Naxitamab-gqgk (Danyelza®)	Place of Service Office Administration Outpatient Facility Infusion Administration Infusion Center Administration HCPCS: **J9348** per 1 mg

Condition(s) listed in policy *(see criteria for details)*

- Neuroblastoma, high-risk

AHFS therapeutic class: Antineoplastic agent
Mechanism of action: GD2-binding monoclonal antibody

(1) Special Instructions and Pertinent Information

Covered under the Medical Benefit, please submit clinical information for prior authorization review via fax.

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for naxitamab-gqgk (Danyelza®) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Neuroblastoma, high-risk

1. Patient has received prior first-line therapy, **AND**
2. Used in combination with granulocyte-macrophage colony stimulating factor (GM-CSF)

Covered Dose
3 mg/kg/day (up to 150 mg/day) IV on Days 1, 3, and 5 of each treatment cycle.

Treatment cycles are repeated every 4 weeks until complete response or partial response, followed by 5 additional cycles every 4 weeks. Subsequent cycles may be repeated every 8 weeks.

Coverage period
Indefinite

ICD-10:
C74.90

(3) The following condition(s) DO NOT require Prior Authorization/Preservice

All requests for naxitamab-gqgk (Danyelza®) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

(4) This Medication is NOT medically necessary for the following condition(s):

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information

How supplied:
40 mg/10 mL (single-dose vial)

(6) References

- AHFS®. Available by subscription at http://www.lexi.com
- Danyelza® (naxitamab-gqgk) [Prescribing Information]. New York, NY: Y-mAbs Therapeutics, Inc.; 11/2020.
- DrugDex®. Available by subscription at http://www.micromedexsolutions.com/home/dispatch

(7) Policy Update

Date of last review: 1Q2023
Date of next review: 1Q2024
Changes from previous policy version:

- No clinical change to policy following routine annual review.

BSC Drug Coverage Criteria to Determine Medical Necessity
Reviewed by P&T Committee