SmartHealth

Ascension

Naxitamab-gqgk

(Danyelza®) J9348 (1mg)

Covered with prior authorization

Naxitamab-gqgk (Danyzela®) may be authorized when the following criteria are met:

- Individual has a diagnosis of high-risk neuroblastoma; **AND**
- Individual is 1 years or older; **AND**
- Individual has disease in the bone or bone marrow; **AND**
- Medication will be used in combination with granulocyte-macrophage colony-stimulating factor; **AND**
- Medication is prescribed by a provider specialized in oncology; **AND**
- Individual has demonstrated a partial or minor response; **OR**
- Individual has a refractory disease with prior therapy.

Exclusion criteria:

Requests may not be approved for the following:

- Product use for non-FDA approved indications or indications not supported by industry-accepted guidelines.
- Doses, durations, or dosing intervals that exceed FDA maximum limits for any FDA-approved indication or are not supported by industry-accepted practice guidelines or peer-reviewed literature for the relevant off-label use.
- Individuals with significant known risk factors unless the record provides an assessment of clinical benefit that outweighs the risk.

Initial authorization is up to 12 months.

Annual reauthorizations will require medical chart documentation that the patient has been seen within the past 12 months and that markers of disease are improved by therapy.

Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

U.S. Food and Drug Administration:

This section is to be used for informational purposes. FDA approval alone is not a basis for coverage.

Danyelza® is a GD2-binding monoclonal antibody indicated:

- in combination with granulocyte-macrophage colony-stimulating factor (GMCSF)
- for the treatment of pediatric patients 1 year of age and older and adult patients
- for relapsed or refractory high-risk neuroblastoma in the bone or bone marrow

- for patients who have demonstrated a partial response, minor response, or stable disease to prior therapy

References:

1. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2023; Updated periodically.
2. *DANYELZA® (Naxitamab-gqgk)*. (2020, February). Y-mAbs Therapeutics, Inc. Retrieved January 24, 2023, from https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/761171lbl.pdf

Date	Summary of Changes
September 2021	Criteria for use summary developed by the Ascension Ambulatory Care Expert Review Panel.
January 2023	Criteria for use summary revised by the Ascension Medical Specialty Prior Authorization Team.
February 2023	Criteria for use summary approved by the Ascension Hematology/Oncology Expert Review Panel.
March 2023	Criteria for use summary approved by the Ascension Therapeutic Affinity Group.

If you have questions, call 833-980-2352 to speak to a member of the Ascension Rx prior authorization team or email your questions to smarthealthspecialty@ascension.org.