Renflexis (infliximab-abda) — HCPCS Q5104

CARECOST ESTIMATE · BILLING CHEAT SHEET

Organon / Samsung Bioepis 100 mg single-dose lyophilized vial IV infusion ≥2 hours (NON-CHEMO) **Biosimilar — NOT interchangeable**

ASP: Q3 2026

HCPCS	5 MG/KG, 70 KG	MODIFIER	ADMIN CPT	MEDICARE ASP+6%
Q5104	**35 units**	**JZ · JW · TB**	**96365 + 96366**	**$26.615**
1 unit = 10 mg	350 mg · 4 vials drawn	JG retired 1/1/2025	**NON-CHEMO** — NOT 96413/96415	/10 mg · $938.11/350 mg dose

BOXED WARNING: Serious infections — TB reactivation, invasive fungal, bacterial sepsis, opportunistic pathogens. AND: Malignancies — lymphoma; HSTCL (mostly fatal) in adolescents/young adults on infliximab + thiopurines for IBD. **Pre-therapy latent TB screening (PPD or IGRA) required.**

CODES, NDC & BIOSIMILAR STATUS

HCPCS	`Q5104` — "Injection, infliximab-abda, biosimilar, (Renflexis), 10 mg"
GENERIC	infliximab-abda (biosimilar to Remicade, BLA 761054, approved 4/21/2017)
INTERCHANGEABLE?	**NO.** Biosimilar only — no infliximab biosimilar currently carries the FDA interchangeable designation.
NDC	`78206-162-01` (100 mg vial) — Organon LLC, labeler 78206. DailyMed-verified.
VIAL	100 mg single-dose lyophilized; reconstitute w/ 10 mL sterile water → 10 mg/mL

DOSING MATRIX — WEIGHT-BASED (MG/KG)

INDICATION	INDUCTION (WK 0/2/6)	MAINTENANCE
RA + MTX	3 mg/kg	3 mg/kg q8wk
Ankylosing spondylitis	5 mg/kg	**5 mg/kg q6wk**
Psoriatic arthritis	5 mg/kg	5 mg/kg q8wk
Plaque psoriasis	5 mg/kg	5 mg/kg q8wk
Crohn's (adult + peds 6+)	5 mg/kg	5 mg/kg q8wk
Ulcerative colitis (a + p)	5 mg/kg	5 mg/kg q8wk

RA only: required combination with methotrexate — document MTX use.

JW WORKED EXAMPLE — CROHN'S, 75 KG, 5 MG/KG

Calculated	5 mg/kg × 75 kg = **375 mg**
Vials drawn	4 × 100 mg = 400 mg
Line 1	`Q5104 · 38 units` (administered, no wastage modifier)
Line 2	`Q5104 · JW · 2 units` (discarded — 40 units drawn − 38 administered)

340B: TB only in 2026. JG retired for ALL 340B-covered entities effective 1/1/2025 (CMS MLN4800856).

ICD-10 BY INDICATION

CODE FAMILY	INDICATION
`M05.x / M06.x`	Rheumatoid arthritis
`M45.x`	Ankylosing spondylitis
`L40.5x / M07.x`	Psoriatic arthritis
`L40.x`	Plaque psoriasis (L40.0)
`K50.x`	Crohn's disease (adult + peds)
`K51.x`	Ulcerative colitis (adult + peds)

2026 PAYER STATUS (VERIFY CURRENT POLICY)

- **UnitedHealthcare:** Renflexis PREFERRED; reference Remicade denied without med-nec override
- **Aetna / Cigna / most BCBS:** biosimilar preferred; PA required
- Step-therapy usually flows the **opposite** direction here — the biosimilar is the default, not the exception

PATIENT ASSISTANCE

- **The Organon Access Program: 866-847-3539** (M–F 8a–8p ET); organonaccessprogram-renflexis.com
- Organon Patient Assistance Program Inc. — free drug for qualifying uninsured/underinsured
- Not valid for government-insured patients (Medicare/Medicaid/TRICARE)

ADMINISTRATION & MODIFIERS

CODE	WHEN
96365	**First hour** — therapeutic IV (NON-CHEMO)
96366	Each additional hour (typical 2-hr infusion = 1 + 1)
96413/96415	**NOT APPROPRIATE** — chemo codes; non-cytotoxic biologic

Chemo-vs-non-chemo is the #1 admin denial. Long infusion time does NOT change the code family.

TOP DENIALS: (1) chemo admin codes (96413/96415) used; (2) 1 mg/unit math instead of 10 mg/unit; (3) wrong J/Q-code vs. NDC drawn; (4) JG used instead of TB on a 340B claim; (5) JW missing on weight-based dose; (6) TB-screening not documented.

Sources: DailyMed / FDA label (BLA 761054), FDA Purple Book, CMS ASP Q3 2026, CMS 340B modifier guidance (MLN4800856), Organon Access Program, UnitedHealthcare commercial drug policy database. Verify against your own source documents before billing.