Mass General Brigham
Health Plan

Danyelza (naxitamab-gqgk)
Effective 01/01/2023

Plan	☐ MassHealth UPPL ☒Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☐ Pharmacy Benefit ☒ Medical Benefit		
Specialty Limitations	N/A		
Contact Information	**Medical and Specialty Medications** All Plans | Phone: 877-519-1908 | Fax: 855-540-3693		
	Non-Specialty Medications All Plans | Phone: 800-711-4555 | Fax: 844-403-1029		
Exceptions	N/A		

Overview
Neuroblastoma is a cancer in which malignant cells form in the neuroblasts in the adrenal glands, neck, chest, or spinal cord.

Danyelza is a GD2-binding monoclonal antibody 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.

Coverage Guidelines
Authorization may be reviewed for members new to the plan who are currently receiving treatment with Danyelza excluding when the product is obtained as samples or via manufacturer's patient assistance programs
OR
Authorization may be granted for members when ALL the following criteria are met, and documentation is provided:

1. The member has a diagnosis of high risk, relapsed or refractory neuroblastoma in the bone of bone marrow
2. The member is ≥ 1 year of age
3. The member has demonstrated a partial, minor response, or stable disease with prior therapy
4. The requested medication will be used in combination with granulocyte-macrophage colony-stimulating factor (GM-CSF) (Leukine [sagramostim])

**Criteria for GM-CSF are located on a separate document.

Continuation of Therapy
Reauthorization may be granted when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

Limitations
Initial approvals and reauthorizations will be for 12 months.

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

Review History
03/17/2021 – Created and Reviewed at March P&T. Effective 05/01/2021
09/22/2021 – Reviewed at September P&T; removed the GM-CSF medications from appendix (Granix, Neupogen, Nivestym, and Zarxio); Leukine is the only GM-CSF and is now included in the coverage requirements. Effective 01/01/2022
09/21/2022 – Reviewed at Sept P&T; Separated Comm/Exch vs MH policies; no clinical updates. Effective 01/01/2023