

EPKINLY® (epcoritamab-bysp)

Permanent HCPCS J9321 Code

The Centers for Medicare & Medicaid Services (CMS) has issued a permanent EPKINLY Healthcare Common Procedure Coding System (HCPCS) J-Code.¹

For all settings of care and across government and commercial payors, the following coding and billing information should be applied¹:

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

Diffuse Large B-Cell Lymphoma and High-Grade B-Cell Lymphoma²

Indication

DLBCL and High-grade B-cell Lymphoma

- 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 (HGBCL) 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 confirmatory trial(s).

Billing unit application for doses of EPKINLY

Providers should denote the billing units as “per 0.16 mg.”² Because EPKINLY is provided in single-use vials, the billing would be the following:

Dose ²	Vial Size/Strength ²	Total 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 payors to confirm code adoption and approved usage prior to submitting claims.

Drug wastage modifiers to be denoted based on the billing units⁴

Example of documentation of drug wastage during the step-up doses and all full doses for **Diffuse Large B-Cell Lymphoma and High-Grade B-Cell Lymphoma** is as follows:

Dose ²	Vial Size/Strength ²	Claim Form Line 1 ^{1,4}	Claim Form Line 2 ^{1,4}
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

Select Important Safety Information

BOXED WARNINGS

- Cytokine release syndrome (CRS), including serious or fatal reactions, can occur in patients receiving EPKINLY. Initiate treatment with the EPKINLY step-up dosage 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.

This resource is for informational purposes only. Payer coding and documentation requirements may change over time, and providers should confirm coding and documentation requirements for each payer. This is not a guarantee of coverage or reimbursement. It is the sole responsibility of healthcare providers to select the appropriate codes and ensure the accuracy of all claims submitted for reimbursement.

Follicular Lymphoma²

Indication

- EPKINLY is indicated in combination with lenalidomide and rituximab for the treatment of adults with relapsed or refractory follicular lymphoma (FL).
- EPKINLY is indicated as monotherapy for the treatment of adults with relapsed or refractory FL after 2 or more lines of systemic therapy.

Billing unit application for doses of EPKINLY

Providers should denote the billing units as “per 0.16 mg.”² Because EPKINLY is provided in single-use vials, the billing would be the following:

Dose ²	Vial Size/Strength ²	Total 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
Step-up dose 3: 3 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.

Drug wastage modifiers to be denoted based on the billing units⁴

Example of documentation of drug wastage during the step-up doses and all full doses for **Follicular Lymphoma** is as follows:

Dose ²	Vial Size/Strength ²	Claim Form Line 1 ^{1,4}	Claim Form Line 2 ^{1,4}
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
Step-up dose 3: 3 mg	4 mg/0.8 mL	J9321 – 19 billable units	J9321 – JW modifier appended 6 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](https://www.mynavcare.com) to learn more.

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IMPORTANT SAFETY INFORMATION

BOXED WARNINGS

- **Cytokine release syndrome (CRS), including serious or fatal reactions, can occur in patients receiving EPKINLY. Initiate treatment with the EPKINLY step-up dosage 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% (80/157) of patients with large B-cell lymphoma (LBCL) receiving EPKINLY at the recommended dosage schedule in EPCORE NHL-1 (37% Grade 1, 17% Grade 2, and 2.5% Grade 3) and recurred in 31% of patients. Most events (92%) occurred during Cycle 1. In Cycle 1, CRS events occurred in 6% of patients after the 0.16 mg dose (Cycle 1, day 1), 12% after the 0.8 mg dose (Cycle 1, day 8), 43% after the first 48 mg dose (Cycle 1, day 15), and 5% after the next 48 mg dose (Cycle 1, day 22). The median time to onset of CRS from the most recent administered dose across all doses was 24 hours (range: 0-10 days). The median time to onset after the first full 48 mg dose was 21 hours (range: 0-7 days).
- CRS occurred in 49% (42/86) of patients with FL receiving EPKINLY monotherapy at the recommended dosage schedule in EPCORE NHL-1 (45% Grade 1, 9% Grade 2) and recurred in 48% of patients. Most events (88%) occurred during Cycle 1. In Cycle 1, CRS events occurred in 12% of patients after the 0.16 mg dose (Cycle 1, day 1), 6% after the 0.8 mg dose (Cycle 1, day 8), 15% after the 3 mg dose (Cycle 1, day 15), and 37% after the first 48 mg dose (Cycle 1, day 22). The median time to onset of CRS from the most recent administered dose across all doses was 59 hours (range: 0.1-7 days). The median time to onset after the first full 48 mg dose was 61 hours (range: 0.1-7 days).
- CRS occurred in 24% (32/131) of patients with FL receiving EPKINLY at the recommended dosage schedule in combination with lenalidomide and rituximab in EPCORE FL-1 (19% Grade 1, 5% Grade 2, and 12% serious adverse reactions due to CRS) and recurred in 41% of patients. Most events (88%) occurred during Cycle 1. In Cycle 1, CRS occurred in 5% of patients after the 0.16 mg dose (Cycle 1, day 1), 3.8% after the 0.8 mg dose (Cycle 1, day 8), 2.3% after the 3 mg dose (Cycle 1, day 15), and 18% after the first 48 mg dose (Cycle 1, day 22). The median time to onset of CRS from the most recent EPKINLY dose was 78 hours (range: 0.2-12 days). The median time to onset after the first 48 mg dose was 41 hours (range: 0.3-12 days).
- For patients with LBCL and FL, assess whether hospitalization or outpatient monitoring for the first 48 mg dose is appropriate based on comorbidities or other situational factors. During outpatient monitoring after the first 48 mg dose, patients should remain in proximity to a healthcare facility that can assess and manage CRS.
- In patients who experienced CRS, the signs and symptoms included pyrexia, hypotension, hypoxia, dyspnea, chills, and tachycardia. CRS resolved in 98% of patients; the median duration of CRS events was 2 days (range: <1-27 days).

