Medical Policy:

Danyelza® (naxitabmab-gqgk) injection

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.325	March 20, 2024	February 2, 2021

Definitions

Danyelza, a glycolipid disialoganglioside (GD2)-binding monoclonal antibody, is indicated, in combination with granulocyte-macrophage colony-stimulating factor (GM-CSF), for the treatment of relapsed or refractory high-risk neuroblastoma in the bone or bone marrow in patients ≥ 1 year of age who have demonstrated a partial response, minor response, or stable disease to prior therapy.

Length of Authorization

Coverage will be provided for 6 months and may be renewed.

Dosing Limits [Medical Benefit]

The recommended dosage is 3 mg/kg/day (maximum 150mg/day) as an intravenous infusion on days 1, 3, and 5 of each 4-week treatment cycle

Max Units (per dose and over time) [HCPCS Unit]:

150 billable units (150 mg) on days 1, 3, 5 of each 28-day treatment cycle for 6-cycles

total followed by subsequent infusions every 8 weeks thereafter

Guideline

I. INITIAL APPROVAL CRITERIA

1. <u>Neuroblastoma</u>

Coverage is provided when the following criteria is met:

A. Patient is ≥ 1 year of age; **AND**
B. Danyelza is prescribed by or in consultation with an oncologist; **AND**
C. Danyelza will be used in combination with granulocyte-macrophage colony-stimulating factor [GM-CSF] (e.g., sargramostim); **AND**
D. Patient has relapsed or refractory disease in the bone or bone marrow; **AND**
E. Patient had at least a partial or minor response or stable disease to at least one prior systemic therapy.

II. RENEWAL CRITERIA

Coverage can be renewed based on the following conditions:

1. Stabilization of disease or absence of disease progression; **AND**
2. Absence of unacceptable toxicity from the drug. *Examples of unacceptable toxicity include the following: serious infusion-related reactions, severe neurotoxicity (neuropathic pain, peripheral neuropathy, transverse myelitis, reversible posterior leukoencephalopathy syndrome, neurological disorders of the eye, and prolonged urinary retention), severe hypertension*, etc.

Applicable Procedure Codes

Code	Description
J9348	Injection, naxitamab-gqgk, 1 mg (effective 7/1/2021)

Applicable NDCs

Code	Description
73042-0201-01	Danyelza 40mg/10ml solution single-dose vial

ICD-10 Diagnoses

Code	Description
C74.90	Malignant neoplasm of unspecified part of unspecified adrenal gland

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	3/20/2024	Annual Review: Updated dosing limits, updated examples of toxicity, no criteria changes
EmblemHealth & ConnectiCare	07/13/2023	Annual Review: No criteria changes
EmblemHealth & ConnectiCare	04/20/2022	Transferred policy to new template

EmblemHealth & ConnectiCare	08/23/2021	Added new J Code – J9348
EmblemHealth & ConnectiCare	02/02/2021	New Medical Policy

References

1. Danyelza injection for intravenous use [prescribing information]. New York, NY: Y-mAbs Therapeutics; November 2020.
2. Pastor ER, Mousa SA. Current management of neuroblastoma and future direction. *Crit Rev Oncol Hematol*. 2019;138:38-43.
3. Whittle SB, Smith V, Doherty E, et al. Overview and recent advances in the treatment of neuroblastoma. *Expert Rev Anticancer Ther*. 2017;17:369-386.
4. Newman EA, Abdessalam S, Aldrink JH, et al. Update on neuroblastoma. *J Pediatr Surg*. 2019;54:383-389.
5. PDQ® Pediatric Treatment Editoral Board. PDQ Neuroblastoma Treatment. Bethesda, MD: National Cancer Institute. Updated: June 8, 2020. Available at https://www.cancer.gov/types/neuroblastoma/hp/neuroblastoma-treatment-pdq. Accessed on December 3, 2020.