Clinical Policy Title:	naxitamab-gqgk
Policy Number:	RxA.666
Drug(s) Applied:	Danyelza®
Original Policy Date:	03/09/2021
Last Review Date:	10/19/2023
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Relapsed or refractory high-risk neuroblastoma (must meet all):

1. Diagnosis of relapsed or refractory high-risk neuroblastoma in the bone or bone marrow;
2. Documented partial to complete response to prior therapy;
3. Prescribed by or in consultation with an oncologist;
4. Prescribed in combination with (all below):
   a. A granulocyte-macrophage colony-stimulating factor GM-CSF;
   b. A prophylactic medication for neuropathic pain (e.g. gabapentin);
   c. An antihistamine, an H2 antagonist, acetaminophen, an antiemetic, with or without intravenous corticosteroid;
5. Age ≥ 1 year;
6. Dose does not exceed 150 mg per day.

Approval Duration
Commercial: 6 months
Medicaid: 6 months

II. Continued Therapy Approval

A. Relapsed or refractory high-risk neuroblastoma (must meet all):

1. Member is currently receiving medication that has been authorized by RxAdvance or documentation supports that member is currently receiving Danyelza® for neuroblastoma and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. Dose does not exceed 150 mg per day;

Approval Duration
Commercial: 6 months
Medicaid: 6 months

References

1. PDQ Pediatric Treatment Editorial Board. Neuroblastoma Treatment (PDQ®): Health Professional Version. In: PDQ Cancer Information Summaries [Internet]. Bethesda (MD): National Cancer Institute (US); 2002–. PMID: 26389190. Published June 9, 2022. Available at: https://pubmed.ncbi.nlm.nih.gov/26389190/. Accessed October 20, 2022.
2. Y-mAbs Therapeutics. A Pivotal Phase 2 Trial of Antibody Naxitamab (hu3F8) and Granulocyte-Macrophage Colony Stimulating Factor (GM-CSF) in High-Risk Neuroblastoma Patients with Primary Refractory Disease or Incomplete

Response to Salvage Treatment in Bone and/or Bone Marrow. Available at: https://clinicaltrials.gov/ct2/show/NCT03363373. NLM Identifier: NCT03363373. Accessed October 20, 2022.
3. Memorial Sloan Kettering Cancer Center. Phase I/II Study of Combination Therapy of Antibody Hu3F8 with Granulocyte- Macrophage Colony Stimulating Factor (GM-CSF) in Patients with Relapsed/Refractory High-Risk Neuroblastoma. Available at: https://clinicaltrials.gov/ct2/show/NCT01757626. NLM Identifier: NCT01757626. Accessed October 20, 2022.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	03/09/2021	03/09/2021
Policy was reviewed. 1. Continued Therapy Approval Criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...". 2. References were reviewed and updated.	12/07/2021	01/17/2022
Policy was reviewed: 1. References were reviewed and updated.	10/20/2022	01/17/2023
Policy was reviewed.	10/19/2023	10/19/2023