



Access and Reimbursement Guide

A guide for helping your patients access DANYELZA[®]

INDICATION

DANYELZA 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 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.

This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

IMPORTANT SAFETY INFORMATION

WARNING: SERIOUS INFUSION-RELATED REACTIONS and NEUROTOXICITY

Serious Infusion-Related Reactions

- DANYELZA can cause serious infusion reactions, including cardiac arrest, anaphylaxis, hypotension, bronchospasm, and stridor. Infusion reactions of any Grade occurred in 94-100% of patients. Severe infusion reactions occurred in 32-68% and serious infusion reactions occurred in 4 - 18% of patients in DANYELZA clinical studies.
- Premedicate prior to each DANYELZA infusion as recommended and monitor patients for at least 2 hours following completion of each infusion. Reduce the rate, interrupt infusion, or permanently discontinue DANYELZA based on severity.

Neurotoxicity

- DANYELZA can cause severe neurotoxicity, including severe neuropathic pain, transverse myelitis and reversible posterior leukoencephalopathy syndrome (RPLS). Pain of any Grade occurred in 94-100% of patients in DANYELZA clinical studies.
- Premedicate to treat neuropathic pain as recommended. Permanently discontinue DANYELZA based on the adverse reaction and severity.

CONTRAINDICATION

DANYELZA is contraindicated in patients with a history of severe hypersensitivity reaction to naxitamab-gqgk. Reactions have included anaphylaxis.

Please see additional Important Safety Information for DANYELZA on the following page, and the accompanying full Prescribing Information and Patient Information for DANYELZA including Boxed Warning on serious infusion-related reactions and neurotoxicity. The Prescribing Information is also available at labeling.ymabs.com/danyelza

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PRODUCT INFORMATION

Dose and schedule of DANYELZA® (naxitamab-gqgk) in combination with GM-CSF for each cycle¹

PRESTART						START				
DAY	-4	-3	-2	-1	0	1	2	3	4	5
Subcutaneous GM-CSF	250 µg/m ² /day					500 µg/m ² /day				
Intravenous DANYELZA						3 mg/kg /day 		3 mg/kg /day 		3 mg/kg /day 

- ▶ GM-CSF must be **administered ≥1 hour** before the DANYELZA infusion on Days 1, 3, and 5; refer to the GM-CSF Prescribing Information for additional recommended dosing information¹
- ▶ DANYELZA is 3 mg/kg/day (up to 150 mg/day) on Days 1, 3, and 5 of each treatment cycle (9 mg/kg/cycle), **administered as an intravenous (IV) infusion** after dilution in combination with GM-CSF subcutaneously. Do not administer DANYELZA as an IV push or bolus¹
 - 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. Discontinue DANYELZA and GM-CSF for disease progression or unacceptable toxicity
- ▶ If a DANYELZA **dose is missed**, administer the missed dose the following week by Day 10. Administer GM-CSF 500 µg/m²/day on the first day of the DANYELZA infusion and on the day before and on the days of the second and third infusions, respectively (ie, a total of 5 days with 500 µg/m²/day)¹

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS

Serious Infusion-Related Reactions

DANYELZA can cause serious infusion reactions requiring urgent intervention including fluid resuscitation, administration of bronchodilators and corticosteroids, intensive care unit admission, infusion rate reduction or interruption of DANYELZA infusion. Infusion-related reactions included hypotension, bronchospasm, hypoxia, and stridor.

Serious infusion-related reactions occurred in 4% of patients in Study 201 and in 18% of patients in Study 12-230. Infusion-related reactions of any Grade occurred in 100% of patients in Study 201 and 94% of patients in Study 12-230. Hypotension of any grade occurred in 100% of patients in Study 201 and 89% of patients in Study 12-230.

