Reference number(s)
4375-A

STANDARD MEDICARE PART B MANAGEMENT

DANYELZA (naxitamab-gqgk)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications
DANYELZA is a GD2-binding monoclonal antibody indicated, in combination with granulocyte-macrophage colony-stimulating factor (GM-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.

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

II. CRITERIA FOR INITIAL APPROVAL

High-risk neuroblastoma
Authorization of 12 months may be granted for treatment of high-risk neuroblastoma when all of the following criteria are met:
1. The member is 1 year of age or older with relapsed or refractory disease in the bone or bone marrow
2. The member has demonstrated any of the following with prior therapy:
   i. Partial response
   ii. Minor response
   iii. Stable disease
3. The requested medication will be used in combination with granulocyte-macrophage colony-stimulating factor (GM-CSF)

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization for 12 months may be granted when all of the following criteria are met:
1. The member is currently receiving therapy with the requested medication
2. The requested medication is being used to treat an indication enumerated in Section II

3. The member is receiving benefit from therapy. Benefit is defined as no evidence of unacceptable toxicity or disease progression while on the current regimen

IV. SUMMARY OF EVIDENCE

The contents of this policy were created after examining the following resources:

1. The prescribing information for Danyelza.
2. The available compendium
    a. National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
    b. Micromedex DrugDex
    c. American Hospital Formulary Service- Drug Information (AHFS-DI)
    d. Lexi-Drugs
    e. Clinical Pharmacology

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Danyelza are covered.

V. EXPLANATION OF RATIONALE

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

VI. REFERENCES

1. Danyelza [package insert]. New York, NY: Y-mAbs Therapeutics, Inc.; November 2020.