DANYELZA® (naxitamab-gqgk) injection

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**Definition**

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

**Length of Authorization**

Coverage will be provided for 6 months and may be renewed

**Dosing**

The recommended dosage is 3 mg/kg/day (maximum 150mg/day) as an intravenous infusion on days 1, 3, and 5 of each 4-week treatment cycle

**Guideline**

I. INITIAL APPROVAL CRITERIA
Neuroblastoma

Coverage is provided when the following criteria is met:

- Patient is ≥ 1 year of age; **AND**
- Danyelza is prescribed by or in consultation with an oncologist; **AND**
- Danyelza will be used in combination with granulocyte-macrophage colony-stimulating factor [GM-CSF] (e.g., sargramostim); **AND**
- Patient has relapsed or refractory disease in the bone or bone marrow; **AND**
- Patient had at least a partial or minor response or stable disease to at least one prior systemic therapy.

II. RENEWAL CRITERIA

Coverage can be renewed based on the following conditions:

- Stabilization of disease or absence of disease progression; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: infusion-related and hypersensitivity reactions, myelosuppression, infections, etc.

Limitations/Exclusions

n/a

Applicable Procedure Codes

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<th>Code</th>
<th>Description</th>
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<tr>
<td>J9999</td>
<td>Not otherwise classified, antineoplastic drugs</td>
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<tr>
<td>C9399</td>
<td>Unclassified drugs and biologicals</td>
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Applicable NDCs

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<td>73042-0201-01</td>
<td>Danyelza 40mg/10ml solution single-dose vial</td>
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Applicable Diagnosis Codes

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<th>ICD-10</th>
<th>ICD-10 Description</th>
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<tr>
<td>C74.90</td>
<td>Malignant neoplasm of unspecified part of unspecified adrenal gland</td>
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Revision History

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<th>Date</th>
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<tbody>
<tr>
<td>2/2/2021</td>
<td>New Medical Policy</td>
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References