Medical Drug Clinical Criteria

Subject:	Danyelza (naxitamab-gqgk)		
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Overview

This document addresses the use of Danyelza (naxitamab-gqgk). Danyelza is a glycolipid disialoganglioside (GD2)-binding recombinant humanized IgG1 antibody that induces cytotoxicity in GD2-overexpressing neuroblastoma cells.

Danyelza is FDA approved in combination with granulocyte-macrophage colony-stimulating factor (CM-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. This indication is approved under accelerated approval; continued approval may be contingent upon verification and description of clinical benefit in a confirmatory trial. Neuroblastomas are a clinically heterogeneous group of tumors that arise from primitive sympathetic ganglion cells. The pathology varies according to the degree of differentiation reached by cancerous cells as they develop. Prognosis largely depends on the extent of metastatic spread and age at diagnosis. Neuroblastoma can be classified into risk categories (low, intermediate, and high) based on various characteristics. High-risk individuals may include those with *MYCN*- amplified disease stage 2 or greater, or *MYCN*-nonamplified stage 4 in patients over the age of 18 months. Treatment for high-risk individuals is multimodal including chemotherapy, surgical resection, stem cell transplant, and radiation therapy.

Danyelza has a black box warning for serious infusion-related reactions and neurotoxicity. Serious infusion reactions including cardiac arrest, anaphylaxis, hypotension, bronchospasm, and stridor can occur. Premedicate as recommended and, based on severity, reduce rate, interrupt, or discontinue infusion. Danyelza can also cause severe neurotoxicity including neuropathic pain, transverse myelitis, and reversible posterior leukoencephalopathy syndrome (RPLS). Premedicate as recommended and permanently discontinue Danyelza based on adverse reaction and severity.

Definitions and Measures

Autologous hematopoietic stem cell transplantation: Infusion of previously harvested hematopoietic stem cells to the same individual from whom they were harvested.

Complete Response (CR): The disappearance of all signs of cancer as a result of treatment; also called complete remission; does not indicate the cancer has been cured.

Partial response (PR): A decrease in the size of a tumor, or in the amount of cancer in the body, resulting from treatment; also called partial remission.

Primary refractory disease: Cancer that does not respond at the beginning of treatment; may also be called resistant disease.

Primary treatment: The first treatment given for a disease. It is often part of a standard set of treatments, such as surgery followed by chemotherapy and radiation. Also called first-line therapy, induction therapy, and primary therapy.

Progressive Disease (PD): Cancer that is growing, spreading, or getting worse.

Refractory Disease: Illness or disease that does not respond to treatment.

Relapse or recurrence: After a period of improvement, during which time a disease (for example, cancer) could not be detected, the return of signs and symptoms of illness or disease. For cancer, it may come back to the same place as the original (primary) tumor or to another place in the body.

Stable disease: Cancer that is not decreasing or increasing in extent or severity.

Clinical Criteria

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Danyelza (naxitamab-gqgk)

Requests for Danyelza (naxitamab-gqgk) may be approved if the following criteria are met:

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

Requests for Danyelza (naxitamab-gqgk) may not be approved if the above criteria are not met and for all other indications.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

HCPCS

J9348	Injection, naxitamab-gqgk, 1 mg [Danyelza]

ICD-10 Diagnosis

C74.00-C74.92	Malignant neoplasm of adrenal gland

Document History

Reviewed: 08/16/2024
Document History:

- 08/16/2024 – Annual Review: No changes. Coding Reviewed: No changes.
- 11/17/2023 – Annual Review: No changes. Coding Reviewed: No changes.
- 11/18/2022 – Annual Review: No changes. Coding Reviewed: No changes.
- 11/19/2021 – Annual Review: No changes. Coding reviewed: No changes.
- 12/14/2020 – Annual Review: Add new clinical criteria document for Danyelza. Coding Reviewed: Added HCPCS J3490, J3590, J9999. Added ICD-10-CM C74.0-C74.92. Effective 7/1/21 Added HCPCS J9348. Removed J3490, J3590, J9999.

References

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: July 5, 2024.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2024; Updated periodically.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.