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Section:	Prescription Drugs	**Effective Date:**	April 1, 2026
Subsection:	Antineoplastic Agents	**Original Policy Date:**	January 8, 2021
Subject:	Danyelza	**Page:**	1 of 5

Last Review Date: March 6, 2026

Danyelza

Description

Danyelza (naxitamab-gqgk)

Background
Danyelza (naxitamab-gqgk) is a monoclonal antibody that binds to the glycolipid GD2. GD2 is a disialoganglioside that is overexpressed on neuroblastoma cells and other cells of neuroectodermal origin, including the central nervous system and peripheral nerves. In vitro, Danyelza was able to bind to cell surface GD2 and induce complement dependent cytotoxicity and antibody dependent cell-mediated cytotoxicity (1).

Regulatory Status
FDA-approved indication: Danyelza is indicated, in combination with granulocyte-macrophage colony-stimulating factor (GM-CSF), for the treatment of pediatric patients 1 year of age and older and adult patients with relapsed or refractory high-risk neuroblastoma in the bone or bone marrow who have demonstrated a partial response, minor response, or stable disease to prior therapy (1).

Danyelza has a boxed warning regarding severe infusion reactions including hypotension, bronchospasm, hypoxia, and stridor. Patients should be premedicated with an antihistamine, acetaminophen, an H2 antagonist, and corticosteroid as recommended. Patients should be monitored closely for signs and symptoms of infusion reactions during and for at least 2 hours following completion of each Danyelza infusion in a setting where cardiopulmonary resuscitation medication and equipment are available (1).

Danyelza also has a boxed warning for neurotoxicity. It can cause severe neurotoxicity, including severe neuropathic pain, transverse myelitis, and reversible posterior leukoencephalopathy syndrome (RPLS). Premedicate to treat neuropathic pain as recommended (1).

Danyelza may also cause hypertension. Danyelza should not be initiated in patients with uncontrolled hypertension. Blood pressure should be monitored during infusion, and at least daily on Days 1 to 8 or each cycle of Danyelza (1).

Danyelza may cause fetal harm when administered to a pregnant woman. Females of reproductive potential, including pregnant women, should be advised of the potential risk to a fetus. Females of reproductive potential should be advised to use effective contraception during treatment with Danyelza and for two months after the final dose (1).

The safety and effectiveness of Danyelza in pediatric patients less than 1 year of age have not been established (1).

Related policies
Iwilfin, Unituxin

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Danyelza may be considered **medically necessary** if the conditions indicated below are met.

Danyelza may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 1 year of age or older

Diagnosis

Patient must have the following:

Relapsed or refractory high-risk neuroblastoma in the bone or bone marrow

AND ALL of the following

1. Patient has demonstrated a partial response, minor response, **OR** stable disease to prior therapy
2. **NO** uncontrolled hypertension
3. Used in combination with a granulocyte-macrophage colony-stimulating factor (GM-CSF)
4. Patient will be monitored for infusion reactions during each infusion and for at least 2 hours following each infusion
5. Prescriber agrees to monitor for neurotoxicity
6. Prescriber agrees to monitor blood pressure during each infusion and daily on Days 1 to 8 of each cycle of Danyelza
7. Females of reproductive potential **only:** patient will be advised to use effective contraception during treatment with Danyelza and for 2 months after the final dose

Prior – Approval *Renewal* Requirements

Age 1 year of age or older

Diagnosis

Patient must have the following:

Neuroblastoma in the bone or bone marrow

AND ALL of the following

1. **NO** disease progression or unacceptable toxicity
2. Used in combination with a granulocyte-macrophage colony-stimulating factor (GM-CSF)
3. Patient will be monitored for infusion reactions during each infusion and for at least 2 hours following each infusion
4. Prescriber agrees to monitor for neurotoxicity
5. Prescriber agrees to monitor blood pressure during each infusion and daily on Days 1 to 8 of each cycle of Danyelza
6. Females of reproductive potential **only:** patient will be advised to use effective contraception during treatment with Danyelza and for 2 months after the final dose

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Danyelza (naxitamab-gqgk) is a monoclonal antibody that binds to the glycolipid GD2. GD2 is a disialoganglioside that is overexpressed on neuroblastoma cells and other cells of neuroectodermal origin, including the central nervous system and peripheral nerves. In vitro, Danyelza was able to bind to cell surface GD2 and induce complement dependent cytotoxicity and antibody dependent cell-mediated cytotoxicity (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Danyelza while maintaining optimal therapeutic outcomes.

References

1. Danyelza [package insert]. New York, NY: Y-mAbs Therapeutics, Inc.; March 2024.
2. NCCN Clinical Practice Guidelines in Oncology® Neuroblastoma (Version 1.2025). National Comprehensive Cancer Network, Inc. April 2025. Accessed on January 22, 2026.

Policy History

Date	Action
January 2021	Addition to PA
March 2021	Annual editorial review
March 2022	Annual review
March 2023	Annual review
June 2023	Annual review
March 2024	Annual review

June 2024	Annual review and reference update
March 2025	Annual review and reference update
June 2025	Annual review and reference update
March 2026	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 6, 2026 and is effective on April 1, 2026.