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PRODUCT INFORMATION (continued)

Infusion reaction premedication¹

- ▶ In clinical studies, DANYELZA[®] (naxitamab-ggqk) has been shown to cause serious infusion-related reactions, including cardiac arrest, anaphylaxis, hypotension, bronchospasm, and stridor

Corticosteroids

Administer IV corticosteroids (eg, methylprednisolone 2 mg/kg with maximum dose of 80 mg or equivalent corticosteroid dose) 30-120 minutes prior to first DANYELZA infusion. Administer for subsequent infusions if a severe reaction occurred with previous infusion or cycle

Antihistamine, H2 antagonist, acetaminophen, and antiemetic

Administer each 30 minutes prior to every DANYELZA infusion

Pain management before and during infusion¹

- ▶ In clinical studies, DANYELZA has been shown to cause pain, including severe neuropathic pain. In Study 201, pain typically began during the infusion and lasted for a median of less than 1 day (range less than 1 day and up to 62 days)

Prophylactic medication for neuropathic pain (eg, gabapentin)

Five days prior to first DANYELZA infusion in each cycle, administer a 12-day course (Day -4 through Day 7) of prophylactic medication for neuropathic pain

Opioids

Administer oral opioids 45-60 minutes prior to each DANYELZA infusion, and additional IV opioids as needed for breakthrough pain during infusion

Ketamine

Consider use of ketamine for pain not adequately controlled by opioids

IMPORTANT SAFETY INFORMATION (continued)

In Study 201, 68% of patients experienced Grade 3 or 4 infusion reactions; and in Study 12-230, 32% of patients experienced Grade 3 or 4 infusion reactions. Anaphylaxis occurred in 12% of patients and two patients (8%) permanently discontinued DANYELZA due to anaphylaxis in Study 201. One patient in Study 12-230 (1.4%) experienced a Grade 4 cardiac arrest 1.5 hours following completion of DANYELZA infusion.

In Study 201, infusion reactions generally occurred within 24 hours of completing a DANYELZA infusion, most often within 30 minutes of initiation. Infusion reactions were most frequent during the first infusion of DANYELZA in each cycle. Eighty percent of patients required reduction in infusion rate and 80% of patients had an infusion interrupted for at least one infusion-related reaction.

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GETTING STARTED

Five steps to help get your appropriate patients started on DANYELZA[®] (naxitamab-gqgk)

- 1** Visit www.ymabsconnect.com to **download the enrollment form** and complete it with your patient or their caregiver and return it to Y-mAbs Connect[®]
- 2** **Verify your patient's coverage** for DANYELZA with their insurance providers. Y-mAbs Connect can provide information or answer questions about this process
- 3** Receive a **patient-unique ID** from Y-mAbs Connect*
*Patient-unique ID is required to order DANYELZA through the specialty distributors.
- 4** **Place an order** for DANYELZA through a participating specialty distributor using the **patient-unique ID**
 - ▶ Further information about how to order DANYELZA can be found in the “How to order” section on page 12
 - ▶ Patients must be enrolled in Y-mAbs Connect for an order to be placed
- 5** **Receive shipment** at the infusion site

IMPORTANT SAFETY INFORMATION (continued)

Premedicate with an antihistamine, acetaminophen, an H2 antagonist and corticosteroid as recommended. Monitor patients closely for signs and symptoms of infusion reactions during and for at least 2 hours following completion of each DANYELZA infusion in a setting where cardiopulmonary resuscitation medication and equipment are available.

Reduce the rate, interrupt infusion, or permanently discontinue DANYELZA based on severity and institute appropriate medical management as needed.

Neurotoxicity

DANYELZA can cause severe neurotoxicity, including severe neuropathic pain, transverse myelitis, and reversible posterior leukoencephalopathy syndrome.

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Y-mAbs Connect is a **patient support program** that provides information about access, insurance, financial support programs, and other resource programs for qualifying patients.

Y-mAbs Connect case managers and Y-mAbs field reimbursement managers (FRMs) can **provide the information you need** to help get your appropriate patients started on DANYELZA® (naxitamab-gqgk).

Y-mAbs Connect case managers

Y-mAbs Connect case managers can provide **access and reimbursement support** for patients prescribed a Y-mAbs medication.

CASE MANAGERS CAN:

- ▶ Conduct a **benefits investigation** to help understand your patient's insurance coverage for DANYELZA
- ▶ Provide **prior authorization** (PA) and appeals information
- ▶ Determine your **patient's eligibility** for Y-mAbs Connect financial support programs
- ▶ Provide information on **third-party programs** that may be able to provide financial or logistical support for your patient
- ▶ Address **logistical questions** around distribution and delivery of DANYELZA



Field reimbursement managers

Y-mAbs FRMs are liaisons to Y-mAbs Connect who are in contact with case managers and are here to **provide the needed information for you and your patients** in matters related to insurance and reimbursement.

