Danyelza (naxitamab-gqgk)
Effective 05/01/2021

Plan	☒ MassHealth ☒Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☐ Pharmacy Benefit ☒ 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.

Danyzelza 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 AllWays Health Partners 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) (See Appendix)

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.

Appendix
Granulocyte-Macrophage Colony-Stimulating Factor (GM-CSF)

- Granix
- Leukine
- Neupogen
- Nivestym
- Zarxio

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

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

Review History
3/17/2021 – Created and Reviewed at March P&T. Effective 05/01/2021

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