Fabrazyme (agalsidase beta) — HCPCS J0180

CARECOST ESTIMATE · BILLING CHEAT SHEET

Sanofi Genzyme 5 mg / 35 mg lyophilized single-dose vials 1 mg/kg IV every 2 weeks (lifelong) **Reviewed:** May 2, 2026 **ASP:** Q2 2026

HCPCS	DOSE	MODIFIER	ADMIN CPT	MEDICARE ASP+6%
J0180	1 mg/kg	JW + JZ	96365 + 96366	$227.580
1 mg = 1 unit	IV q2wk · ~70 units adult	Waste line + admin line	Therapeutic IV (2–4 hr)	/mg · $15,930.60/70 mg

CODES & NDC

HCPCS	J0180 — "Injection, agalsidase beta, 1 mg" (permanent code)
NDC (5 MG)	58468-0040-01 — 5 mg lyophilized SDV; reconstitute with 1.1 mL sterile water
NDC (35 MG)	58468-0041-01 — 35 mg lyophilized SDV; reconstitute with 7.2 mL sterile water
LABELER	58468 (Sanofi Genzyme)
BENEFIT	Medical (provider buy-and-bill)
FDA	BLA 103979 (Apr 2003); pediatric ≥2 yr added 2018

DOSING & VIAL MATH

- **1 mg/kg IV q2wk**, lifelong
- Initial infusion max rate **0.25 mg/min** (~15 mg/hr) → 70 mg dose runs ~4.7 hr
- Vials: 5 mg + 35 mg combinations to match patient weight
- 26 doses/year typical (q2wk)
- Year-1 70 kg adult: **1,820 units** (26 × 70 mg)

WT (KG)	DOSE	VIALS	DRAWN	ADMIN	WASTE
60	60 mg	1×35 + 5×5	60	60	0 (JZ)
67	67 mg	1×35 + 7×5	70	67	3 (JW)
70	70 mg	2×35	70	70	0 (JZ)
78	78 mg	2×35 + 2×5	80	78	2 (JW)
92	92 mg	2×35 + 5×5	95	92	3 (JW)

PREMEDICATION CHECKLIST

Recommended (not formally required by label). ~50% of patients have IARs; antibody formation is common.

- ☐ Acetaminophen 650–1000 mg PO, 30–60 min pre-infusion
- ☐ Diphenhydramine 25–50 mg PO/IV, 30–60 min pre-infusion
- ☐ Methylprednisolone 20–100 mg IV (optional; for prior IARs / high antibody titers)
- ☐ Famotidine 20–40 mg IV (optional H2 blocker)
- ☐ IAR response kit at bedside; vital signs q15 min × first hour
- ☐ Document premed protocol on infusion record

Bill premeds separately: J1200 (diphenhydramine 50 mg), J2920/J2930 (methylprednisolone), 96374 (IV push). Acetaminophen PO not separately billable.

ICD-10 — FABRY DISEASE

CODE	FOR
E75.21	**Fabry disease (primary)**
I42.1 / I42.2	Hypertrophic cardiomyopathy
I49.x / I50.x	Arrhythmia / heart failure
N18.1–N18.6	CKD by stage
R80.x	Proteinuria
I63.x / G45.x	Stroke / TIA
G93.89	White-matter disease (MRI)
G62.89	Small-fiber neuropathy
L98.8	Angiokeratoma
H18.9 / H35.81	Cornea verticillata / retinal vascular

Multi-system documentation required. E75.21 alone often denied. Add cardiac + renal + CNS codes per documented findings.

FABRY CLASS COMPARISON

	FABRAZYME	ELFABRIO	GALAFOLD
HCPCS	J0180	J0219	Pharmacy
Mfr	Sanofi Genzyme	Chiesi/Protalix	Amicus
FDA	Apr 2003	May 2023	Aug 2018
Route	IV q2wk	IV q2wk (PEGylated)	Oral QOD
Eligibility	Any GLA mut.	Any GLA mut.	**Amenable missense only**
Pediatric	≥2 yr	Adult only	Adult only

Replagal NOT FDA-approved in US (EU only). Pediatric stays on Fabrazyme.

ADMINISTRATION & MODIFIERS

CODE	WHEN
96365	Therapeutic IV, initial hour (primary)
96366	Each additional hour, max 8 hr total
96374	IV push (premeds: diphenhydramine, methylprednisolone)
96413	**NOT appropriate** — Fabrazyme is non-chemo ERT

JW is the rule: Fixed 5/35 mg vials + weight-based dosing → partial-vial waste on most days. Bill JW with discarded mg on a separate line; JZ on the admin line for true zero-waste days.

PAYER REQUIREMENTS (MAY 2026)

PAYER	PA	DIAGNOSTIC STANDARD
UnitedHealthcare	Yes	Low α-Gal A and/or pathogenic GLA + specialist
Aetna	Yes	Same + documented organ involvement
BCBS plans	Yes	FOS/AAN-aligned + FDA label
Medicare (MAC)	Generally no	Documented Fabry dx for FDA indication

Annual reauth. Submit organ-function labs + clinical response + specialist supervision. Galafold-amenable patients may need step rationale.

MEDICARE REIMBURSEMENT (Q2 2026)

FIELD	VALUE
ASP + 6%	**$227.580 / mg** (effective 4/1 – 6/30/2026)
50 mg dose	~$11,379.00 (50 × $227.580)
70 mg dose	**$15,930.60** (70 × $227.580)
Annual (70 kg, 26 doses)	**~$414,196**
After ~2% sequestration	~$402,800/yr actual paid

SITE OF CARE

SETTING	POS	NOTES
Specialist office	11	Preferred once stable
Ambulatory infusion suite	49	Preferred
Hospital outpatient	19/22	UHC/Aetna disfavor after first months
Patient home	12	Common after IAR-free establishment

PATIENT ASSISTANCE — SANOFI PATIENT CONNECTION

- **Phone: 1-800-745-4447** (Sanofi Patient Connection)
- Ask for **rare-disease team** for Fabrazyme
- **Commercial copay:** for eligible commercially-insured (excludes Medicare/Medicaid)
- **PAP:** free drug for uninsured/underinsured meeting income
- **Foundations (Medicare):** PAN, HealthWell, NORD — verify open Fabry funds quarterly
- Web: sanofipatientconnection.com / fabrazyme.com

W&P (no Boxed): Infusion reactions (~50% of patients), antibody formation (most seroconvert by 3–6 mo — may worsen reactions / reduce efficacy), hypersensitivity, embryo-fetal toxicity. Premedicate routinely; monitor IgG anti-agalsidase titers in patients with worsening response.

Sources: FDA Fabrazyme label (BLA 103979, 2018 pediatric expansion), CMS ASP Q2 2026, Sanofi Patient Connection, UHC LSD **carecostestimate.com/drugs/fabrazyme** ERT policy, Aetna CPB 0729, NEJM BALANCE trial (2023), AAN/EFNS Fabry guidelines, FOS data. Pending SME review.