FRMs CAN:

- ▶ **Answer** any questions prior to and during the benefits investigation
- ▶ Answer questions about PAs and appeals
- ▶ Answer billing, coding, and reimbursement questions



Throughout the guide, this icon will appear to indicate where an FRM may be able to provide support or information

Get connected today by calling **Y-mAbs Connect** at **1-833-33Y-MABS** (1-833-339-6227), option (2), and ask to be connected to an FRM.



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IMPORTANT SAFETY INFORMATION (continued)

Pain

Pain, including abdominal pain, bone pain, neck pain, and extremity pain, occurred in 100% of patients in Study 201 and 94% of patients in Study 12-230. Grade 3 pain occurred in 72% of patients in Study 201. One patient in Study 201 (4%) required interruption of an infusion due to pain. Pain typically began during the infusion of DANYELZA and lasted a median of less than one day in Study 201 (range less than one day and up to 62 days).

Premedicate with drugs that treat neuropathic pain (e.g., gabapentin) and oral opioids. Administer intravenous opioids as needed for breakthrough pain. Permanently discontinue DANYELZA based on severity.

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Financial and logistical assistance programs

If your patient is uninsured or needs help affording DANYELZA® (naxitamab-gqgk), they may be eligible for the following programs:



FRMs can answer questions about these programs or this process, especially prior to enrollment

Y-mAbs Connect Co-Pay Program

If your patient has **commercial or private insurance**, they may be eligible* for the Co-pay Program. This program could help reduce out-of-pocket costs of DANYELZA to \$0 for eligible patients.

*Patients must be enrolled in Y-mAbs Connect for this program. Eligibility criteria include but are not limited to patients who have commercial or private insurance, are US or US territory residents and are actively insured at time of treatment. Government-insured or publicly insured patients are not eligible. Please visit www.ymabsconnect.com for additional eligibility criteria and terms and conditions.

Note: Y-mAbs Therapeutics, Inc. reserves the right at any time, and without notice, to modify or discontinue this program and any support provided to the patient.

Y-mAbs Connect Patient Assistance Program (PAP)

If your patient is **uninsured or rendered underinsured for DANYELZA** through their health plan, they may be eligible* for the PAP. This program may be able to provide DANYELZA to eligible patients at no cost.

*Patients must be enrolled in Y-mAbs Connect and must meet certain eligibility criteria for this program. Please visit www.ymabsconnect.com for eligibility criteria.

Note: Y-mAbs Therapeutics, Inc. reserves the right at any time, and without notice, to modify or discontinue this program and any support provided to the patient.

Y-mAbs Connect can provide information about other available third-party organizations that may provide:

- ▶ Financial support
- ▶ Travel support such as lodging and travel costs to infusion site

Note: Third-party organizations are not associated with Y-mAbs Therapeutics, Inc.; specific details and eligibility requirements may vary by organization.

IMPORTANT SAFETY INFORMATION (continued)

Transverse Myelitis

Transverse myelitis has occurred with DANYELZA. Permanently discontinue DANYELZA in patients who develop transverse myelitis.

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Financial and logistical assistance programs (continued)

Enrollment form

Patients must be enrolled in Y-mAbs Connect prior to beginning DANYELZA® (naxitamab-gqgk) infusion. To sign up for Y-mAbs Connect, fill out our [enrollment form](#) located at ymabsconnect.com.

To fill out the enrollment form you will need:

- ▶ Basic **patient information**, including name, address, DOB, and email
- ▶ Patient **medical insurance information**, including plan and policy holder name and member ID
- ▶ **Prescriber information**, including NPI, center/hospital name, and direct contact number
- ▶ **Clinical information**, including primary and secondary ICD-10-CM codes
- ▶ **Product information**, including quantity needed and date of infusion

The enrollment form can be emailed, faxed, or mailed back to Y-mAbs Connect



ymabsconnect@pharmacord.com



1-877-209-6227



PO Box 5490, Louisville, KY 40255

IMPORTANT SAFETY INFORMATION (continued)

Reversible Posterior Leukoencephalopathy Syndrome (RPLS)

Reversible posterior leukoencephalopathy syndrome (RPLS) (also known as posterior reversible encephalopathy syndrome or PRES) occurred in 2 (2.8%) patients in Study 12-230. Events occurred 2 and 7 days following completion of the first cycle of DANYELZA. Monitor blood pressure during and following DANYELZA infusion and assess for neurologic symptoms. Permanently discontinue DANYELZA in case of symptomatic RPLS.

