

Mylotarg (gemtuzumab ozogamicin) — HCPCS J9203

CARECOST ESTIMATE · BILLING CHEAT SHEET

Pfizer 4.5 mg single-dose lyophilized vial IV over 2 hr; fractionated D1/D4/D7 **Reviewed:** May 22, 2026 **ASP:** Q2 2026

HCPCS J9203 1 unit = 0.1 mg	DOSE 3 mg/m² (max 4.5) D1/D4/D7 induction	MODIFIER JZ Full vial typical; JW only if BSA < 1.5	ADMIN CPT 96413+96415 Every dose (2-hr infusion)	MEDICARE ASP+6% \$240.165 /0.1 mg unit · ~\$10,807/4.5 mg dose
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CODES & NDC

HCPCS	J9203 — "Injection, gemtuzumab ozogamicin, 0.1 mg" (permanent)
NDC 4.5 MG	0008-4510-01 (10) / 00008-4510-01 (11) — N4
VIAL	One 4.5 mg single-dose lyophilized vial per carton. Reconstitute with 5 mL SWFI → 1 mg/mL (delivers 4.5 mL). Dilute in 0.9% NaCl per label volume. Refrigerate; protect from light; DO NOT FREEZE .
FILTER	Low-protein-binding 0.2-micron in-line PES filter
BENEFIT	Medical (provider buy-and-bill); not specialty pharmacy

DOSING & VIAL MATH

- 3 mg/m² per dose, capped at 4.5 mg (one vial)**
- Newly-dx induction: D1, D4, D7 + dauno + cytarabine (7+3+GO)
- Newly-dx consolidation: D1 only, up to 2 cycles
- R/R monotherapy: D1, D4, D7 single induction (peds ≥ 2 yr)
- BSA 1.85 → 5.55 mg calc → **4.5 mg cap** → 45 units JZ exact
- BSA 1.3 → 3.9 mg calc → 4.5 mg vial drawn → 39 JZ + 6 JW
- Infuse over **2 hours**; pre-med acetaminophen + DPH + steroid 1 hr prior

FRACTIONATED D1/D4/D7 VS HISTORICAL SINGLE 9 MG/M²

	CURRENT (2017)	HISTORICAL (2000-10)
Schedule	3 mg/m ² D1/D4/D7	Single 9 mg/m ² q2w
Per-dose cap	4.5 mg (one vial)	No cap
Trial	ALFA-0701, MyloFrance-1	SWOG S0106 (excess mort)
FDA status	Approved (Sep 1, 2017)	Withdrawn Jun 2010

Single 9 mg/m² orders should never reach pharmacy. Clarify with oncologist — intent is the fractionated D1/D4/D7 regimen.

ICD-10 — CD33+ AML

CODE	FOR
C92.00	AML, NOT in remission (newly-dx induction)
C92.01	AML, in remission (consolidation cycles)
C92.02	AML, in relapse (R/R monotherapy)
Z51.11	Encounter for antineoplastic chemo (primary)
Z51.12	Encounter for immunotherapy (some payers for ADCs)
Z48.290	Aftercare s/p stem-cell transplant (post-HSCT VOD monitoring)

CD33+ lives in pathology, not ICD-10. Always attach flow cytometry or IHC report showing "CD33-positive" on diagnostic blasts. Match indication to disease state: C92.00 (newly-dx), C92.01 (consolidation), C92.02 (R/R).

TOP DENIALS — FIX LIST

- #1: CD33+ doc missing** → attach flow / IHC report ("CD33-positive")
- Baseline LFTs / bilirubin missing** → chart AST/ALT/T-bili/AlkP before each dose
- Wrong schedule (single 9 mg/m²)** → re-issue as fractionated D1/D4/D7
- Newly-dx vs R/R mismatch** → align ICD-10 to disease state (C92.00 / 01 / 02)
- Pediatric age not documented** → ≥ 1 mo (newly-dx combo) / ≥ 2 yr (R/R mono)
- Post-HSCT VOD monitoring missing** → chart wt, RUQ exam, T-bili, ascites checks
- Wrong admin (96365)** → resubmit 96413 + 96415
- Missing 96415** → add × 1 for the 2nd hour
- JW missing (low BSA)** → add separate JW line for discarded mg
- Dose > 4.5 mg per fraction** → apply vial cap; recalc

ADMINISTRATION & MODIFIERS

CODE	WHEN
96413	Chemo IV first hour — every dose
96415	Each addl hour — every dose (2-hr infusion)
96365	NOT appropriate — ADC bills as chemo admin per CPT
JZ	Administered-units line (req since 7/1/23) — full vial = JZ exact
JW	Waste-units line — only when calc dose < 4.5 mg (BSA < 1.5)

BSA 1.85 (typical adult): Line 1: J9203 × 45 units + JZ. **BSA 1.3 (peds):** Line 1: 39 units + JZ. Line 2: 6 units + JW. Admin: 96413 + 96415 × 1.

PAYERS (MAY 2026)

PAYER	PA	NOTES
UnitedHealthcare	Yes	CD33+ strict; fractionated schedule + baseline LFTs
Aetna	Yes	CD33+ confirmation; pediatric age verification
BCBS plans	Yes	NCCN-aligned; plan-specific UM
Medicare (Original)	No PA	MAC LCDs; inpatient bundles into DRG (834-836)
MA / Medicaid	Varies	Often commercial-style UM

MEDICARE REIMBURSEMENT (Q2 2026)

FIELD	VALUE
ASP + 6%	\$240.165 / 0.1 mg unit (\$2,401.65 / mg)
4.5 mg dose (45 units)	~\$10,807.43 / dose
Induction (3 doses)	~\$32,422
Full course (induction + 2 consol)	~\$54,037 drug only
R/R monotherapy (3 doses)	~\$32,422 drug only

PATIENT ASSISTANCE — PFIZER ONCOLOGY TOGETHER

- **Phone:** 1-877-744-5675 (Mon–Fri 8am–8pm ET)
- **Fax PAP enrollment:** 1-877-736-6506
- **Web:** pfizeroncologytogether.com / pfizertogether.com/patient/mylotarg
- **Pfizer PAP:** free product if uninsured / under-insured & ≤ 300% FPL (2026)
- **Commercial copay:** Pfizer Oncology Together Co-Pay program (excludes federal)
- **Medicare / federal:** PAN Foundation (AML), HealthWell, LLS Co-Pay, CancerCare

BOXED WARNING: Hepatotoxicity, including severe / fatal hepatic veno-occlusive disease (VOD / sinusoidal obstruction syndrome). Assess LFTs + total bilirubin **before each dose**. VOD risk substantially elevated in patients proceeding to HSCT within 3 months. Monitor weight, RUQ pain, ascites, hepatomegaly, bilirubin post-HSCT.