

# Gazyva (obinutuzumab) — HCPCS J9301

CARECOST ESTIMATE · BILLING CHEAT SHEET

Genentech (Roche) 1,000 mg / 40 mL single-dose vial IV infusion 4+ hr first / ~90 min subsequent **Reviewed:** May 22, 2026 **ASP:** Q2 2026

<b>HCPCS</b> <b>J9301</b> 1 unit = 10 mg	<b>STANDARD DOSE</b> <b>100 units</b> 1,000 mg flat IV	<b>MODIFIER</b> <b>JZ</b> No waste (1 vial = dose)	<b>ADMIN CPT</b> <b>96413 + 96415×3</b> First infusion (4+ hr)	<b>MEDICARE ASP+6%</b> <b>\$81.806</b> /10 mg · \$8,180.60/1,000 mg
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**HBV SEROLOGY REQUIRED — Boxed Warning.** Screen HBsAg AND anti-HBc before initiation. Hep B reactivation can result in fulminant hepatitis / hepatic failure / death. Missing serology documentation is the #1 denial trigger. Second Boxed Warning: PML.

## CODES & NDC

HCPCS	J9301 — "Inj, obinutuzumab, 10 mg" (permanent eff 1/1/2015)
GENERIC	obinutuzumab (Type II humanized anti-CD20, glycoengineered)
NDC	50242-070-01 — N4 qualifier in 24A shaded
VIAL	1,000 mg / 40 mL (25 mg/mL) single-dose vial — SOLE SKU
BIOSIMILARS	None — Genentech sole manufacturer
BENEFIT	Medical (provider buy-and-bill)

## ICD-10 BY INDICATION

CODE	FOR
C91.10	CLL of B-cell type, not in remission
C91.11	CLL of B-cell type, in remission
C91.12	CLL of B-cell type, in relapse
C82.0x – C82.9x	Follicular lymphoma grade I/II/III + 5th-char site
C83.30 – C83.39	DLBCL by anatomic site (Columvi pretreat context)
Z85.72	Personal history of lymphoma (FL maintenance phase)
Z51.11	Antineoplastic therapy encounter (secondary)

**CD20+ histology required:** Flow cytometry (CLL) or IHC (FL/DLBCL) in chart. FL refractory needs prior rituximab regimen + progression docs.

## DOSING BY INDICATION

INDICATION	REGIMEN	COMBO
<b>CLL 1L (CLL11)</b>	C1D1 100 mg + C1D2 900 mg + C1D8/D15 1,000 mg; C2–C6 D1 1,000 mg	Chlorambucil PO
<b>FL untreated (GALLIUM)</b>	C1 D1/8/15 + C2–C6 D1 = 1,000 mg each; maint q2mo × 2 yr	CHOP / CVP / benda
<b>FL rituximab-refractory (GADOLIN)</b>	C1 D1/8/15 + C2–C6 D1 = 1,000 mg each; maint q2mo × 2 yr	Bendamustine
<b>Columvi pretreatment</b>	Single 1,000 mg Day -7 (DLBCL)	Columvi (J9286) C1D1 = Day +7

## PAYER REQUIREMENTS (MAY 2026)

PAYER	PA	REQUIRED DOCUMENTATION
Medicare (MAC LCDs)	Generally no	CD20+ + HBV serology + FDA indication match + NCCN comp for off-label
UnitedHealthcare	Yes	HBsAg + anti-HBc + CD20+ + indication evidence; FL refractory needs prior rituximab regimen
Aetna	Yes	NCCN + FDA aligned; HBV serology; site-of-care UM
BCBS plans	Yes	NCCN aligned; HBV serology; plan-specific site-of-care

## UNIT MATH (1,000 MG STANDARD)

- 1,000 mg flat dose → 1,000 ÷ 10 = **100 units J9301** with **JZ** (no waste)
- CLL C1D1 100 mg ramp → **10 units JZ** (vial shared with D2 within 24 hr stability)
- CLL C1D2 900 mg → **90 units JZ** (from same vial Day 1, or fresh vial → JW for 100 mg discard)
- Columvi pretreat Day -7 → 1,000 mg = **100 units J9301**, separate claim from Columvi

