

Amvuttra (vutrisiran) — HCPCS J0225

CARECOST ESTIMATE · BILLING CHEAT SHEET

Alnylam Pharmaceuticals 25 mg / 0.5 mL single-dose prefilled syringe (GalNAc-siRNA) **SC injection every 3 months — only 4 doses/year**

Reviewed: May 2, 2026 ASP: Q2 2026

HCPCS J0225 1 mg = 1 unit	DOSE 25 units 25 mg SC q3mo · 4/yr	MODIFIER JZ Required (single-dose PFS, no waste)	ADMIN CPT 96372 Therapeutic SC, non-chemo	MEDICARE ASP+6% \$5,019.273 /mg · \$125,481.83/dose
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q3mo SC dosing — only 4 doses per year. Major adherence advantage vs Onpattro (J0222) IV q3wk + 4-agent premed (~17 doses/yr). Most Onpattro patients have transitioned to Amvuttra.

CODES & NDC

HCPCS	J0225 — "Inj, vutrisiran, 1 mg" (permanent)
NDC	71336-1003-1 (10) / 71336-1003-01 (11) — N4 qualifier
DEVICE	25 mg / 0.5 mL single-dose prefilled syringe (50 mg/mL); GalNAc-conjugated siRNA
BENEFIT	Medical (provider buy-and-bill)
SISTER PRODUCT	Onpattro (patisiran, J0222) — IV q3wk; hATTR-PN only

DOSING — Q3MO SC (ONLY 4/YR)

- **25 mg SC every 3 months (every 12 weeks)** — fixed dose, NOT weight-based
- 1 prefilled syringe per dose; abdomen, thigh, or upper arm; rotate sites
- 1–2 minute injection by HCP; **no premedication**
- **4 doses/year** total
- Annual J0225 units: **100** (4 × 25)
- If dose missed, give ASAP and resume original schedule

INDICATIONS (FDA)

INDICATION	STATUS
hATTR-PN (polyneuropathy)	2022 approval (NDA 215515)
ATTR-CM (cardiomyopathy, wt or hereditary)	March 2025 expansion (HELIOS-B)

HELIOS-B: reduced all-cause mortality + recurrent CV events in ATTR-CM. Major billing growth driver — ATTR-CM far more prevalent than hATTR-PN.

ICD-10 — HATTR-PN

CODE	FOR
E85.1	Heredofamilial amyloidosis, neuropathic (primary)
G62.81	Peripheral neuropathy (additional)
G63	Polyneuropathy in amyloidosis (code-also)
G90.09	Autonomic neuropathy

ICD-10 — ATTR-CM

CODE	FOR
E85.82	Wild-type ATTR amyloidosis
E85.1	Hereditary ATTR amyloidosis
I43	Cardiomyopathy in dx classified elsewhere
I50.x	Heart failure (NYHA-driven 4th/5th char)

Pair amyloidosis + cardiac codes. Reporting only I43/I50.x without E85.x denies.

HATTR / ATTR-CM LANDSCAPE

DRUG	HCPCS	ROUTE / INTERVAL	INDICATIONS
Amvuttra	J0225	SC q3mo	hATTR-PN + ATTR-CM
Onpattro	J0222	IV q3wk	hATTR-PN only
Wainua (eplontersen)	J1305	SC q4wk	hATTR-PN
Vyndamax/Vyndaqel (tafamidis)	Oral / NDC	Daily PO	ATTR-CM (stabilizer)
Tegsedi (inotersen)	J3490	SC weekly	hATTR-PN (older)

ADMINISTRATION & MODIFIERS

CODE	WHEN
96372	Primary — therapeutic SC, non-chemo
96365	NOT — that's IV (correct for Onpattro)
96413	NOT — chemo admin; vutrisiran isn't chemo
96401	NOT — chemo SC; vutrisiran isn't anti-neoplastic

Common error: Practices switching from Onpattro carry over 96365 IV. Vutrisiran is SC — use 96372.

REQUIRED WORKUP

- **hATTR-PN:** TTR genetic testing (CPT 81404) showing pathogenic variant
- **ATTR-CM:** PYP scan Perugini grade 2/3 (CPT 78803 / 78813) or biopsy + TTR confirmation
- **ATTR-CM AL exclusion:** SPEP (84165), UPEP (84166), serum free light chains (83883) — all negative
- NT-proBNP, troponin, NYHA class
- Specialist (neuro or cardio amyloid) prescription

AL amyloidosis must be excluded for every ATTR-CM PA. Without it, denials are automatic.

ONPATTRO VS AMVUTTRA

	ONPATTRO J0222	AMVUTTRA J0225
Route	IV (~80 min)	SC (1–2 min)
Interval	q3wk	q3mo
Doses/yr	~17	4
Premed	4-agent IV	None
Indications	hATTR-PN	hATTR-PN + ATTR-CM
Admin CPT	96365	96372

Most Onpattro patients have switched. Switching requires fresh PA (different J-code, different formulation).

PAYER REQUIREMENTS (MAY 2026)

PAYER	PA	NOTES
UnitedHealthcare	Yes	TTR variant + neuro Rx (PN); PYP/biopsy + AL exclusion (CM)
Aetna	Yes	Stage 1/2 PN; NYHA I–III for CM
BCBS	Yes	FDA label + AAN / AHA-ACC guidance
Medicare MAC	Coverage criteria	FDA label-aligned (post-2025)

No step therapy typically required. Some payers want prior tafamidis trial for ATTR-CM (not universal).

MEDICARE REIMBURSEMENT (Q2 2026)

FIELD	VALUE
ASP + 6%	\$5,019.273 / mg (4/1–6/30/2026)
25 mg dose	\$125,481.83 (25 × ASP+6%)
Annual (4 doses)	~\$501,927
Comparison: Onpattro J0222	~\$1,008.96 / mg (variable weight-based)

VITAMIN A — REQUIRED

- **2,500 IU/day oral** vitamin A during therapy
- Vutrisiran reduces serum vitamin A ~70% via TTR knockdown
- Do NOT exceed 2,500 IU/day (teratogenic risk)
- Refer to ophtho if night vision changes
- Document supplementation in chart + PA letter

SITE OF CARE

SETTING	POS	NOTES
Neuro / cardio office	11	Preferred
Ambulatory infusion suite	49	Preferred
Hospital outpatient	19/22	Disfavored; not needed
Patient home	12	Some plans + specialty vendor

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 hATTR/ATTR-CM funds
- Same program covers Onpattro & Amvuttra
- **Web:** alnylam.com/alnylam-assist

W&P (no Boxed): Reduced serum vit A (supplement required), arthralgia, dyspnea, pain in extremity, UTI.

Sources: Alnylam Assist HCP (Mar 2026), FDA label (NDA 215515, 2025 ATTR-CM expansion), HELIOS-B (NEJM), CMS ASP Q2 [carecostestimate.com/drugs/amvuttra](https://www.cms.gov/medicare/coverage/determination-process/carecostestimate.com/drugs/amvuttra) 2026, UHC/Aetna/BCBS vutrisiran policies, AAN hATTR + AHA/ACC ATTR-CM guidelines. Pending SME review.