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

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**Specialty Limitations**  
N/A

**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

**Contact Information**

**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 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 or 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**

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

**Disclaimer**
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