

Janssen Biotech (J&J) 100 mg/5 mL & 400 mg/20 mL single-dose vials (20 mg/mL) 16 mg/kg IV — weekly → q2wk → q4wk

Reviewed: May 2, 2026 ASP: Q2 2026

HCPCS J9145 10 mg = 1 unit	DOSE (75 KG) 120 units 1,200 mg = 16 mg/kg · 3×400 mg vials	MODIFIER JZ / JW Vial-draw dependent — one required	ADMIN CPT 96413 +96415 Chemo IV (3–8 hr)	MEDICARE ASP+6% \$70.774 /10 mg unit · \$8,492.88/1,200 mg
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TYPE & SCREEN MUST BE OBTAINED BEFORE THE FIRST DOSE. Daratumumab binds CD38 on red blood cells → positive Coombs / interferes with pre-transfusion compatibility testing for up to 6 months post-dose. Notify the blood bank at therapy start. Use DTT-treated reagent cells or RBC genotyping for subsequent T&S. Failure to baseline T&S can delay urgent transfusion later.

CODES & NDC

HCPCS	J9145 — "Inj, daratumumab, 10 mg" (permanent, eff. 1/1/2018)
NDC (100 MG)	57894-502-05 / 57894-0502-05 — 100 mg/5 mL SDV
NDC (400 MG)	57894-502-20 / 57894-0502-20 — 400 mg/20 mL SDV (workhorse)
VIAL	20 mg/mL single-dose; 100 mg/5 mL or 400 mg/20 mL
SISTER PRODUCT	Darzalex Faspro (SC) — J9144, NDC 57894-502-15 (1,800 mg/15 mL); CPT 96401
BENEFIT	Medical (provider buy-and-bill)

ICD-10 — MULTIPLE MYELOMA

CODE	FOR
C90.00	MM, NOS, not in remission
C90.01	MM in remission (maintenance)
C90.02	MM in relapse (R/R)
Z51.12	Encounter for antineoplastic immunotherapy (secondary)

ICD-10 — AL AMYLOIDOSIS

CODE	FOR
E85.81	Light chain (AL) amyloidosis — D-VCd combo
E85.82	Wild-type transthyretin amyloidosis

Combo backbones: DRd (+Rev/dex), DVd (+Vel/dex), DKd (+Kyp/dex), D-VMP, D-VTd, D-RVd (NDMM); D-VCd (AL). Document backbone in PA.

DOSING — 16 MG/KG IV

- **Weekly** wks 1–8 (8 doses)
- **q2wk** wks 9–24 (8 doses)
- **q4wk** wk 25+ until progression (~10/yr)
- Year 1: ~26 doses; Year 2+: ~13 doses/yr
- Split-first-dose option: 8 mg/kg D1 + 8 mg/kg D2
- 1st infusion 6–8 hr; 2nd 4 hr; subsequent ≥3 hr
- **Premed required** every infusion: steroid + APAP + diphenhydramine 1 hr pre + post-infusion oral steroid × 2 days. HSV/VZV antiviral prophylaxis throughout.

DOSE CALC BY WEIGHT

WT	DOSE	UNITS	VIALS · WASTE
50 kg	800 mg	80	2×400 · 0 (JZ)
60 kg	960 mg	96	2×400+2×100 · 40 mg (JW 4)
70 kg	1,120 mg	112	2×400+4×100 · 80 mg (JW 8)
75 kg	1,200 mg	120	3×400 · 0 (JZ)
80 kg	1,280 mg	128	3×400+1×100 · 20 mg (JW 2)
90 kg	1,440 mg	144	3×400+3×100 · 60 mg (JW 6)
100 kg	1,600 mg	160	4×400 · 0 (JZ)

PAYER REQUIREMENTS (MAY 2026)

PAYER	PA	NOTES
UnitedHealthcare	Yes	All MM lines; site-of-care UM disfavors HOPD >3 mo
Aetna	Yes	Often prefers Faspro SC for chair-time / site-of-care
BCBS	Yes	NCCN MM-aligned; line-of-therapy required
Trad Medicare FFS	No	MAC LCDs cover all FDA-labeled indications

Documentation needed: dx (CRAB / biomarker), line of therapy + prior regimens, combo backbone, T&S baseline, HBV serology.

ADMINISTRATION & MODIFIERS

CODE	WHEN
96413	Chemo IV first hour (x 1)
96415	Each add'l hour (x N: 1st inf 5–7; 2nd 3; subseq 2)
96365	NOT appropriate — daratumumab is chemo admin per AMA
Premed admin	96372 / 96374 / 96365 per route

JZ/JW required since 7/1/2023. One must be on every J9145 claim. Reconcile vials drawn vs mg administered every encounter; post JW units explicitly when partial-vial waste exists.

MEDICARE REIMBURSEMENT (Q2 2026)

FIELD	VALUE
ASP + 6%	\$70.774 / 10 mg unit (eff. 4/1 – 6/30/2026)
1,200 mg dose (75 kg)	\$8,492.88 (120 units)
1,600 mg dose (100 kg)	\$11,323.84 (160 units)
Year 1 (75 kg, 26 doses)	~\$220,815 ASP+6%
Year 2+ (75 kg, 13 doses)	~\$110,408 ASP+6%

SITE OF CARE

SETTING	POS	NOTES
Physician oncology office	11	Preferred by commercial UM
Ambulatory infusion suite	49	Preferred
Oncology ASC	24	Acceptable
Hospital outpatient	19/22	Disfavored after first 3 months

PATIENT ASSISTANCE — JANSSEN CAREPATH

- **Phone:** 1-877-CarePath (1-877-227-3728)
- **CarePath Savings Program (commercial):** \$0 first dose; up to ~\$20,000/year
- **J&J Patient Assistance Foundation:** free product for uninsured (income-tested)
- **Medicare patients:** PAN, HealthWell, CancerCare, LLS Co-Pay (verify open MM funds)
- **Web:** janssencarepath.com/patient/darzalex

W&P (no Boxed): infusion reactions ~50% on 1st infusion (split-dose option mitigates), neutropenia, thrombocytopenia, herpes zoster reactivation (antiviral prophylaxis required), embryo-fetal toxicity. Verify HBV serology before start.