

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

<b>Plan</b>	<input checked="" type="checkbox"/> MassHealth UPPL <input type="checkbox"/> Commercial/Exchange	<b>Program Type</b>	<input checked="" type="checkbox"/> Prior Authorization <input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
<b>Benefit</b>	<input type="checkbox"/> Pharmacy Benefit <input checked="" type="checkbox"/> Medical Benefit (NLX)		
<b>Specialty Limitations</b>			
<b>Contact Information</b>	<b>Specialty Medications</b>		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	<b>Non-Specialty Medications</b>		
	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
	<b>Medical Specialty Medications (NLX)</b>		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
<b>Exceptions</b>			

### 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.

No PA	Drugs that require PA
Unituxin <sup>®</sup> (dinutuximab) <sup>H</sup>	Danyelza <sup>®</sup> (naxitamab-gqgk)

<sup>H</sup> This drug is available only in an inpatient hospital setting.

### Coverage Guidelines

Authorization may be reviewed on a case by case basis for members who are new to the plan currently receiving treatment with requested medication 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:

#### Neuroblastoma of Bone or Bone Marrow

1. Appropriate diagnosis
2. Prescriber is an oncologist

3. Appropriate dosing
4. The member is  $\geq 1$  year of age
5. The member's tumor is high risk
6. The member had demonstrated a partial response, minor response, or stable disease to prior treatment (e.g., vincristine, cyclophosphamide, topotecan, doxorubicin, cisplatin, and etoposide)
7. The requested medication will be used in combination with granulocyte-macrophage colony-stimulating factor (GM-CSF) agent

**Continuation of Therapy**

Reauthorization by physician will infer a positive response to therapy.

**Limitations**

Initial approvals and reauthorizations will be for 6 months.

Drug	Dosing
Danyelza <sup>®</sup> (naxitamab-gqgk) <b>Vial:</b> 40 mg/10 mL	2 mg/kg/day (up to 150 mg/day) on Days 1, 3, and 5 of each treatment cycle, administered as an IV infusion after dilution in combination with GM-CSF SC  Treatment cycles are repeated every four weeks until complete response or partial response, followed by five additional cycles every four weeks. Subsequent cycles may be repeated every eight weeks.

GM-CSF=granulocyte-macrophage colony-stimulating factor, IV=intravenous, SC=subcutaneous

**References**

1. Danyelza<sup>®</sup> (naxitamab-gqgk) [prescribing information]. New York (NY): Y-mAbs Therapeutics, Inc.; 2020 Nov.
2. FDA Approves Y-mAbs' DANYELZA<sup>®</sup> (naxitamab-gqgk) for the Treatment of Neuroblastoma [press release on the internet]. Pipeline Review; 2020 Nov 26 [cited 2021 Feb 21]. Available from: <https://pipelinereview.com/index.php/2020112676664/Antibodies/FDA-Approves-Y-mAbs-DANYELZA-naxitamab-gqgk-for-the-Treatment-of-Neuroblastoma.html>.
3. Key Statistics About Neuroblastoma [webpage on the internet]. American Cancer Society; 2020 Jan 8 [cited 2021 Feb 21]. Available from: <https://www.cancer.org/cancer/neuroblastoma/about/key-statistics.html>.
4. Unituxin<sup>®</sup> (dinutixumab) [prescribing information]. Research Triangle Park (NC): United Therapeutics Corp; 2020 Sept.
5. Shohet JM, Lowas SR, Nuchtern JG. Treatment and prognosis of neuroblastoma. In: Basow DS (Ed). UpToDate [database on the internet]. Waltham (MA): UpToDate; 2021 Nov [cited 2021 Dec 20]. Available from: <https://www.uptodate.com/contents/treatment-and-prognosis-of-neuroblastoma>.

**Review History**

09/21/2022 – Reviewed and Created for Sept P&T; matched MH UPPL.

