MyNavCare™ PATIENT SUPPORT

EPKINLY™ (epcoritamab-bysp)

Permanent HCPCS J9321 Code

Effective January 1, 2024

The Centers for Medicare & Medicaid Services (CMS) has issued a permanent EPKINLY Healthcare Common Procedure Coding System (HCPCS) J-Code, effective for services on or after January 1, 2024.[1]

For all settings of care and across government and commercial payors, the following coding and billing information should be applied:[1]

Product Name	HCPCS Code	Description and Billing Unit
EPKINLY (epcoritamab-bysp)	J9321	Injection, epcoritamab-bysp, 0.16 mg

Billing unit application for doses of EPKINLY:

Providers should denote the billing units as "per 0.16 mg". Because EPKINLY is provided in single use vials, the billing would be the following:

Dose[2]	Vial Size/Strength[2]	Billing Units	NDC[3]
Step-up dose 1: 0.16 mg	4 mg/0.8 mL	25	82705-0002-01
Step-up dose 2: 0.8 mg	4 mg/0.8 mL	25	82705-0002-01
Full dose: 48 mg	48 mg/0.8 mL	300	82705-0010-01

NDC = National Drug Code. Each provider is responsible for ensuring all coding is accurate and documented in the medical record based on the condition of the patient. The use of this information does not guarantee reimbursement. Healthcare providers are encouraged to contact payers to confirm code adoption and approved usage prior to submitting claims.

Medicare drug wastage modifiers to be denoted based on the billing units[4]

Example of documentation of drug wastage during the 2 step-up doses and all full doses is as follows:

Dose[2]	Vial Size/Strength[2]	Claim Form Line 1	Claim Form Line 2
Step-up dose 1: 0.16 mg	4 mg/0.8 mL	J9321 1 billable unit	J9321 – JW modifier appended 24 billable units
Step-up dose 2: 0.8 mg	4 mg/0.8 mL	J9321 5 billable units	J9321 – JW modifier appended 20 billable units
Full dose: 48 mg	48 mg/0.8 mL	J9321 – JZ modifier appended 300 billable units	Not applicable

Have Questions?

Contact a *MyNavCare*™ Support Specialist by calling **1-866-NAV-CAR1** (1-866-628-2271), Monday-Friday, 8 AM-8 PM ET, or visit **MyNavCare.com** to learn more.

Please see Indication and Important Safety Information, including Boxed Warnings for cytokine release syndrome (CRS) and Immune effector cell-associated neurotoxicity syndrome (ICANS), on the back page. Please see full Prescribing Information, including Boxed Warnings.

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INDICATION[2]

EPKINLY is indicated for the treatment of adults with relapsed or refractory diffuse large B-cell lymphoma (DLBCL), not otherwise specified (NOS), including DLBCL arising from indolent lymphoma, and high-grade B-cell lymphoma (HGBL) after 2 or more lines of systemic therapy.

This indication is approved under accelerated approval based on response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

IMPORTANT SAFETY INFORMATION[2]

BOXED WARNINGS

- **Cytokine release syndrome (CRS), including serious or life-threatening reactions, can occur in patients receiving EPKINLY. Initiate treatment with the EPKINLY step-up dosing schedule to reduce the incidence and severity of CRS. Withhold EPKINLY until CRS resolves or permanently discontinue based on severity.**
- **Immune effector cell–associated neurotoxicity syndrome (ICANS), including life-threatening and fatal reactions, can occur with EPKINLY. Monitor patients for neurological signs or symptoms of ICANS during treatment. Withhold EPKINLY until ICANS resolves or permanently discontinue based on severity.**

CRS

- CRS occurred in 51% of patients in the clinical trial (37% grade 1, 17% grade 2, and 2.5% grade 3) and recurred in 16% of patients. Most events (92%) occurred during cycle 1, with 61% occurring after the 48 mg dose in cycle 1, day 15. In patients who experienced CRS, the signs and symptoms included pyrexia, hypotension, hypoxia, dyspnea, chills, and tachycardia. Concurrent neurological adverse reactions associated with CRS occurred in 2.5% of patients and included headache, confusional state, tremors, dizziness, and ataxia.
- Administer pretreatment medications to reduce the risk of CRS. Following administration of the first 48 mg dose, patients should be hospitalized for 24 hours.
- Monitor patients for potential CRS. At the first signs or symptoms of CRS, manage per current practice guidelines and administer supportive care as appropriate.

