Givlaari (givosiran) — HCPCS J0223

CARECOST ESTIMATE · BILLING CHEAT SHEET

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

ASP: Q4 2026

HCPCS	DOSE (70 KG)	MODIFIERS	ADMIN CPT	MEDICARE ASP+6%
J0223	350 units	JZ / JW	96372	$120.744
0.5 mg = 1 unit	175 mg SC monthly · ~13/yr	JZ no waste; JW for partial-vial discard	Therapeutic SC, non-chemo	/0.5 mg unit · $42,344/dose (70 kg)

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)

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 × 2.5 = 175 mg ÷ 0.5 = **350 units**
- **60 kg patient:** 60 × 2.5 = 150 mg ÷ 0.5 = **300 units**
- **90 kg patient:** 90 × 2.5 = 225 mg ÷ 0.5 = **450 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 coproporphyria)	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.

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.

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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 (Q4 2026)

FIELD	VALUE
ASP + 6%	**$120.744 / 0.5 mg unit** (4/1–6/30/2026)
Per-mg equivalent	~$241.83 / mg
175 mg dose (70 kg, 350 units)	**$42,320.25**
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, Oxlumo, Givlaari

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

Sources: Alnylam Assist HCP (Mar 2026), FDA label NDA 212194 (Nov 2019), ENVISION trial (NEJM 2020), CMS ASP Q4 2026, UHC/Aetna/BCBS givosiran policies, American Porphyria Foundation guidance. Reviewed by Erin Rose.