



Danyelza® (naxitamab-gqgk) (Intravenous)

Document Number: IC-0581

Last Review Date: 01/05/2023

Date of Origin: 01/05/2021

Dates Reviewed: 01/2021, 07/2021, 01/2022, 01/2023

I. Length of Authorization

Coverage is provided for 6 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 on days 1, 3, 5 of each 28-day treatment cycle for 6-cycles total followed by subsequent infusions, 150 billable units, every 8 weeks thereafter

III. Initial Approval Criteria ^{1,2}

Coverage is provided in the following conditions:

- Patient is at least 1 year of age; **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 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, etc.

V. Dosage/Administration ¹

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

HCP 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.; November 2020. Accessed December 2022.
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: <https://www.cms.gov/medicare-coverage-database/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

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PCHP:

Provides free aids and services to people with disabilities to communicate effectively with us, such as:

- Qualified sign language interpreters
- Written information in other formats (large print, audio, accessible electronic formats, other formats)

Provides free language services to people whose primary language is not English, such as:

- Qualified interpreters
- Information written in other languages

If you need these services, contact a Grievance Specialist.

If you believe that PCHP has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with:

Grievance Specialist
PreferredOne Community Health Plan
PO Box 59052
Minneapolis, MN 55459-0052
Phone: 1.800.940.5049 (TTY: 763.847.4013)
Fax: 763.847.4010
customerservice@preferredone.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, a Grievance Specialist is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at:

U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
1-800-368-1019, 800-537-7697 (TDD)

Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>.

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ATTENTION: If you do not speak English, language assistance services, free of charge, are available to you. Call 1.800.940.5049 (TTY: 763.847.4013).

ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al 1.800.940.5049 (TTY: 763.847.4013).

LUS CEEV: Yog tias koj hais lus Hmoob, cov kev pab txog lus, muaj kev pab dawb rau koj. Hu rau 1.800.940.5049 (TTY: 763.847.4013).

XIYYEEFFANNAA: Afaan dubbattu Oroomiffa, taiaajiila qarqaarsa afaanii, kanfaltiidhaan ala, ni argama. Bilbilaa 1.800.940.5049 (TTY: 763.847.4013).

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ማስታወሻ፡ የሚናገሩት ቋንቋ አማርኛ ከሆነ የትርጉም እርዳታ ድርጅቶች፡ በነጻ ሊያግዝዎት ተዘጋጅተዋል፡ ወደ ሚከተለው ቁጥር ይደውሉ 1.800.940.5049 (መስማት ለተሳናቸው፡ 763.847.4013) .

ဟ်သုာ်ဟ်သး- နမာ်ကတိ၊ ကညီ ကိာ်အယံ၊ နမာ် ကိာ်အတၢ်မၤစၢၤလၢ တလၢာ်ဘၣ်လၢာ်စၢၤ နီတမံၤဘၣ်သန့လီၤ. ကိံး 1.800.940.5049 (TTY: 763.847.4013).

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Minneapolis, MN 55459-0212
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U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
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