ICANS

- ICANS occurred in 6% of patients in the clinical trial (4.5% grade 1, 1.3% grade 2, 0.6% fatal). Of the 10 ICANS events, 9 occurred in cycle 1 of treatment. The onset of ICANS can be concurrent with CRS, following resolution of CRS, or in the absence of CRS. Clinical manifestations of ICANS included, but were not limited to, confusional state, lethargy, tremor, dysgraphia, aphasia, and non-convulsive status epilepticus.
- Monitor patients for potential ICANS. At the first signs or symptoms of ICANS, manage per current practice guidelines and administer supportive care as appropriate.

Infections

- EPKINLY can cause serious and fatal infections. In the clinical trial, serious infections, including opportunistic infections, were reported in 15% of patients treated with EPKINLY at the recommended dose (14% grade 3 or 4, 1.3% fatal).
- Monitor patients for signs and symptoms of infection prior to and during treatment and treat appropriately. Avoid administration in patients with active infections. Withhold or consider permanent discontinuation of EPKINLY based on severity. Prior to starting EPKINLY, provide *Pneumocystis jirovecii* pneumonia (PJP) prophylaxis and consider prophylaxis against herpes virus.

Cytopenias

- EPKINLY can cause serious or severe cytopenias. In the clinical trial, grade 3 or 4 events occurred in 32% (neutropenia), 12% (anemia), and 12% (thrombocytopenia) of patients. Febrile neutropenia occurred in 2.5%.
- Monitor complete blood counts throughout treatment. Based on severity of cytopenias, temporarily withhold or permanently discontinue EPKINLY. Consider prophylactic granulocyte colony-stimulating factor administration as applicable.

Embryo-Fetal Toxicity

- EPKINLY may cause fetal harm when administered to a pregnant woman. Advise females of reproductive potential to use effective contraception during treatment with EPKINLY and for 4 months after the last dose. Verify pregnancy status in females of reproductive potential prior to initiating EPKINLY.

Adverse Reactions

- Most common (≥20%) adverse reactions were CRS, fatigue, musculoskeletal pain, injection site reactions, pyrexia, abdominal pain, nausea, and diarrhea. Most common grade 3 to 4 laboratory abnormalities (≥10%) were decreased lymphocytes, decreased neutrophils, decreased white blood cells, decreased hemoglobin, and decreased platelets.

Lactation

- Advise women not to breastfeed during treatment and for 4 months after the last dose of EPKINLY.

Please see full Prescribing Information, including Boxed Warnings.

References: 1. Centers for Medicare & Medicaid Services. 2023 HCPCS Application Summary for Quarter 3, 2023 Drugs and Biologicals. October 2023. Accessed October 19, 2023. https://www.cms.gov/files/document/2023-hcpcs-application-summary-quarter-3-2023-drugs-and-biologicals.pdf **2.** EPKINLY. Prescribing Information. Genmab A/S; 2023. **3.** United Healthcare. National drug code (NDC) requirement policy, professional and facility. Updated October 8, 2023. Accessed October 17, 2023. https://www.uhcprovider.com/content/dam/provider/docs/public/policies/comm-reimbursement/COMM-National-Drug-Code-Requirement-Policy.pdf **4.** Centers for Medicare & Medicaid Services. Billing and Coding: JW and JZ Modifier Billing Guidelines. 1/10/23. https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=55932&ver=14&=

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