERTs) including AVLAYAH. Symptoms of anaphylaxis that have occurred with AVLAYAH included tachycardia, hypotension, wheezing, vomiting, hives, lip and tongue swelling. Anaphylaxis has occurred during the early course of ERT and after extended duration of therapy.

  Administer AVLAYAH under the supervision of a healthcare provider knowledgeable in the management of hypersensitivity reactions including anaphylaxis and in a healthcare setting with appropriate medical monitoring and support measures, including access to cardiopulmonary resuscitation equipment.

  Prior to AVLAYAH administration, consider pre-treatment with antihistamines, antipyretics, and/or corticosteroids.

  - If a severe hypersensitivity (including anaphylaxis) reaction occurs, discontinue AVLAYAH and immediately initiate appropriate medical treatment, including use of epinephrine. Consider the risks and benefits of re-administering AVLAYAH following a severe reaction (including anaphylaxis). If the decision is made to re-administer, re-evaluate pre-treatment medications, consider slowing the infusion rate, and/or reducing the AVLAYAH dose.
  - If a mild or moderate hypersensitivity reaction occurs, temporarily hold the infusion, and/or reduce the infusion rate by 50%, then titrate up to the recommended rate as tolerated. Re-evaluate the pre-treatment medication regimen.

Please see the full **Prescribing Information**, including BOXED WARNING, for additional Important Safety Information.

- **Infusion-Associated Reactions:**
  Infusion-associated reactions (IARs) occurred in patients treated with AVLAYAH with symptoms including chills, angioedema, hypotension, tachycardia, urticaria, vomiting, wheezing, pyrexia, flushing, erythema, rash, cough, diarrhea, abdominal pain, retching, headache, irritability, and papules.

  Prior to AVLAYAH administration, consider pre-treatment with antihistamines, antipyretics, and/or corticosteroids to reduce the risk of IARs. IARs may still occur in patients after receiving pre-treatment. Onset of IARs was most common during the first 8 weeks of treatment with a median time to onset of approximately 2 weeks for the first IAR; IARs declined in frequency with continued use of AVLAYAH. IARs may still occur despite extended duration of AVLAYAH treatment. Appropriate medical monitoring and support measures, including cardiopulmonary resuscitation equipment, should be readily available during AVLAYAH administration.

  - If a severe IAR occurs, discontinue AVLAYAH and immediately initiate appropriate medical treatment. Consider the risks and benefits of re-administering AVLAYAH following a severe IAR and monitor patients closely upon re-administration of AVLAYAH. Re-evaluate pre-treatment medications, consider slowing the infusion rate, and/or reducing the AVLAYAH dose.
  - If a mild or moderate IAR occurs, temporarily hold the infusion, and/or reduce the infusion rate by at least 50%, then titrate up to the recommended rate as tolerated.

  If the dose is reduced, when it is appropriate to increase the dosage level, follow the recommended dose escalation regimen to achieve the maintenance dose.

  Patients with Hunter syndrome may have compromised cardiac and respiratory function which may predispose them to a higher risk of severe complications from IARs. Closely monitor patients with compromised cardiac and respiratory function following AVLAYAH administration.

- **Anemia:**
  Anemia has been reported in patients treated with AVLAYAH. Obtain hemoglobin levels prior to initiating AVLAYAH, 3 months after initiation, and periodically thereafter as clinically indicated. Appropriate supportive measures for anemia should be applied based on clinical judgment.

- **Membranous Nephropathy:**
  Steroid-refractory membranous nephropathy with immune complex deposits in the kidney was reported in an AVLAYAH-treated patient. Monitor serum creatinine and urinary protein to creatinine ratio. If suspected, conduct diagnostic evaluation and institute appropriate treatment. Consider risks and benefits of continuing AVLAYAH in patients who develop membranous nephropathy.

Most Common Adverse Reactions:

The most common adverse reactions (≥20%) were IAR, upper respiratory tract infection, ear infection, pyrexia, anemia, cough, vomiting, diarrhea, rash, COVID-19, rhinorrhea, nasal congestion, fall, headache, skin abrasion, and urticaria.

