

# Saphnelo (anifrolumab-fnia) — HCPCS J0491

CARECOST ESTIMATE · BILLING CHEAT SHEET

AstraZeneca 300 mg / 2 mL single-dose vial IV infusion 30 min every 4 weeks **Reviewed:** May 2, 2026 **ASP:** Q2 2026

<b>HCPCS</b> <b>J0491</b> 1 mg = 1 unit	<b>DOSE</b> <b>300 units</b> 300 mg q4wk · 1 vial · fixed	<b>MODIFIER</b> <b>JZ</b> Single-dose vial · no waste	<b>ADMIN CPT</b> <b>96365</b> Therapeutic IV (non-chemo)	<b>MEDICARE ASP+6%</b> <b>\$18.307</b> /mg · \$5,492.10/dose
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**FIRST-IN-CLASS — type I IFN receptor (IFNAR1) antagonist.** Blocks signaling from all type I interferons (IFN- $\alpha$ , IFN- $\beta$ , IFN- $\omega$ , IFN- $\kappa$ ) — mechanistically distinct from BAFF/B-cell biologics (Benlysta) and CD20-depletion (Rituxan off-label).

**NOT for active lupus nephritis (LN) or active CNS lupus.** FDA label excludes; phase 3 TULIP-LN failed primary endpoints. Major payers enforce LN exclusion in PA. **For SLE + LN, use Benlysta (J0490) or Lupkynis.**

## CODES & NDC

HCPCS	J0491 — "Inj anifrolumab-fnia 1 mg" (permanent, eff. 1/1/2023; pre-2023 used C9085 or J3490)
NDC	0310-1450-02 (10) / 00310-1450-02 (11) — N4 qualifier
VIAL	300 mg / 2 mL (150 mg/mL) single-dose
FDA APPROVAL	August 2, 2021 (BLA 761123)
BENEFIT	Medical (provider buy-and-bill); not specialty pharmacy

## DOSING

- **300 mg IV q4wk — FIXED dose, NOT weight-based**
- 30-min infusion; dilute in 100 mL 0.9% NaCl
- 1 vial per dose; no loading dose
- First-dose observation period recommended
- Premedication: **not routinely required**
- 13 doses/year typical (q4w × 52 weeks)
- Year-1 total: **3,900 units** (13 × 300)
- Pediatric (<18 yrs): **not approved**

## LUPUS BIOLOGIC CLASS COMPARISON

DRUG	MECH	SLE	LN
Saphnelo (J0491)	Anti-IFNAR1	Yes	<b>NO</b>
Benlysta (J0490)	Anti-BAFF	Yes	<b>YES</b>
Rituxan (J9312)	Anti-CD20	Off-label	Off-label
Lupkynis (oral)	Calcineurin inh	No	<b>YES</b>

**Choice:** SLE no LN → Saphnelo or Benlysta. SLE + LN → Benlysta. Pure LN → Lupkynis (+ MMF/steroid). Refractory CNS/heme → Rituxan off-label.

## ICD-10 — M32.X SLE FAMILY

CODE	FOR
M32.10	<b>Primary</b> — SLE, organ involvement unspecified
M32.11 – M32.13	Endocarditis / pericarditis / pulmonary in SLE
M32.14 / M32.15	Glomerular / tubulo-interstitial — <b>CAUTION (active LN exclusion)</b>
M32.19	Other organ — mucocutaneous, MSK, heme
M32.8 / M32.9	Other / unspecified SLE (avoid M32.9)
M32.0	<b>NO</b> — drug-induced SLE excluded from label

## PAYER REQUIREMENTS (MAY 2026)

PAYER	PA	STEP / STANDARD-THERAPY FAILURE
UnitedHealthcare	Yes	HCQ + steroid + 1 DMARD failure; rheum consult; renal labs ≤6 mo
Aetna	Yes	HCQ + steroid taper + DMARD; nephrology consult if any LN history
BCBS plans	Yes	ACR/EULAR-aligned; step-therapy varies
Medicare LCDs	Generally no PA	Cover label indication (no active LN)

**Standard-therapy failure required:** HCQ + corticosteroids + at least 1 DMARD (MTX, MMF, AZA). Rheumatology consult required by UHC and Aetna.

## MEDICARE REIMBURSEMENT (Q2 2026)

FIELD	VALUE
ASP + 6%	<b>\$18.307 / mg</b> (effective 4/1 – 6/30/2026)
300 mg dose	<b>\$5,492.10</b> (300 × \$18.307)
Annual (13 doses)	<b>~\$71,397</b>
After ~2% sequestration	~\$69,400/year actual paid

## ADMINISTRATION & MODIFIERS

CODE	WHEN
96365	Therapeutic IV initial, up to 1 hr (primary) — <b>non-chemo</b>
96366	Each additional hour (rare for Saphnelo)
96413 / 96415	<b>NOT appropriate</b> — Saphnelo is not chemo

**JZ:** required on virtually every claim (single-dose vial, dose = vial size). **JW:** rare — only mid-infusion discontinuation.

## SITE OF CARE

SETTING	POS	NOTES
Rheumatology office	11	<b>Preferred</b>
Ambulatory infusion (AIC)	49	<b>Preferred</b>
Hospital outpatient	19/22	Disfavored after first few doses
Patient home	12	Possible (commercial); rare

## PATIENT ASSISTANCE — AZ ACCESS 360

- **Phone:** 1-844-275-2360 (AZ Access 360)
- **Commercial copay:** \$0 first dose; up to **\$20,000/year**
- **PAP:** free product for uninsured/underinsured (AZ Patient Assistance Foundation)
- **Foundations (Medicare):** PAN, HealthWell, PAF lupus funds (verify open status)
- **Web:** [saphnelo.com](http://saphnelo.com) / [myazcareconnect.com](http://myazcareconnect.com)

**W&P (no Boxed):** Serious infections (URI, LRI, herpes zoster); hypersensitivity reactions; theoretical malignancy class risk; **avoid live vaccines** before, during, and shortly after therapy.