CARECONTINUUM™

UTILIZATION MANAGEMENT MEDICAL POLICY

POLICY: Oncology (Injectable – Anti-GD2 Antibody) – Danyelza Utilization Management Medical Policy
- Danyelza® (naxitamab-gqgk intravenous infusion – Y-mAbs Therapeutics)

REVIEW DATE: 01/07/2026

OVERVIEW

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.[1] This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

Disease Overview

Neuroblastoma is a rare cancer; however, it is the most common extracranial solid tumor of childhood.[2] Neuroblastoma originates from primordial neural crest cells[3] that develop into sympathetic neural ganglia and adrenal medulla.[2] There are approximately 700 cases diagnosed each year in the US,[4] and around 90% of cases are diagnosed in patients < 5 years of age.[5] Patients most commonly present with an abdominal mass,[4,5] most often arising from the adrenal gland.[2] The mass may be asymptomatic or associated with abdominal pain, hypertension, distension, and constipation. Other tumors may also initiate in the neck, chest, and pelvis.[4] In 10% to 15% of patients, the tumor extends to the epidural or intradural space and may result in spinal cord compression and paraplegia.[2] Patients may also present with proptosis and periorbital ecchymosis, bone pain, pancytopenia, watery diarrhea, presence of Horner syndrome, and subcutaneous skin nodules.[5]

Dosing Information

The recommended dose of Danyelza is 3 mg/kg/day (up to 150 mg/day) on Days 1, 3, and 5 of each treatment cycle, administered as an intravenous infusion in combination with GM-CSF.[1] Treatment cycles are repeated every 4 weeks until complete response or partial response, followed by five additional 4 week cycles. Subsequent cycles may be repeated every 8 weeks until disease progression or unacceptable adverse events.

Guidelines

The National Comprehensive Cancer Network neuroblastoma (version 1.2025 – April 16, 2025) clinical practice guidelines recommend Danyelza for chemoimmunotherapy in combination with temozolomide, irinotecan, and sargramostim following induction or consolidation for high risk disease (category 2A)[6]

POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of Danyelza. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indication. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director

or Pharmacist). All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Danyelza as well as the monitoring required for adverse events and long-term efficacy, approval requires Danyelza to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Danyelza is recommended in those who meet the following criteria:

FDA-Approved Indication

1. **Neuroblastoma.** Approve for 1 year if the patient meets ALL of the following (A, B, and C):
   - **A)** Patient is ≥ 1 year of age; AND
   - **B)** The medication is used as subsequent therapy; AND
   - **C)** The medication is prescribed by or in consultation with an oncologist.

   Dosing. Approve up to 150 mg/day administered by intravenous infusion no more frequently than three times in each treatment cycle.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Danyelza is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Danyelza intravenous infusion [prescribing information]. New York, NY: Y-mAbs Therapeutics; August 2025.
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: November 12, 2024. Available at https://www.cancer.gov/types/neuroblastoma/hp/neuroblastoma-treatment-pdq. Accessed on January 27, 2025.
6. The NCCN Neuroblastoma Clinical Practice Guidelines in Oncology (version 1.2025 – April 16, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on December 22, 2025.
7. The NCCN Drugs and Biologics Compendium. © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on December 22, 2025. Search term: naxitamab-gqgk.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	01/10/2024
Annual Revision	No criteria changes.	01/29/2025
Update	04/08/2025: The policy name was changed from "Oncology (Injectable) – Danyelza UM Medical Policy" to "Oncology (Injectable – Anti-GD2 Antibody) – Danyelza UM Medical Policy".	N/A
Annual Revision	No criteria changes.	01/07/2026