Danyelza (naxitamab-gqgk)

Override(s)	Approval Duration
Prior Authorization	1 year

Medications
Danyelza (naxitamab-gqgk) Intravenous Injection

APPROVAL CRITERIA

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.

Note: 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.

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2020. URL: http://www.clinicalpharmacology.com. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: December 8, 2020.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2020; 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.