

Sandoz Inc. 300 mg / 15 mL single-dose vial IV infusion every 4 weeks Reviewed: May 2, 2026 ASP: Q2 2026

HCPCS Q5134 1 mg = 1 unit	DOSE 300 units 300 mg q4wk · 1 vial	MODIFIER JZ? May NOT apply — verify CMS	ADMIN CPT 96365 Therapeutic IV (1 hr)	MEDICARE ASP+6% \$24.321 /mg · \$7,296.30/dose
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CODES & NDC	
HCPCS	Q5134 — "Inj, natalizumab-sztn (tyruko), biosimilar, 1 mg" (permanent, eff. 4/1/2024; pre-2024 used J3490/J3590)
NDC	61314-543-94 (10) / 61314-0543-94 (11) — N4 qualifier
VIAL	300 mg / 15 mL (20 mg/mL) single-dose
REFERENCE	Tysabri (natalizumab, J2323) — Biogen, NDC 59075-0730-15
BENEFIT	Medical (provider buy-and-bill); not specialty pharmacy

DOSING
<ul style="list-style-type: none"> 300 mg IV over ~1 hour, every 4 weeks (no loading) 1 vial per dose; ~5 mg/min infusion rate 1-hr observation post-infusion (first 12 doses) 13 doses/year typical (q4wk × 52 weeks) Year-1 total: 3,900 units

TYRUKO REMS — REQUIRED
<p>Separate from Tysabri's TOUCH. Sites must enroll independently in TYRUKO REMS even if already TOUCH-certified.</p> <ul style="list-style-type: none"> Phone: 800-489-7856 (Sandoz REMS Coordinating Center) Web: tyrukorems.com Prescriber + site + pharmacy + patient enrollment all required Anti-JCV antibody testing baseline + every 6 mo MRI baseline + 3 mo + 6 mo + every 6 mo on therapy + 6 mo post-discontinuation <p>Common error: using existing TOUCH cert for Tyruko. Triggers REMS audit + payer recoupment.</p>

ADMINISTRATION & MODIFIERS	
CODE	WHEN
96365	Therapeutic IV, 1 hr (primary) — non-chemo
96413	Not appropriate — natalizumab is non-chemo
Home admin: S9329 + 99601/99602 (REMS-certified vendor only)	
<p>JZ/JW caveat: Per BuyAndBill, Q5134 may not be on CMS single-dose container list — JZ/JW may not apply. Verify CMS list at billing time.</p>	

ICD-10 — MS FAMILY	
CODE	FOR
G35.A	RRMS (primary)
G35.C1	Active SPMS
G35.D	MS unspecified
G37.9	CIS
G35.B0-B2	NO — not approved for PPMS

ICD-10 — CROHN'S FAMILY	
CODE	FOR
K50.00 / K50.01x	Crohn's small intestine
K50.10 / K50.11x	Crohn's large intestine
K50.80 / K50.81x	Crohn's both
K50.90 / K50.91x	Crohn's unspecified
<p>Both indications covered. Tyruko inherits Tysabri's MS + Crohn's coverage.</p>	

PAYER REQUIREMENTS (MAY 2026)		
PAYER	PA	STEP / PREFERENCE
UnitedHealthcare	Yes	Combined w/ Tysabri at parity
Aetna	Yes	Tyruko + Tysabri preferred MS alternatives (alongside Ocrevus)
Carelon / Anthem	Yes	Combined natalizumab policy (PAM-077)
BCBS FEP	Yes	Combined natalizumab policy (5.60.013)
<p>No step therapy through other MS DMTs. PA criteria focus on Dx, anti-JCV testing, and TYRUKO REMS enrollment.</p>		

MEDICARE REIMBURSEMENT (Q2 2026)	
FIELD	VALUE
ASP + 6%	\$24.321 / mg (effective 4/1 – 6/30/2026)
300 mg dose	\$7,296.30 (300 × \$24.321)
Annual (13 doses)	~\$94,852
Tysabri J2323 ASP+6%	\$24.321/mg (currently identical — pricing parity)

SITE OF CARE

SETTING	POS	NOTES
Physician office	11	1-hr fits cleanly
Ambulatory infusion suite	49	Common
Hospital outpatient	19/22	UHC/Aetna disfavor
Patient home	12	REMS-certified vendor only

PATIENT ASSISTANCE — SANDOZ ONE SOURCE

- **Phone:** 1-844-726-3691 (Sandoz One Source)
- **Commercial copay:** up to **\$10,000/year**
- **PAP:** free drug for uninsured/underinsured
- **Product Replacement:** spoiled/damaged
- **REMS Coordinating Center:** 800-489-7856
- **Web:** tyruko.com/tyruko-patient-support/sandoz-one-source/

BOXED WARNING — PML: Progressive multifocal leukoencephalopathy. Anti-JCV antibody testing required. MRI surveillance: baseline + 3mo + 6mo + q6mo + 6mo post-discontinuation.