Specialty Distributors for EPKINLY

EPKINLY can be purchased from the following Specialty Distributors. If you prefer, EPKINLY can also be dispensed through an exclusive network of specialty pharmacies. Please call *MyNavCare*™ Support at **1-866-NAV-CAR1** (1-866-628-2271) to determine if your patient is eligible to access this medication through Genmab's specialty pharmacy partners.

epkinly™
epcoritamab-bysp
SUBCUTANEOUS INJECTION 4mg | 48mg

SPECIALTY DISTRIBUTORS

Specialty Distributor	Telephone Number	Email Address	Distributor Ordering Numbers	
			EPKINLY 4 mg/0.8 mL NDC 82705-0002-01	EPKINLY 48 mg/0.8 mL NDC 82705-0010-01
ASD Healthcare	800-746-6273	service@asdhealthcare.com	10280264	10280198
BioCare SD (Institutional)	(800) 304-3064	order@biocaresd.com	1000364	1000365
BioCare SD (Clinic)	(800) 304-3064	order@biocaresd.com	1000368	1000369
Cardinal SPD Acute	855-855-0708	GMB-spd-csorderentry@cardinalhealth.com	5849179	5849187
Cardinal SPD Provider	877-453-3972	spdoncologyteam@cardinalhealth.com	5849195	5849203
McKesson Plasma and Biologics	877-625-2566	mpborders@mckesson.com	2821452	2821460
McKesson Specialty Care Distribution	800-482-6700	oncologycustomersupport@mckesson.com	5014883	5014884
Morris & Dickson Specialty	800-388-3833	customerservice@morrisdickson.com	001256	001959
Oncology Supply	800-633-7555	service@oncologysupply.com	10280263	10280254

INDICATION

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

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.

Please see additional Important Safety Information on next page.

AVAILABLE STRENGTHS FOR EPKINLY

epkinly™
epcoritamab-bysp
SUBCUTANEOUS INJECTION 4mg|48mg

Images are not to scale; for illustrative purposes only

For each step-up dose*

One 4 mg per 0.8 mL single-dose vial

*See Prescribing Information for Day 1 (0.16 mg) and Day 8 (0.8 mg) dose preparation instructions

For full doses

One 48 mg per 0.8 mL single-dose vial

Administration	Healthcare provider-administered	Healthcare provider-administered
Injection Type	Subcutaneous injection	Subcutaneous injection
HCPCS J Code	J9321	J9321
NDC Number	82705-0002-01	82705-0010-01
Distribution	Specialty distributor	Specialty distributor

IMPORTANT SAFETY INFORMATION *(continued)*

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 accompanying full Prescribing Information, including Boxed Warnings.

LEARN MORE AT EPKINLYHCP.COM

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