Peripheral Neuropathy

Peripheral neuropathy, including peripheral sensory neuropathy, peripheral motor neuropathy, paresthesia, and neuralgia, occurred in 32% of patients in Study 201 and in 25% of patients in Study 12-230. Most signs and symptoms of neuropathy began on the day of the infusion and neuropathy lasted a median of 5.5 days (range 0 to 22 days) in Study 201 and 0 days (range 0 to 22 days) in Study 12-230.

Permanently discontinue DANYELZA based on severity.

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NAVIGATING THE COVERAGE APPROVAL PROCESS FOR DANYELZA® (naxitamab-gqgk)

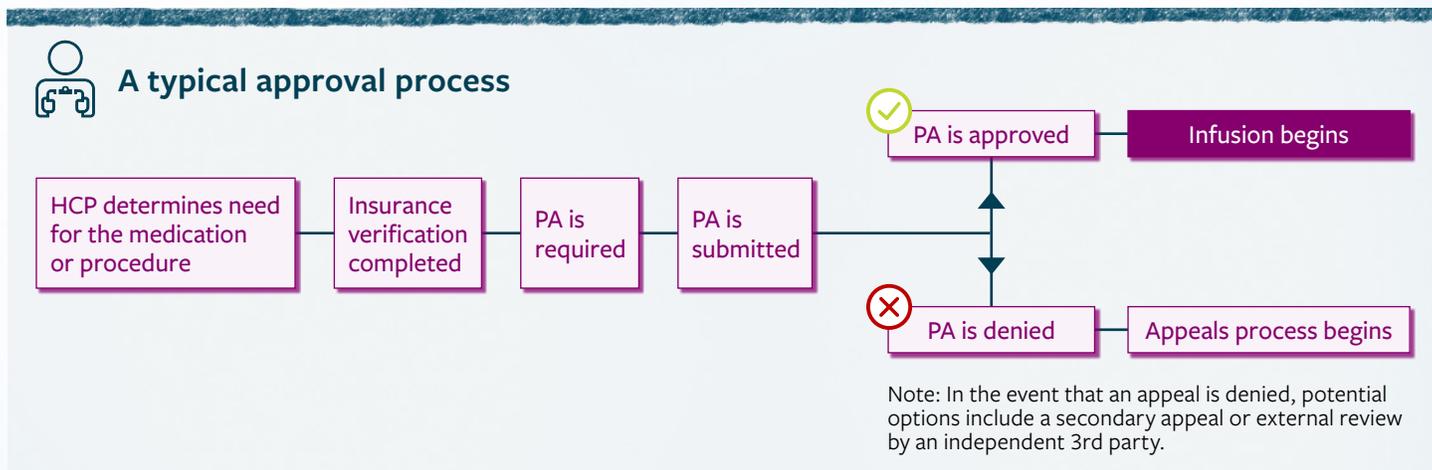


Health plans sometimes require proof that a prescribed medication is medically necessary before agreeing to pay for it, but coverage rules vary among health plans.

This section will provide general guidance on the **approval process** but is not a comprehensive list of all potential documentation required to ensure coverage.

Prior authorization (PA)

A PA is a requirement from a health plan that a health care provider (HCP) needs to determine a medication as medically necessary for the patient. Essentially, a health plan may require specific information from the HCP to approve a medication for the patient. A typical PA approval process looks something like this:



Health plans may have a specific form or process for completing a PA. HCPs may want to supplement this with additional documentation to make the **case for their patient's necessary medication**.

IMPORTANT SAFETY INFORMATION (continued)

Neurological Disorders of the Eye

Neurological disorders of the eye including unequal pupils, blurred vision, accommodation disorder, mydriasis, visual impairment, and photophobia occurred in 24% of patients in Study 201 and 19% of patients in Study 12-230. Neurological disorders of the eye lasted a median of 17 days (range 0 to 84 days) in Study 201 with two patients (8%) experiencing an event that had not resolved at the time of data cutoff, and a median of 1 day (range less than one day to 21 days) in Study 12-230. Permanently discontinue DANYELZA based on severity.