Please see the full **Prescribing Information**, including BOXED WARNING, for additional Important Safety Information.

References: 1. AVLAYAH. Prescribing Information. Denali Therapeutics; 2026. **2.** Nan H, et al. *Biomed Res Int*. 2020;2020:2408402. doi:10.1155/2020/2408402. **3.** Zanetti A, Tomanin R. *BioDrugs*. 2024;38(5):639-655. doi:10.1007/s40259-024-00675-0. **4.** Lau H, et al. *Mol Genet Metab Rep*. 2023;37:101005. doi:10.1016/j.ymgmr.2023.101005. **5.** Scarpa M, Lampe C. Mucopolysaccharidosis Type II. 2007 Nov 6 [Updated 2025 Jan 16]. In: Adam MP, Feldman J, Mirzaa GM, et al, editors. GeneReviews® [Internet]. Seattle (WA): University of Washington, Seattle; 1993-2025. **6.** Yund B, et al. *Mol Genet Metab*. 2015;114(2):170-177. doi:10.1016/j.ymgme.2014.12.299. **7.** Data on file. Denali Therapeutics. **8.** Bhalla A, et al. *Int J Mol Sci*. 2020;21(15):5188. doi:10.3390/ijms21155188. **9.** Concolino D, et al. *Ital J Pediatr*. 2018;44(suppl 2):120. doi:10.1186/s13052-018-0562-1. **10.** Muenzer J, et al. *Mol Genet Metab*. 2024;142:10853. doi:10.1016/j.ymgme.2024.108535. **11.** Viana GM, et al. *J Clin Med*. 2020;9:396. doi:10.3390/jcm9020396. **12.** Chuang C-K, et al. *Orphanet J Rare Dis*. 2014;9:135. doi:10.1186/s13023-014-0135-3.

C-US-UNB-00081 05/26

SAPHNELO® (anifrolumab-fnia) injection, for intravenous, or subcutaneous use

Clinical Executive Summary (Last Updated: July 2026) | AstraZeneca Pharmaceuticals LP, Wilmington, DE

This information is not intended to offer recommendations for administering this product in a manner inconsistent with its approved labeling. Please consult the complete Prescribing Information for SAPHNELO.

Distinguishing Characteristics[1]

- MOA: SAPHNELO is a type I IFN receptor antagonist. Blockade of receptor mediated type I IFN signaling inhibits IFN responsive gene expression as well as downstream inflammatory and immunological processes.
- Dosing: SAPHNELO is given as a fixed dose that is not based on body weight; a loading dose is not required
- Administration: SAPHNELO is administered as one 30-minute infusion every 4 weeks or subcutaneous injection weekly

Select key points from the 2025 ACR and 2023 EULAR SLE Guidelines[2,3]

- Target DORIS remission: Prompt initiation of treatment aiming at DORIS remission or low disease activity
- Treat early: Use of hydroxychloroquine and early initiation of immunosuppressants and/or biologic therapy are recommended to minimize steroid toxicity
- Minimize steroid use: Steroid maintenance dose should be reduced – taper OCS to ≤**5** mg/day and withdraw, if possible

SAPHNELO Indications[1]

Indications and Usage	Recommended Dosage	Limitations of Use
For the treatment of adult patients with moderate to severe SLE, who are receiving standard therapy.	Intravenous: 300 mg every 4 weeks Subcutaneous: 120 mg once every week	Not for use in severe active lupus nephritis or severe active central nervous system lupus.

Clinical Data[1]

Phase III, randomized, placebo-controlled, 52 week trials in adults with moderate to severe SLE receiving standard therapy. Patients with a baseline OCS ≥10 mg/day were required to taper their OCS dose to ≤7.5 mg/day.

