Reference number(s)
4372-A

SPECIALTY GUIDELINE 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 are considered experimental/investigational and not medically necessary.

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 a partial or minor response or stable disease with prior therapy
3. The requested medication will be used in combination with granulocyte-macrophage colony-stimulating factor (GM-CSF)

III. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section II when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

IV. REFERENCES

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