NAVIGATING THE COVERAGE APPROVAL PROCESS FOR DANYELZA[®] (naxitamab-gqgk) (continued)



Prior authorizations (continued)

Below is a checklist to help you gather necessary information to avoid treatment delays. Having this information available may assist in the PA submission process.



Common information required to submit a PA:

- ✓ Identifying **patient information**, including name and DOB
- ✓ Patient **insurance information**, including company and policy #
- ✓ **HCP information**, including contact information and NPI #
- ✓ **Patient diagnosis**, including relevant ICD-10-CM codes
- ✓ **DANYELZA infusion information** and estimated number of cycles

Additional information

This information is likely not required but may be helpful to include:

- ▶ **Specific information** regarding prescriptions
- ▶ Any information related to the **treatment decision**
- ▶ Peer-reviewed **journal articles**

Letter of medical necessity

A letter of medical necessity can be used to summarize the information needed for payers to make a decision on the medical necessity of a drug for a patient.



Sample letter of medical necessity

Visit ymabsconnect.com to download a sample letter of medical necessity.

IMPORTANT SAFETY INFORMATION (continued)

Prolonged Urinary Retention

Urinary retention occurred in 1 (4%) patient in Study 201 and in 3 patients (4%) in Study 12-230. All events in both studies occurred on the day of an infusion of DANYELZA and lasted between 0 and 24 days. Permanently discontinue DANYELZA in patients with urinary retention that does not resolve following discontinuation of opioids.

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NAVIGATING THE COVERAGE APPROVAL PROCESS FOR DANYELZA[®] (naxitamab-gqgk) (continued)



Denials and appeals

Sometimes, a health plan will **deny coverage for treatment**. In this case, you may need to file an appeal to challenge denial of coverage determination.

Some common reasons PAs may be denied include:

- ✓ **Missing codes** and/or documentation
- ✓ Suggested usage of the drug is **not consistent** with the existing coverage policy
- ✓ **Medical necessity** is not adequately established

If a PA submission is denied, an appeal can be filed to request reconsideration of the initial decision. The HCP can initiate an appeal.



An FRM can answer any questions about this part of the appeals process

Appeals processes vary but typically begin with a written explanation of why the prescribed medication is clinically appropriate for the patient (for more information, view our sample appeals letter below).



Sample appeals letter

Similar to a letter of medical necessity, an appeals letter can be used to summarize the information needed for the HCP to make an appeal to the payer's denial.

Visit ymabsconnect.com to download a sample letter of appeal.

When preparing to **appeal a coverage denial**, here are some things to consider:

- ✓ Review the denial notice to understand the **reason for denial** and to identify the appeals process requirements (documentation, time frame, etc)
- ✓ Review **accuracy and completeness** of the original PA request (patient information, documentation, etc)
- ✓ Create a comprehensive **letter of appeal** (demographic, diagnostic, and treatment information)
- ✓ Provide **supporting documentation** as required by the payer (denial letter, letter of medical necessity, patient records/electronic medical records, etc)

IMPORTANT SAFETY INFORMATION (continued)

Hypertension

Hypertension occurred in 44% of patients in Study 201 and 28% of patients in Study 12-230 who received DANYELZA. Grade 3 or 4 hypertension occurred in 4% of patients in Study 201 and 7% of patients in Study 12-230. Four patients (6%) in Study 12-230 permanently discontinued DANYELZA due to hypertension. In both studies, most events occurred on the day of DANYELZA infusion and occurred up to 9 days following an infusion of DANYELZA.

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HOW TO ORDER DANYELZA® (naxitamab-gqgk)



1 Prescriber enrolls your patient in Y-mAbs Connect®

- ▶ Visit www.ymabsconnect.com to download the Y-mAbs Connect enrollment form
- ▶ Submit a completed **enrollment form** to Y-mAbs Connect
- ▶ Verify **patient's coverage** for DANYELZA*
- ▶ Receive a **patient-unique ID** from Y-mAbs Connect

2 Place an order for DANYELZA through a participating specialty distributor using the patient-unique ID from Y-mAbs Connect

- ▶ If a patient is **already enrolled** in Y-mAbs Connect, you can call 1-833-33Y-MABS (1-833-339-6227), option (2), Monday through Friday, 8am to 8pm ET, to receive the patient-unique ID
- ▶ For **subsequent orders**, Y-mAbs Connect will follow up with you after your last shipment to generate a re-order ID if needed

3 Receive the DANYELZA shipment at the infusion site

*Y-mAbs Connect case managers may provide insurance verification support.

