

Danyelza® (naxitamab-gqgk) (Intravenous)

Document Number: IC-0581

Last Review Date: 01/06/2025

Date of Origin: 01/05/2021

Dates Reviewed: 01/2021, 07/2021, 01/2022, 01/2023, 1/2024, 01/2025

I. Length of Authorization

Coverage is provided for 6 months and may be renewed.

II. Dosing Limits

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

- 480 billable units every 28 days

III. Initial Approval Criteria ^{1,2}

Coverage is provided in the following conditions:

- Patient is at least 1 year of age; **AND**

Universal Criteria ¹

- Will not be used in combination with other GD2-binding monoclonal antibodies (i.e., dinutuximab, etc.); **AND**
- Patient does not have uncontrolled hypertension; **AND**

High-Risk Neuroblastoma † Φ ^{1,2}

- Used in combination with granulocyte-macrophage colony-stimulating factor [GM-CSF] (e.g., sargramostim); **AND**
- Patient has relapsed or refractory disease in the bone or bone marrow; **AND**
- Patient had at least a partial or minor response or stable disease to at least one prior systemic therapy

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Φ Orphan Drug

IV. Renewal Criteria ¹

Coverage can be renewed based upon the following criteria:

- Patient continues to meet the universal and other indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section III; **AND**
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: 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, orthostatic hypotension, myocarditis, etc.

V. Dosage/Administration ¹

Indication	Dose
High-Risk Neuroblastoma	Administer 3mg/kg/day (up to 150 mg/day) intravenously on Days 1, 3, and 5 of each 28-day treatment cycle until disease progression or unacceptable toxicity. <ul style="list-style-type: none"> – Treatment cycles are repeated every 4 weeks until complete response or partial response, followed by 5 additional cycles every 4 weeks with subsequent cycles being repeated every 8 weeks.

VI. Billing Code/Availability Information

HCPCS Code:

- J9348 – Injection, naxitamab-gqgk, 1 mg; 1 billable unit = 1 mg

NDC:

- Danyelza 40 mg/10 mL single-dose vial: 73042-0201-xx

VII. References

1. Danyelza [package insert]. New York, NY; Y-mAbs Therapeutics, Inc.; March 2024. Accessed November 2024.
2. Mora J, Chan GCF, Morgenstern DA, et al. Naxitamab, a new generation anti-GD2 monoclonal antibody (mAb) for treatment of relapsed/refractory high-risk neuroblastoma (HR-NB). *Journal of Clinical Oncology* 2020 38:15_suppl, 10543-10543.
3. Kushner BH, Modak S, Ellen M, Basu EM, et al. High-dose naxitamab plus stepped-up dosing of GM-CSF for high-risk neuroblastoma (HR-NB): Efficacy against histologically-evident primary refractory metastases in bone marrow (BM). *Journal of Clinical Oncology* 2019 37:15_suppl, 10024-10024.

Appendix 1 – Covered Diagnosis Codes

ICD-10 Codes	Description
C74.90	Malignant neoplasm of unspecified part of unspecified adrenal gland

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: <https://www.cms.gov/medicare-coverage-database/search.aspx>. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCA/LCD): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC