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.

No PA	Drugs that require PA
Unituxin® (dinutuximab)[H]	Danyelza® (naxitamab-gqgk)

[H] 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 ≥ 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® (naxitamab-gqgk) **Vial:** 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® (naxitamab-gqgk) [prescribing information]. New York (NY): Y-mAbs Therapeutics, Inc.; 2020 Nov.
2. FDA Approves Y-mAbs' DANYELZA® (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® (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.