

Alnylam Pharmaceuticals 189 mg/mL single-dose vial (GalNAc-siRNA) **SC injection monthly — 2.5 mg/kg, lifelong** **Reviewed:** May 2, 2026

ASP: Q2 2026

HCPCS J0223 0.5 mg = 1 unit	DOSE (70 KG) 350 units 175 mg SC monthly · ~13/yr	MODIFIERS JZ / JW JZ no waste; JW for partial-vial discard	ADMIN CPT 96372 Therapeutic SC, non-chemo	MEDICARE ASP+6% \$120.983 /0.5 mg unit · \$42,344/dose (70 kg)
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1 unit = 0.5 mg (NOT 1 mg) — J0223 biller error trap. Practices that bill total mg as units UNDER-bill by exactly 50% (~\$21,000 missed per dose, \$275K+/year). Always: **units = (weight kg × 2.5 mg/kg) ÷ 0.5 mg/unit**. 70 kg → 175 mg → 350 units.

CODES & NDC

HCPCS	J0223 — "Inj, givosiran, 0.5 mg" (permanent)
NDC	71336-1001-1 (10) / 71336-1001-01 (11) — N4 qualifier
DEVICE	189 mg/mL single-dose vial; GalNAc-conjugated siRNA targeting hepatic ALAS1
BENEFIT	Medical (provider buy-and-bill)
SISTER PRODUCTS	Onpattro J0222, Amvuttra J0225, Oxlumo J0224 (all Alnylam siRNA)

ICD-10 — PRIMARY FOR CHRONIC GIVLAARI

CODE	FOR
E80.21	AIP (most common) — primary
E80.20	Porphyria, unspecified (general AHP)
E80.29	Other porphyria (HCP, VP, ADP)
Z79.899	Long-term biologic (supplementary)

Don't use R10.x (abdominal pain) or G93.49 (acute encephalopathy) as primary for chronic prevention claims. Those are attack-visit codes only.

DOSING & UNIT MATH (70 KG EXAMPLE)

- 2.5 mg/kg SC monthly** (every 4 weeks) — weight-based, lifelong
- 189 mg/mL single-dose vial; partial-vial use creates real waste → JW
- ~13 doses/year; observe ~30–60 min for anaphylaxis post-injection
- 70 kg patient:** $70 \times 2.5 = 175 \text{ mg} \div 0.5 = 350 \text{ units}$
- 60 kg patient:** $60 \times 2.5 = 150 \text{ mg} \div 0.5 = 300 \text{ units}$
- 90 kg patient:** $90 \times 2.5 = 225 \text{ mg} \div 0.5 = 450 \text{ units}$
- Annual J0223 units (70 kg): **~4,550** (350×13)

INDICATION (FDA 2019)

AHP TYPE	GENE	NOTES
AIP (acute intermittent porphyria)	HMBS	~80% of AHP — most common
HCP (hereditary coproporphyrin)	CPOX	Less common
VP (variegate porphyria)	PPOX	Less common
ADP (δ-ALAD deficiency)	ALAD	Ultra-rare

ENVISION (NEJM 2020): ~74% reduction in annualized attack rate vs placebo. Established standard of care for chronic AHP attack prevention.

ALNYLAM SIRNA PORTFOLIO

DRUG	HCPCS	UNIT	INDICATION	INTERVAL
Givlaari	J0223	0.5 mg	AHP	SC monthly
Onpattro	J0222	0.1 mg	hATTR-PN	IV q3wk
Oxlumo	J0224	0.5 mg	PH1	SC monthly → q3mo
Amvuttra	J0225	1 mg	hATTR-PN/CM	SC q3mo
Leqvio	J1306	1 mg	ASCVD/heFH	SC q6mo

Givlaari + Oxlumo share the unusual 0.5 mg unit basis. Amvuttra + Leqvio = 1 mg/unit. Onpattro = 0.1 mg/unit. Read descriptor literally.

MONITORING PROTOCOL (FDA LABEL)

TEST	CADENCE
ALT, AST	Baseline + monthly × 6 mo , then PRN
Total bili, ALP	Baseline + with LFTs
SCr / eGFR	Baseline + every 6 months
Urine PBG, ALA	Periodic (quarterly yr 1 typical)
Anaphylaxis observation	Each injection visit

LFT monitoring is non-negotiable. >3× ULN → consider dose interruption / reduction; severe DILI → discontinue. Continuation PA needs current LFTs.

ADMINISTRATION & MODIFIERS

CODE	WHEN
96372	Primary — therapeutic SC, non-chemo
96365	NOT — that's IV; givosiran is SC
96413 / 96401	NOT — chemo admin; givosiran isn't anti-neoplastic
JZ	Full-vial use, no waste (single-dose container)
JW	Partial-vial discard (weight-based dose < full vial); document waste

JW is common for J0223 because of weight-based dosing from a 189 mg vial. Bill discard on separate line.

PRE-TREATMENT WORKUP (PA-REQUIRED)

- **Genetic:** HMBS (AIP, CPT 81406), CPOX/PPOX/ALAD (CPT 81479) variant report
- **Biochemical:** Urine PBG (84110) + ALA (82135), ideally during/after attack
- **Attack history:** ≥2 attacks/year requiring hospitalization, IV hemin, or urgent care
- **Specialist:** hepatology, hematology, clinical genetics, or porphyria-center consult
- **Baseline labs:** ALT, AST, total bilirubin, ALP, SCr, eGFR

PAYER REQUIREMENTS (MAY 2026)

PAYER	PA	NOTES
UnitedHealthcare	Yes	Genetic + biochemical + attack hx + specialist
Aetna	Yes	Continuation requires demonstrated attack reduction
BCBS	Yes	FDA label + APF / EHC guidance
Medicare MAC	Coverage criteria	FDA label-aligned

Continuation: document attack frequency reduction vs baseline (~74% ENVISION benchmark) + current LFT/SCr.

MEDICARE REIMBURSEMENT (Q2 2026)

FIELD	VALUE
ASP + 6%	\$120,983 / 0.5 mg unit (4/1–6/30/2026)
Per-mg equivalent	~\$241.97 / mg
175 mg dose (70 kg, 350 units)	\$42,344.05
Annual ~13 doses (70 kg)	~\$550,473
Annual ~13 doses (90 kg, 450 units)	~\$707,750

SITE OF CARE

SETTING	POS	NOTES
Hepatology / hematology office	11	Preferred
Ambulatory infusion suite	49	Preferred
Hospital outpatient	19/22	Disfavored after first dose
Patient home	12	Uncommon (anaphylaxis + lab access)

PATIENT ASSISTANCE — ALNYLAM ASSIST

- **Phone:** 1-833-256-2748 (Alnylam Assist)
- **Commercial copay:** Alnylam Assist Co-Pay Program
- **PAP:** Alnylam Patient Foundation (uninsured/underinsured)
- **Foundations:** PAN, HealthWell — verify open AHP funds
- **APF** (porphyriafoundation.org): patient ed + drug-trigger DB
- Same Alnylam Assist covers Onpattro, Amvuttra, Oxlummo, Givlaari

W&P (no Boxed): Anaphylaxis (rare), hepatic transaminase elevations, decreased eGFR, injection-site reactions. Not chemo — do not use chemo CPTs.