Coverage of any drug intervention discussed in the plans prior authorization guideline is subject to the limitations and exclusions outlined in the member's benefit certificate or policy and to applicable state and/or federal laws.

Danyelza® (naxitamab-gqgk) (Intravenous)

Document Number: IC-0581

Last Review Date: 07/20/2022
Date of Origin: 01/05/2021
Dates Reviewed: 01/2021, 07/2021, 07/2022
Customization Date: 07/20/2022
Effective Date: 01/01/2023

I. Length of Authorization

Coverage is provided for six months and may be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- Danyelza 40 mg/10 mL single-dose vial: 12 vials every 28 days for 6 cycles total followed by 12 vials every 56 days thereafter

B. 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

III. Initial Approval Criteria [1,2]

Coverage is provided in the following conditions:

- Patient is at least 1 year or older; AND

Universal Criteria

- 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

- 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-labeled 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 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 severe neurotoxicity (peripheral neuropathy, transverse myelitis, reversible posterior leukoencephalopathy syndrome, neurological disorders of the eye, and severe urinary retention), severe hypertension, etc.

V. Dosage/Administration

Indication	Dose
High-risk neuroblastoma	Administer, intravenously, 3mg/kg/day (up to 150 mg/day) on days 1, 3, and 5 of each 28-day treatment cycle until disease progression or unacceptable toxicity. – 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:

- J9999 – not otherwise classified, antineoplastic drugs *(Discontinue on 07/01/21)*
- J9348 – Injection, naxitamab-gqgk, 1 mg: 1 billable unit = 1 mg (*Effective 07/01/21*)

NDC:

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

VII. References

1. Danyelza [package insert]. New York, NY; Y-mAbs Therapeutics, Inc. ; November 2020. Accessed December 2020.

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)

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 Determination (NCD), Local Coverage Articles (LCAs) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx. Additional indications may be covered 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, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
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