

Enhertu (fam-trastuzumab deruxtecan-nxki) — HCPCS J9358

CARECOST ESTIMATE · BILLING CHEAT SHEET

Daichi Sankyo / AstraZeneca 100 mg single-dose lyophilized vial (recon to 20 mg/mL) IV q3w (90 min cycle 1, 30 min cycles 2+)

Reviewed: May 2, 2026 ASP: Q2 2026

HCPCS J9358 1 mg = 1 unit	DOSE 5.4 mg/kg q3w · 6.4 mg/kg gastric	MODIFIER JW+JZ Two lines — waste virtually always	ADMIN CPT 96413 +96415 × 1 cycle 1 only (90 min)	MEDICARE ASP+6% \$31.262 /mg · \$12,504.80/400 mg
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BOXED WARNING — ILD/pneumonitis ~12% (sometimes fatal) + embryo-fetal toxicity. Baseline chest CT before cycle 1. Pulmonary symptom screen every cycle (cough/dyspnea/fever/hypoxia). Hold for any suspected ILD; **permanently discontinue Grade 2+**. Verify pregnancy + counsel contraception.

CODES & NDC

HCPCS	J9358 — "Inj fam-trastu deru-nxki 1mg" (permanent)
NDC	65597-406-01 (10) / 65597-0406-01 (11) — N4 qualifier
VIAL	100 mg single-dose lyophilized; recon w/ 5 mL SWFI → 20 mg/mL
DILUTION	Final dose in 100 mL D5W; do NOT co-admin in same line
BENEFIT	Medical (provider buy-and-bill); medically integrated dispensing also common

WORKED UNIT MATH

PATIENT	CALC	BILL
70 kg HER2+ breast (5.4)	378 mg, 4 vials drawn (400 mg), 22 mg waste	378 JZ + 22 JW = 400 units
80 kg HER2+ gastric (6.4)	512 mg, 6 vials (600 mg), 88 mg waste	512 JZ + 88 JW = 600 units
60 kg HER2-low breast (5.4)	324 mg, 4 vials (400 mg), 76 mg waste	324 JZ + 76 JW = 400 units
90 kg HER2-mut NSCLC (5.4)	486 mg, 5 vials (500 mg), 14 mg waste	486 JZ + 14 JW = 500 units

DOSING MATRIX (BY INDICATION)

INDICATION	DOSE
HER2+ breast (2L+)	5.4 mg/kg q3w
HER2-low metastatic breast	5.4 mg/kg q3w
HER2-ultralow metastatic breast	5.4 mg/kg q3w
HER2+ gastric / GE junction	6.4 mg/kg q3w
HER2-mutant NSCLC	5.4 mg/kg q3w
HER2+ tumor-agnostic (accel)	5.4 mg/kg q3w

Dose pitfall: 6.4 mg/kg only for gastric/GEJ. All other indications 5.4. Pharmacy reconciliation should flag mismatches.

ICD-10 BY INDICATION

CODE	FOR
C50.x	HER2+, HER2-low, HER2-ultralow breast (+ C77-C79 mets)
C16.x	HER2+ gastric (4th char by site)
C16.0 / C15.5	GE junction (verify per path)
C34.x	HER2-mutant NSCLC
Site-specific C-codes	HER2+ tumor-agnostic (e.g., C18-C20 CRC, C25 pancreas, C56 ovary, C53 cervix) + HER2 IHC 3+ docs

HER2 BIOMARKER TIERS

TIER	DEFINITION
HER2+	IHC 3+ or 2+/ISH+
HER2-low	IHC 1+ or 2+/ISH-
HER2-ultralow	IHC 0 with faint, incomplete membrane staining (path report MUST call this out)
HER2-mutant	NSCLC only — activating mutation by NGS (typically exon 20 ins)

HER2-ultralow trap: default IHC 0 reads do NOT qualify. Need explicit ultralow language from path.

ADMINISTRATION & MODIFIERS

CODE	WHEN
96413	Chemo IV first hour — every cycle
96415 ×1	Each additional hour — cycle 1 only (90 min)
96365	NOT appropriate — ADC = chemo admin per CPT
96367/68/75	Antiemetic admin (5-HT3 + dex ± NK-1)

JW required: 100 mg vial + weight-based = waste on virtually every dose. Bill JZ on administered line + JW on waste line. CMS audits catch missing JW often.

PAYER REQUIREMENTS (MAY 2026)

PAYER	PA	KEY REQUIREMENT
UnitedHealthcare	Yes	HER2 IHC + ISH report; tumor-agnostic needs NCCN docs; Optum site-of-care UM after cycles 1-2
Aetna	Yes	HER2 matched to indication tier; HER2-low/ultralow need explicit path language
BCBS plans	Yes	NCCN-aligned; plan-specific site-of-care UM
Medicare LCD	No PA	Covers all approved on-label indications w/ HER2 docs

Step therapy: HER2+ breast needs prior trastuzumab + pertuzumab and/or T-DM1. HER2+ gastric needs prior trastuzumab regimen. HER2-low/ultralow need prior chemo in metastatic setting.

MEDICARE REIMBURSEMENT (Q2 2026)

FIELD	VALUE
ASP + 6%	\$31,262 / mg (effective 4/1 – 6/30/2026)
378 mg admin (70 kg, 5.4)	\$11,817.04
400 mg billed (admin + JW waste)	\$12,504.80
Annual (~17 cycles q3w)	~\$212,582 (before sequestration)
After ~2% sequester	~\$208,300/yr actual paid

SITE OF CARE

SETTING	POS	NOTES
Physician oncology office	11	Preferred by commercial UM
Ambulatory infusion (AIC)	49	Preferred by commercial UM
Oncology ASC	24	Acceptable
Hospital outpatient	19/22	Disfavored after cycles 1-2 (cycle 1 exception OK)
Patient home	12	Generally not appropriate (ILD/IRR risk)

PATIENT ASSISTANCE

- **AstraZeneca AccessSupport:** 1-833-340-2462 (Enhertu hub)
- **Daiichi Sankyo Patient Access Network** (co-development partner)
- **Co-Pay Savings Program:** up to **\$25,000/year** for commercial insured (excludes Medicare/Medicaid/federal)
- **PAP:** free drug for uninsured/underinsured
- **Foundations (Medicare):** PAN, HealthWell, CancerCare — verify open breast/gastric/lung funds quarterly
- Web: azaccesssupport.com / enhertu.com

Pending SME review. Staff-authored from FDA, CMS, manufacturer, payer sources. Final review by Catherine Rose (CPC) in progress.

Verify HER2 tier definitions and ILD protocol against current FDA label revision before high-stakes use.

Sources: FDA label most recent rev (BLA 761139), AstraZeneca AccessSupport 2026, CMS ASP Q2 2026, NCCN Breast/Gastric/NSCLC, UHC/Aetna oncology policies, SEER CanMED J9358.

carecostestimate.com/drugs/enhertu