PRIOR AUTHORIZATION POLICY

POLICY: Oncology (Injectable) – Danyelza Prior Authorization Policy
- Danyelza® (naxitamab-gqgk intravenous infusion – Y-mAbs Therapeutics)

REVIEW DATE: 01/10/2024

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]

Guidelines
The National Comprehensive Cancer Network has not addressed Danyelza.

POLICY STATEMENT
Prior Authorization is recommended for prescription benefit coverage of Danyelza. 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) Danyelza is used as subsequent therapy; AND
   C) Danyelza is prescribed by or in consultation with an oncologist.

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; November 2020.
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 Editoral Board. PDQ Neuroblastoma Treatment. Bethesda, MD: National Cancer Institute. Updated: December 22, 2023. Available at https://www.cancer.gov/types/neuroblastoma/hp/neuroblastoma-treatment-pdq. Accessed on January 9, 2024.