**JZ is default.** One vial = one dose. Bill 100 units on a single line with JZ for standard 1,000 mg infusion.

## GAZYVA VS RITUXAN (J9301 VS J9312)

	GAZYVA J9301	RITUXAN J9312
Class	Type II humanized (afucosylated, enhanced ADCC)	Type I chimeric
Unit basis	10 mg/unit	10 mg/unit
CLL 1L	<b>Yes</b> (+ chlorambucil)	No (off-label 1L)
RA / GPA / PV	No	<b>Yes</b>
Columvi pretreat	<b>Yes</b> (mandatory)	No
Premed every infusion	<b>Mandatory</b>	First only (may taper)
ASP / 10 mg	<b>\$81.806</b>	\$74.158 (biosim from \$13.69)
Biosimilars	<b>None</b>	Q5115, Q5119, Q5123

**Not interchangeable.** Reconcile chemo order / MAR / pharmacy dispense before posting claim.

## ADMINISTRATION & MODIFIERS

CODE	WHEN
96413	Chemo IV up to 1 hr (primary) — bill once per encounter
96415 x 3	<b>First infusion (~4 hr titrated 50→400 mg/hr)</b>
96415 x 1	Subsequent infusion (~90 min if tolerated)
96417	Sequential second chemo agent (e.g., bendamustine after Gazyva in FL)
96365	Most major payers including Medicare expect <b>chemo</b> codes, not 96365

**Premed mandatory at EVERY infusion:** dex 20 mg IV + DPH 50 mg IV + acetaminophen 650–1,000 mg PO, 30–60 min before start. Not optional per FDA label.

## MEDICARE REIMBURSEMENT (Q2 2026)

FIELD	VALUE
ASP + 6%	<b>\$81,806 / 10 mg unit</b> (eff. 4/1 – 6/30/2026)
1,000 mg flat dose	<b>\$8,180.60</b> (100 units)
CLL 1L full course (~8,000 mg)	<b>\$65,444.80</b> (~800 units across 6 cycles)
FL induction (~8,000 mg)	<b>\$65,444.80</b>
FL maintenance 2-yr (~12,000 mg)	<b>\$98,167.20</b>
Columvi pretreat Day -7	<b>\$8,180.60</b> (single dose)

## SITE OF CARE

SETTING	POS	NOTES
Hospital outpatient (on-campus)	22	<b>Preferred for first infusion</b> (4-hr titrate + IRR monitoring)
HOPD off-campus PBD	19	Acceptable first infusion; commercial may steer subsequent
Oncology office	11	Acceptable for tolerated subsequent infusions
AIC	49	Verify IRR/CRS escalation capability
Home infusion	12	<b>Not appropriate</b> for Gazyva

## TOP DENIALS

- **#1 HBV serology missing** — HBsAg + anti-HBc must be in chart (Boxed Warning)
- CD20+ histology not confirmed — flow / IHC pathology report required
- Prior rituximab not documented (FL refractory / GADOLIN PA)
- Wrong HCPCS (J9312 Rituxan) — not interchangeable with J9301
- Insufficient 96415 add-ons for first infusion — need x 3 for ~4 hr
- Wrong NDC format (vial-level) — use carton NDC 50242-070-01 + N4 qualifier

## PATIENT ASSISTANCE — GENENTECH ACCESS SOLUTIONS

- **Phone:** 1-866-422-2377 (Genentech Access Solutions)
- **Co-pay (commercial):** as little as **\$5/infusion**; annual benefit cap applies
- **Genentech Patient Foundation:** 1-888-941-3331 — free product for uninsured / underinsured (~400–500% FPL)
- **Foundations (Medicare):** PAN, HealthWell, LLS Co-Pay, CancerCare — verify open CLL/NHL/lymphoma funds
- Web: genentech-access.com

**CLL11 trial result:** Gazyva + chlorambucil showed superior PFS vs Rituxan + chlorambucil in untreated CLL — this is why CLL 1L is a J9301 indication and not a J9312 indication. Submitting Rituxan for untreated CLL will fail medical-necessity review.

(Sehn Lancet Onc 2016), GALLIUM (Marcus NEJM 2017).