	TULIP-1[4] (52 wk, N=457)	**TULIP-2**[5] (52 wk, N=362)	**TULIP SC**[6] (52 wk, N=362)
Disease activity	Primary endpoint (SRI-4 response at Week 52) not statistically significant: 49% Anifrolumab vs 43.0% placebo (difference 6%, 95% CI [-4.2,16.2]) BICLA response: 47.1% Anifrolumab vs 30.2% placebo (difference 17%, 95% CI [7.2 to 26.8]).	Primary endpoint (BICLA response) statistically significant: 47.8% Anifrolumab vs 31.5% placebo (difference 16.3%, 95% CI [6.3-26.3], p=0.001). Response observed early (~Week 4) and sustained through Week 52. SRI-4 response: 55.5% Anifrolumab vs 37.3% placebo (difference 18.2%, 95% CI [8.1–28.3]).	BICLA response (primary endpoint): 58.5% Anifrolumab vs 43.2% placebo (difference 15.3%, 95% CI [2.1-28.5], p=0.0231). BICLA sustained response at Week 52: 41.5% Anifrolumab vs 22.6% placebo LLDAS attainment:40.1% Anifrolumab vs 26.0% placebo (difference 14.1%, 95% CI [4.6 to 23.6])
DORIS Remission	pooled TULIP-1 and 2: 15.3% Anifrolumab vs 6.6% placebo (OR: 2.6, 95% CI [1.6 to 4.3])		29.0% Anifrolumab vs 14.7% placebo (difference 14.2%, 95% CI [5.6 to 22.8])
OCS Use	49% of Anifrolumab-treated patients vs 32% of placebo patients achieved a dose reduction to ≤7.5 mg/day at Week 52 (among those with baseline OCS ≥10 mg/day) (difference 16.7%, 95% CI [3.5-29.8]).	Significantly reduced OCS dosage to ≤7.5 mg/day from Week 40 to Week 52 among patients with baseline OCS dosage ≥10 mg/day: 51.5% Anifrolumab vs 30.2% placebo (difference 21.2%, 95% CI [6.8-35.7], p=0.01).	Significantly increased proportion of patients who achieved BICLA response and maintained a low/reduced GC dose: 56.2% Anifrolumab vs 34.0% placebo (difference 22.3%, 95% CI [12.3-32.2], p<0.0001)

Safety[1]

Most common adverse reactions (incidence ≥5%)

- Nasopharyngitis, upper respiratory tract infections, bronchitis, infusion related reactions, herpes zoster and cough.

Please refer to the complete SAPHNELO Prescribing Information for information, including Contraindications, Warnings and Precautions.

Abbreviations:

ACR = American College of Rheumatolgoy; BICLA = British Isles Lupus Assessment Group based Composite Lupus Assessment; DORIS = Definitions Of Remission In SLE; EULAR = European Alliance of Associations for Rheumatology; IFN = interferon; LLDAS = ; MOA = mechanism of action; OCS = oral corticosteriods; SLE = systemic lupus erythematosus; SRI-4 = SLE Responder Index.

References:

[1] SAPHNELO. Prescribing Information. May 2026.
[2] Fanouriakis A et al. *Ann Rheum Dis*. 2024;83(1):15-29.

[3] American College of Rheumatology. 2025 American College of Rheumatology (ACR) Guideline for the Treatment of Systemic Lupus Erythematosus. Published November 2025. Accessed March 24, 2026. https://doi.org/10.1002/acr.25690
[4] Furie RA, Morand EF, Bruce IN, et al; TULIP-1 Study Investigators. Type I interferon inhibitor anifrolumab in active systemic lupus erythematosus (TULIP-1): a randomised, controlled, phase 3 trial. *Lancet Rheumatol.* 2019;1(4):e208-e219.
[5] Morand EF, Furie R, Tanaka Y, et al; TULIP-2 Trial Investigators. Trial of anifrolumab in active systemic lupus erythematosus. *N Engl J Med.* 2020;382(3):211-221
[6] Manzi S, Bruce IN, Morand EF, et al. Efficacy and safety of subcutaneous anifrolumab in systemic lupus erythematosus: a randomized, phase 3 study. Arthritis Rheumatol. 2026;78(6):1258-1267.