

Novartis (licensed from Alnylam) 284 mg/1.5 mL single-dose prefilled syringe Subcutaneous — NOT infusion Once, 3mo, then q6mo

ASP: Q3 2026

HCPCS

J1306

1 unit = 1 mg

FIXED DOSE

284 units

284 mg · no wt-based math

MODIFIER

JZ (usual) · TB

JG retired 1/1/2025

ADMIN CPT

96372

subQ injection — NOT
96365/96413

MEDICARE ASP+6%

\$12.905

/mg · \$3,581.24/284 mg dose

NOT AN INFUSION. Leqvio is a subQ injection billed with **96372** only. No boxed warning; label carries a hypersensitivity/anaphylaxis warning and a contraindication for prior serious hypersensitivity to inclisiran or its excipients.

CODES, NDC & MECHANISM

HCPCS	J1306 — "Injection, inclisiran, 1 mg"
GENERIC	inclisiran sodium (siRNA; GalNAc-conjugated; PCSK9 mRNA silencer)
NDC	0078-1000-60 (284 mg/1.5 mL PFS) — Novartis, labeler 0078. DailyMed-verified.
NOT THE SAME AS	PCSK9 monoclonal antibodies Repatha (evolocumab) / Praluent (alirocumab) — different mechanism, different code, different schedule

SAMPLE CMS-1500 LINE (PER NOVARTIS BILLING GUIDE)

24A shaded (NDC)	N400078100060ML1.5
Line 1	J1306 · JZ · 284 units
Line 2	96372 · 1 unit

340B: TB only in 2026. JG retired for ALL 340B-covered entities effective 1/1/2025 (CMS MLN4800856); Novartis sample forms show TB alongside J1306.

DOSING SCHEDULE (FIXED — NO MG/KG MATH)

DOSE	TIMING	UNITS
284 mg SC	Day 1 (initial)	J1306 × 284
284 mg SC	Month 3	J1306 × 284
284 mg SC	Every 6 months after	J1306 × 284

Missed >3 months: restart initial-then-3-month schedule. No weight/renal/hepatic dose adjustment per label.

ICD-10 (REPRESENTATIVE — SEE FULL NOVARTIS LIST)

CODE	FOR
E78.00	Pure hypercholesterolemia, unspecified
E78.011 / E78.010	HeFH / HoFH
I25.10, I21.4, I63.9, I70.x	ASCVD (examples)
E11, N18, I10	Diabetes / CKD / HTN (risk factors)
Z83.42	Family history of FH

ADMINISTRATION & MODIFIERS

CODE	WHEN
96372	Every administration — SC/IM therapeutic injection
96365 / 96413 / 96401	NOT APPROPRIATE — not an infusion, not chemo

#1 error: defaulting to an infusion admin code out of habit. Leqvio has zero infusion time.

PA / STEP THERAPY — UHC EXAMPLE (VERIFY PER PLAN)

- Dx: HeFH, ASCVD, or primary hyperlipidemia
- AND documented statin trial OR prior PCSK9 mAb use
- AND separately: documented PCSK9 mAb failure/contraindication/intolerance
- LDL-C ≥ 55 mg/dL; prescriber = cardiology/endo/lipid specialist
- NOT combined with a PCSK9 inhibitor; initial auth ≤12 months

SOURCING & PATIENT ASSISTANCE

- Buy-and-bill OR specialty pharmacy — confirm required channel per payer before ordering
- LEQVIO Co-pay Program: commercial pts as low as \$0/tx; T&Cs apply; not valid for govt insurance
- LEQVIO Service Center: 833-LEQVIO2 (833-537-8462); LEQVIOhcp.com

TOP DENIALS: (1) infusion/chemo admin code used instead of 96372; (2) wrong sourcing channel for the payer; (3) missing PCSK9-failure documentation on PA; (4) billed while patient still on a PCSK9 inhibitor; (5) LDL-C threshold not documented; (6) JG used instead of TB on a 340B claim.

Sources: DailyMed / FDA label (NDA 214012), Novartis LEQVIO Billing and Coding Guide, CMS ASP Q3 2026, CMS 340B modifier guidance (MLN4800856), UnitedHealthcare commercial drug policy 2026D0101L, leqvio.com. Verify against your own source documents before billing.

carecostestimate.com/drugs/leqvio