

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

Plan	<input type="checkbox"/> MassHealth UPPL <input checked="" type="checkbox"/> Commercial/Exchange	Program Type	<input checked="" type="checkbox"/> Prior Authorization <input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Benefit	<input type="checkbox"/> Pharmacy Benefit <input checked="" type="checkbox"/> Medical Benefit (NLX)		
Specialty Limitations	N/A		
Contact Information	Specialty Medications		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
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 or bone marrow
2. The member is \geq 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

