Part B Prior Authorization Guidelines

Neuroblastoma

Danyelza (naxitamab-gqgk) J9348

Prior Authorization Request
Medicare Part B Form

*Instructions: * Indicates required information – Form may be returned if required information is not provided. Please fax this request to the appropriate fax number listed at the bottom of the page.*

☐	**Standard Request– (72 Hours)**	☐	**Urgent Request** (standard time frame could place the member's life, health or ability in serious jeopardy)
	Date Requested _____		
	Requestor _____ Clinic name: _____ Phone / Fax		

MEMBER INFORMATION

*Name:_____ *ID#:_____ *DOB:_____

PRESCRIBER INFORMATION

*Name:_____ ☐MD ☐FNP ☐DO ☐NP ☐PA *Phone:_____

*Address:_____ *Fax:_____

DISPENSING PROVIDER / ADMINISTRATION INFORMATION

*Name:_____ Phone:_____

*Address:_____ Fax:_____

PROCEDURE / PRODUCT INFORMATION

HCPC Code	Name of Drug	Dose (Wt: _____ kg Ht:_____)	Frequency	End Date if known

☐ **Self-administered** ☐ **Provider-administered** ☐ **Home Infusion**

☐Chart notes attached. **Other important information:**_____

Diagnosis: ICD10: _____ **Description**: _____

☐ Provider attests the diagnosis provided is an FDA-Approved indication for this drug

CLINICAL INFORMATION

☐ **New Start or Initial Request: (Clinical documentation required for all requests)**

- ☐ Patient has a diagnosis of relapsed or refractory high-risk neuroblastoma; AND
- ☐ Patient has disease in the bone or bone marrow; AND
- ☐ Patient has demonstrated a partial response, minor response, or stable disease to prior therapy; AND
- ☐ Patient is using in combination with GM-CSF (sargramostim).

☐ **Continuation Requests: (Clinical documentation required for all requests)**

- ☐ Patient had an adequate response or significant improvement while on this medication.

If not, please provide clinical rationale for continuing this medication: _____

_____

ACKNOWLEDGEMENT

Request By (Signature Required): _____ **Date:**_____ /____ /____

Any person who knowingly files a request for authorization of coverage of a medical procedure or service with the intent to injure, defraud or deceive any insurance company by providing materially false information or conceals material information for the purpose of misleading, commits a fraudulent insurance act, which is a crime and subjects such person to criminal and civil penalties. **THIS AUTHORIZATION IS NOT A GUARANTEE OF PAYMENT.** PAYMENT IS BASED ON BENEFITS IN EFFECT AT THE TIME OF SERVICE, MEMBER ELIGIBILITY AND MEDICAL NECESSITY.

Prior Authorization Group – Neuroblastoma Drug PA

Drug Name(s):
DANYELZA **NAXITAMAB-GQGK**

Criteria for approval of Prior Authorization Drug:

1. Prescribed for an approved FDA diagnosis (as listed below):
2. Member does not have any clinically relevant contraindications, or CMS/Plan exclusions, to the requested drug.

- If the member meets all these criteria, they may be approved by the Plan for the requested drug.
- Quantity limits and Tiering will be determined by the Plan.

Exclusion Criteria:
N/A

Prescriber Restrictions:
Pediatric Oncologist or related specialist

Coverage Duration:
Initial approval for 6 months
Continuation will be approved for 12 months.

FDA Indications:
Danyelza

- Neuroblastoma, Relapsed or refractory high-risk disease in bone or bone marrow, in combination with granulocyte-macrophage colony-stimulating factor, in patients with a partial response, minor response, or stable disease to prior therapy

Off-Label Uses:
N/A

Age Restrictions:

- 1 year or older

Other Clinical Considerations:
Black Box Warning:

- Warning: Serious Infusion-related Reactions and Neurotoxicity
- Serious Infusion-related Reactions: Naxitamab-gqgk can cause serious infusion reactions, including cardiac arrest, anaphylaxis, hypotension, bronchospasm, and stridor. Premedicate prior to each naxitamab-gqgk infusion as recommended. Reduce the rate, interrupt infusion, or permanently discontinue naxitamab-gqgk based on severity.
- Neurotoxicity: Naxitamab-gqgk can cause severe neurotoxicity, including severe neuropathic pain, transverse myelitis, and reversible posterior leukoencephalopathy syndrome (RPLS). Premedicate to treat neuropathic pain as recommended. Permanently discontinue naxitamab-gqgk based on the adverse reaction and severity

Resources:
https://www.micromedexsolutions.com/micromedex2/librarian/CS/FE8FA1/ND_PR/evidencexpert/ND_P/evidencexpert/DUPLICATIONSHIELDSYNC/CAFD38/ND_PG/evidencexpert/ND_B/evidencexpert/ND_AppProduct/evidencexpert/ND_T/evidencexpert/PFActionId/evidencexpert.GoToDashboard?docId=933111&contentSetId=100&title=Naxitamab-gqgk&servicesTitle=Naxitamab-gqgk&brandName=Danyelza&UserMdxSearchTerm=Danyelza&=null#