Concurrent neurological adverse reactions associated with CRS occurred in 2.5% of patients with LBCL, 4.7% of patients with FL receiving EPKINLY monotherapy, and 1.5% of patients receiving EPKINLY in combination with lenalidomide and rituximab (reactions included headache, confusional state, tremors, dizziness, and ataxia).

- Administer pretreatment medications to reduce the risk of CRS.
- Monitor patients for potential CRS. At the first signs or symptoms of CRS, immediately evaluate patients for hospitalization, manage per current practice guidelines, and administer supportive care as appropriate.

ICANS

- ICANS occurred in 6% (10/157) of patients with LBCL receiving EPKINLY at the recommended dosage schedule in EPCORE NHL-1 (4.5% Grade 1, 1.3% Grade 2, 0.6% fatal). Of the 10 ICANS events, 9 occurred within Cycle 1 of treatment, with a median time to onset of 16.5 days (range: 8-141 days) from the start of treatment. Relative to the most recent administered dose, the median time to onset was 3 days (range: 1-13 days). The median duration of ICANS was 4 days (range: 0-8 days), with ICANS resolving in 90% of patients with supportive care.
- ICANS occurred in 6% (8/127) of patients with FL receiving EPKINLY monotherapy following the 2-step up dosage schedule in EPCORE NHL-1 (3.9% Grade 1, 2.4% Grade 2). The median time to onset was 22 days (range: 14-66 days) from the start of treatment. Relative to the most recent administered dose, the median time to onset of ICANS was 3 days (range: 0.4-7 days). The median duration of ICANS was 2 days (range: 1-7 days), with ICANS resolving in 100% of patients.
- Among patients with FL who received EPKINLY at the recommended dosage schedule in combination with lenalidomide and rituximab in EPCORE FL-1, ICANS occurred in 0.8% (1/131, Grade 1).
- 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, immediately evaluate patient, provide supportive therapy based on severity, and manage per current practice guidelines.

Infections

- EPKINLY can cause fatal and serious infections. Serious infections, including opportunistic infections, were reported in 15% of patients with LBCL in EPCORE NHL-1 (most common: 4.5% sepsis, 3.2% pneumonia). Fatal infections occurred in 1.3% of patients (1.3% COVID-19).
- Serious infections, including opportunistic infections, were reported in 40% of patients with FL receiving EPKINLY monotherapy, following the 2-step up dosage schedule in EPCORE NHL-1 (most common: 20% COVID-19, 13% pneumonia, 3% urinary tract infections). Fatal infections occurred in 6% of patients (5% COVID-19, 0.8% pneumonia, 0.8% sepsis).
- Among 243 patients with FL who received EPKINLY in combination with lenalidomide and rituximab in EPCORE FL-1, serious infections occurred in 28% of patients. The most common serious infections were pneumonia (15%), COVID-19 (7%), opportunistic infections (5%) and upper respiratory infections (3.3%). The most common opportunistic infections of any grade were cytomegalovirus (CMV) infection (7%) and herpesvirus infection (7%).

