

Medical Policy:

Danyelza® (naxitabmab-gqgk) injection

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

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The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as “EmblemHealth”), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

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. Neuroblastoma

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 Editorial 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.