BlueCross BlueShield of North Carolina

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Corporate Medical Policy

Naxitamab-gqgk (Danyelza®)

File Name:	naxitamab_danyelza
Origination:	1/2021
Last CAP Review:	n/a
Next CAP Review:	8/2021
Last Review:	1/2021

Description of Procedure or Service

Naxitamab-gqgk (Danyelza) is a GD2-binding monoclonal antibody that is indicated, in combination with granulocyte-macrophage colony-stimulating factor (GM-CSF), for the treatment of pediatric patients 1 year of age and older and adults with relapsed or refractory high-risk neuroblastoma in the bone or bone marrow who have demonstrated a partial response, minor response, or stable disease with prior therapy.

Related Medical Policies:
White Blood Cell Growth Factors

******Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.***

Policy

BCBSNC will provide coverage for naxitamab-gqgk (Danyelza) when it is determined to be medically necessary because the medical criteria and guidelines noted below are met.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Naxitamab-gqgk (Danyelza) is covered

Initial Therapy

Naxitamab-gqgk (Danyelza) is considered medically necessary for the treatment of adult and pediatric patients (≥ 1 year of age) with neuroblastoma when the following criteria are met:

1. The patient has a diagnosis of relapsed or refractory high-risk neuroblastoma; **and**
2. The patient has disease in the bone or bone marrow; **and**
3. The patient has demonstrated a partial response, minor response, or stable disease with prior therapy; **and**
4. Naxitamab is administered in combination with a granulocyte-macrophage colony-stimulating factor (GM-CSF) (e.g., sargramostim).

Initial authorization: 12 months

Continuation Therapy

Continuation of treatment with naxitamab-gqgk (Danyelza) beyond 12 months after initiation of therapy, and every 12 months thereafter, is considered medically necessary for the treatment of relapsed or refractory high-risk neuroblastoma when the following criteria are met:

1. The patient is currently receiving naxitamab-gqgk, and continues to meet or would have met initial criteria at the time of therapy initiation; **and**
2. The patient has continued clinical benefit on naxitamab-gqgk therapy as demonstrated by tumor response or lack of disease progression, and an acceptable toxicity profile.

Use of naxitamab-gqgk (Danyelza) may be considered medically necessary for clinical indications not listed above when the drug is prescribed for the treatment of cancer either:

- In accordance with FDA label (when clinical benefit has been established, (see Policy Guidelines); **OR**

- In accordance with specific strong endorsement or support by nationally recognized compendia, when such recommendation is based on strong/high levels of evidence, and/or uniform consensus of clinical appropriateness has been reached.

When Naxitamab-gqgk (Danyelza) is not covered

Naxitamab-gqgk (Danyelza) is considered **investigational** and therefore not covered when the above criteria are not met.

Naxitamab-gqgk (Danyelza) is considered investigational when used for:

1. Non-cancer indications; **OR**

2. When criteria are not met regarding FDA labeling **OR** strong endorsement/support by nationally recognized compendia, as stated under "When Naxitamab-gqgk (Danyelza) is covered."

Policy Guidelines

The recommended dose of Danyelza is 3 mg/kg/day (up to 150 mg/day), administered as an intravenous infusion 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.

Granulocyte-macrophage colony-stimulating factor (GM-CSF) should be administered subcutaneously prior to and during each treatment cycle. Danyelza (and GM-CSF) should be discontinued if disease progression or unacceptable toxicity occurs.

Drugs prescribed for treatment of cancer in accordance with FDA label may be considered medically

necessary when clinical benefit has been established, and should not be determined to be investigational as defined in Corporate Medical Policy (CMP), "Investigational (Experimental) Services."

Please refer to CMP "Investigational (Experimental) Services" for a summary of evidence standards from nationally recognized compendia.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable codes: *C9999, J3490, J3590, J9999, S0353, S0354*

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

U.S. Food and Drug Administration. FDA grants accelerated approval to naxitimab for high-risk neuroblastoma in bone or bone marrow. November 25, 2020. Available at: https://www.bluecrossnc.com/sites/default/files/document/attachment/services/public/pdfs/medicalpolicy/fam_trastuzumab_deruxtecan_enhertu.pdf#search=. Last accessed January 2021.

Y-mAbs Therapeutics, Inc. Danyelza (naxitamab-gqgk) for injection, for intravenous use. Highlights of prescribing information. November 2020. Available at: https://labeling.ymabs.com/danyelza. Last accessed January 2021.

Medical Director review 1/2021

Policy Implementation/Update Information

1/26/21 New policy developed. Danyelza is considered medically necessary for the treatment of adult and pediatric patients (≥ 1 year of age) with neuroblastoma when specific medical criteria and guidelines are met. Added HCPCS codes C9399, J3490, J3590, J9999, S0353, S0354 to Billing/Coding section. References added. Medical Director review 1/2021. (krc)