Please see additional Important Safety Information on [page 4](#). Please see full [Prescribing Information](#), including Boxed Warnings.

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- Progressive multifocal leukoencephalopathy (PML), including fatal cases, has occurred in patients treated with EPKINLY. Across a broader clinical trial population, PML was reported in 0.4% (11/3,072) of patients, including in the first-line treatment setting. Of the 11 cases of PML, 6 resulted in fatal outcomes and 1 was unresolved at the time of death.
- Monitor patients for signs and symptoms of infection and treat appropriately. Avoid administration in patients with active infections. Withhold or consider permanent discontinuation of EPKINLY based on severity. Provide *Pneumocystis jirovecii* pneumonia (PJP) prophylaxis during treatment with EPKINLY and consider prophylaxis against herpesvirus.

Cytopenias

- EPKINLY can cause serious or severe cytopenias. In the clinical trial of patients with LBCL, Grade 3 or 4 decreased neutrophils occurred in 32% (Grade 4, 14%), decreased hemoglobin in 12% (Grade 4, 0%), and decreased platelets in 12% (Grade 4, 7%) of patients. Febrile neutropenia occurred in 2.5% (Grade 4, 0.6%).
- In the clinical trial of patients with FL who received EPKINLY monotherapy following the 2-step up dosage schedule, Grade 3 or 4 decreased neutrophils occurred in 30% (Grade 4, 17%), decreased hemoglobin in 10% (Grade 4, 0%), and decreased platelets in 8% (Grade 4, 4%) of patients. Febrile neutropenia occurred in 3.1% (Grade 4, 0%).
- In patients with FL who received EPKINLY in combination with lenalidomide and rituximab, Grade 3 or 4 decreased neutrophils occurred in 67% (Grade 4, 41%), decreased lymphocytes in 62% (Grade 4, 13%), decreased hemoglobin in 7%, and decreased platelets in 10% (Grade 4, 4.1%) of patients. Febrile neutropenia occurred in 6% (Grade 4, 2.1%).
- 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

- EPKINLY as monotherapy for LBCL or FL: Most common ($\geq 20\%$) adverse reactions were CRS, injection site reactions, fatigue, musculoskeletal pain, fever, diarrhea, COVID-19, rash, and abdominal pain. Most common Grade 3 to 4 laboratory abnormalities ($\geq 10\%$) were decreased lymphocytes, decreased neutrophils, decreased hemoglobin, and decreased platelets.
- EPKINLY in combination with lenalidomide and rituximab for FL: Most common ($\geq 20\%$) adverse reactions were rash, upper respiratory tract infections, fatigue, injection site reactions, constipation, diarrhea, CRS, pneumonia, COVID-19, and fever. The most common Grade 3 to 4 laboratory abnormalities ($\geq 10\%$) were decreased neutrophils, decreased lymphocytes, and decreased platelets.

Use in Specific Populations

- Lactation:** Advise women not to breastfeed during treatment and for 4 months after the last dose of EPKINLY.
- Geriatric Use:** In patients with relapsed or refractory FL who received EPKINLY in EPCORE NHL-1, 52% were ≥ 65 years old, and 13% were ≥ 75 years old. A higher rate of fatal adverse reactions, primarily infections, including COVID-19, was observed in patients ≥ 65 years old compared to younger adult patients. No overall difference in efficacy was observed.

Please see full [Prescribing Information](#), including **Boxed Warnings**.

References: 1. Centers for Medicare & Medicaid Services (CMS). October 2025 n-Numeric HCPCS File (ZIP). Open Zip File. Open HCPC2025_OCT_ANWEB_v4. Accessed February 10, 2026. <https://www.cms.gov/medicare/coding-billing/healthcare-common-procedure-system/quarterly-update> 2. EPKINLY® (epcoritamab-bysp) Prescribing Information. Genmab A/S; Revised 3/2026. <https://www.genmab-pi.com/prescribing-information/epkinly-pi.pdf> 3. UnitedHealthcare. National Drug Code (NDC) Requirement Policy, Professional and Facility. Updated December 14, 2025. Accessed February 10, 2026. <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. Medicare Program Discarded Drugs and Biologicals – JW Modifier and JZ Modifier Policy Frequently Asked Questions. Updated December 23, 2025. Accessed February 10, 2026. <https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps/downloads/jw-modifier-faqs.pdf>

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