DANYELZA can be ordered through one of these participating specialty distributors:

ASD Healthcare	Cardinal Health	McKesson Plasma & Biologics
Phone: 1-800-746-6273 Fax: 1-800-547-9413	Phone: 1-866-681-3261	Phone: 1-877-625-2566 Fax: 1-888-752-7626
asd.customerservice@asdhealthcare.com	gmb-spd-mfgservicessp@cardinalhealth.com	mpborders@mckesson.com
asdhealthcare.com	N/A	N/A

Delivery schedule

DANYELZA is delivered Monday-Friday.

- ▶ 2-day delivery for new accounts. 1-day delivery for existing accounts

When ordering DANYELZA for an infusion cycle beginning on a Monday:

- ▶ For new accounts, please place order by 2 pm ET the Wednesday prior for 2-day delivery
- ▶ For existing accounts, please place order by 2 pm ET the Thursday prior for 1-day delivery

Note: For delivery to accounts in Alaska or Hawaii, please reach out to Y-mAbs Connect for timing information.

IMPORTANT SAFETY INFORMATION (continued)

Hypertension (continued)

Do not initiate DANYELZA in patients with uncontrolled hypertension. Monitor blood pressure during infusion, and at least daily on Days 1 to 8 of each cycle of DANYELZA and evaluate for complications of hypertension including RPLS. Interrupt DANYELZA infusion and resume at a reduced rate, or permanently discontinue DANYELZA based on the severity.

Embryo-Fetal Toxicity

Based on its mechanism of action, DANYELZA may cause fetal harm when administered to a pregnant woman. Advise females of reproductive potential, including pregnant women, of the potential risk to a fetus. Advise females of reproductive potential to use effective contraceptive during treatment with DANYELZA and for two months after the final dose.

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BILLING AND CODING

 **Certain codes** including ICD-10-CM, HCPCS codes, and CPT® codes may be required for reimbursement for DANYELZA® (naxitamab-gqgk). Please see relevant HCPCS code information below. For other details, including the ICD-10-CM and CPT codes, please download our complete billing and coding guide at www.ymabsconnect.com.

DANYELZA has been assigned a **permanent HCPCS J-code** (below) and has received Medicare pass-through status under the hospital outpatient prospective payment system.²

DANYELZA³:	
J9348	Injection, naxitamab-gqgk, 1 mg
GM-CSF³:	
J2820	Injection, sargramostim (gm-csf), 50 mcg

GM-CSF=granulocyte-macrophage colony-stimulating factor; HCPCS=Healthcare Common Procedural Coding System.

 For additional assistance regarding billing and coding for DANYELZA, visit www.ymabsconnect.com to download our complete billing and coding guide

 FRMs can answer any questions you have about billing and coding for DANYELZA

IMPORTANT SAFETY INFORMATION (continued)

ADVERSE REACTIONS

The most common adverse reactions in Studies 201 and 12-230 (≥25% in either study) were infusion-related reaction, pain, tachycardia, vomiting, cough, nausea, diarrhea, decreased appetite, hypertension, fatigue, erythema multiforme, peripheral neuropathy, urticaria, pyrexia, headache, injection site reaction, edema, anxiety, localized edema and irritability. The most common Grade 3 or 4 laboratory abnormalities (≥5% in either study) were decreased lymphocytes, decreased neutrophils, decreased hemoglobin, decreased platelet count, decreased potassium, increased alanine aminotransferase, decreased glucose, decreased calcium, decreased albumin, decreased sodium and decreased phosphate.

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References: 1. DANYELZA. Prescribing information. Y-mAbs Therapeutics, Inc.; 2020. 2. Pub 100-04 Medicare claims processing: July 2021 update of the hospital outpatient prospective payment system (OPPS). Centers for Medicare & Medicaid Services. June 11, 2021. Accessed August 2, 2021. <https://www.cms.gov/files/document/r10825cp.pdf> 3. HCPCS release & code sets. Centers for Medicare & Medicaid Services; Medicare Coverage Database. Updated May 5, 2021. Accessed August 2, 2021. <https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/HCPCS-Quarterly-Update>

