DANYELZA®
(naxitamab-gqgk)
40mg/10mL Injection

Billing and Coding Guide

This billing and coding guide is intended to provide an overview of coding information related to DANYELZA.

IMPORTANT BILLING CODES

Healthcare providers can use this guide, in addition to other sources of information, to assist in determining the appropriate codes to file for DANYELZA-related services. Y-mAbs does not guarantee payment or coverage for any product or service.

Information specific to billing and coding should be verified by the provider for each patient prior to treatment. A provider should contact patients' payers directly for any revised or additional requirements, information, or guidance.

It is always the provider's responsibility to determine the appropriate healthcare setting, and to submit true and correct claims for the products and services rendered.

J-codes

J-codes are a subset of the HCPCS Level II code set primarily used to identify injectable drugs.[1] DANYELZA has a unique, permanent J-code (see below). Also included is the J-code for GM-CSF (used in combination with DANYELZA).

DANYELZA[2]:	
J9348	Injection, naxitamab-gqgk, 1 mg

GM-CSF[2]:	
J2820	Injection, sargramostim (GM-CSF), 50 mcg

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

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 throughout. Please see full Prescribing Information and Patient Information for DANYELZA including Boxed Warning on serious infusion-related reactions and neurotoxicity.

DANYELZA® (naxitamab-gqgk) information

Additional assistance

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 can put you in contact with field reimbursement managers (FRMs); **dedicated liaisons** available to help with matters related to insurance and reimbursement.

Call **Y-mAbs Connect** at **1-833-33YMABS** (1-833-339-6227), option 2, and ask to be connected to an FRM

CPT® codes

CPT® codes indicate specific medical procedures and services.[3] Including the appropriate CPT® codes when administering DANYELZA may be required for reimbursement. The following codes may cover services needed during DANYELZA infusion:

CPT® codes[4]:	
96413	Chemotherapy administration, intravenous infusion technique; up to one hour, single or initial substance
96415	Chemotherapy administration, intravenous infusion technique; each additional hour

ICD-10-CM codes:

Primary diagnosis[5]:	
C74.0	Malignant neoplasm of cortex of adrenal gland
C74.00	Malignant neoplasm of cortex of unspecified adrenal gland
C74.01	Malignant neoplasm of cortex of right adrenal gland
C74.02	Malignant neoplasm of cortex of left adrenal gland
C74.1	Malignant neoplasm of medulla of adrenal gland
C74.10	Malignant neoplasm of medulla of unspecified adrenal gland
C74.11	Malignant neoplasm of medulla of right adrenal gland
C74.12	Malignant neoplasm of medulla of left adrenal gland
C74.9	Malignant neoplasm of unspecified part of adrenal gland
C74.90	Malignant neoplasm of unspecified part of unspecified adrenal gland
C74.91	Malignant neoplasm of unspecified part of right adrenal gland
C74.92	Malignant neoplasm of unspecified part of left adrenal gland
Secondary diagnosis[6]:	
C79.5	Secondary malignant neoplasm of bone and bone marrow
C79.51	Secondary malignant neoplasm of bone
C79.52	Secondary malignant neoplasm of bone marrow

CPT=Current Procedural Terminology; ICD-10-CM=International Classification of Diseases, Tenth Revision, Clinical Modification.

IMPORTANT SAFETY INFORMATION (cont)

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.

DANYELZA® (naxitamab-gqgk) information (cont)

10-digit NDC[7]	Dosage form and strength[7]
73042-201-01	40 mg/10 mL (4 mg/mL) in a single-dose vial

Premedications and supportive medications

Premedications and supportive medications for pain management and infusion-related reactions for DANYELZA infusion require appropriate coding, which is not detailed here.

DANYELZA can be ordered through a distribution network consisting of 3 specialty distributors:		
Cardinal Health	AmerisourceBergen	McKesson

For more information about how to order DANYELZA, please visit **www.ymabsconnect.com** to download the Product Ordering Instructions

NDC=National Drug Code.

IMPORTANT SAFETY INFORMATION (cont)

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.

Caution is advised in patients with pre-existing cardiac disease, as this may exacerbate the risk of severe hypotension.

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.

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.

Transverse Myelitis

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

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

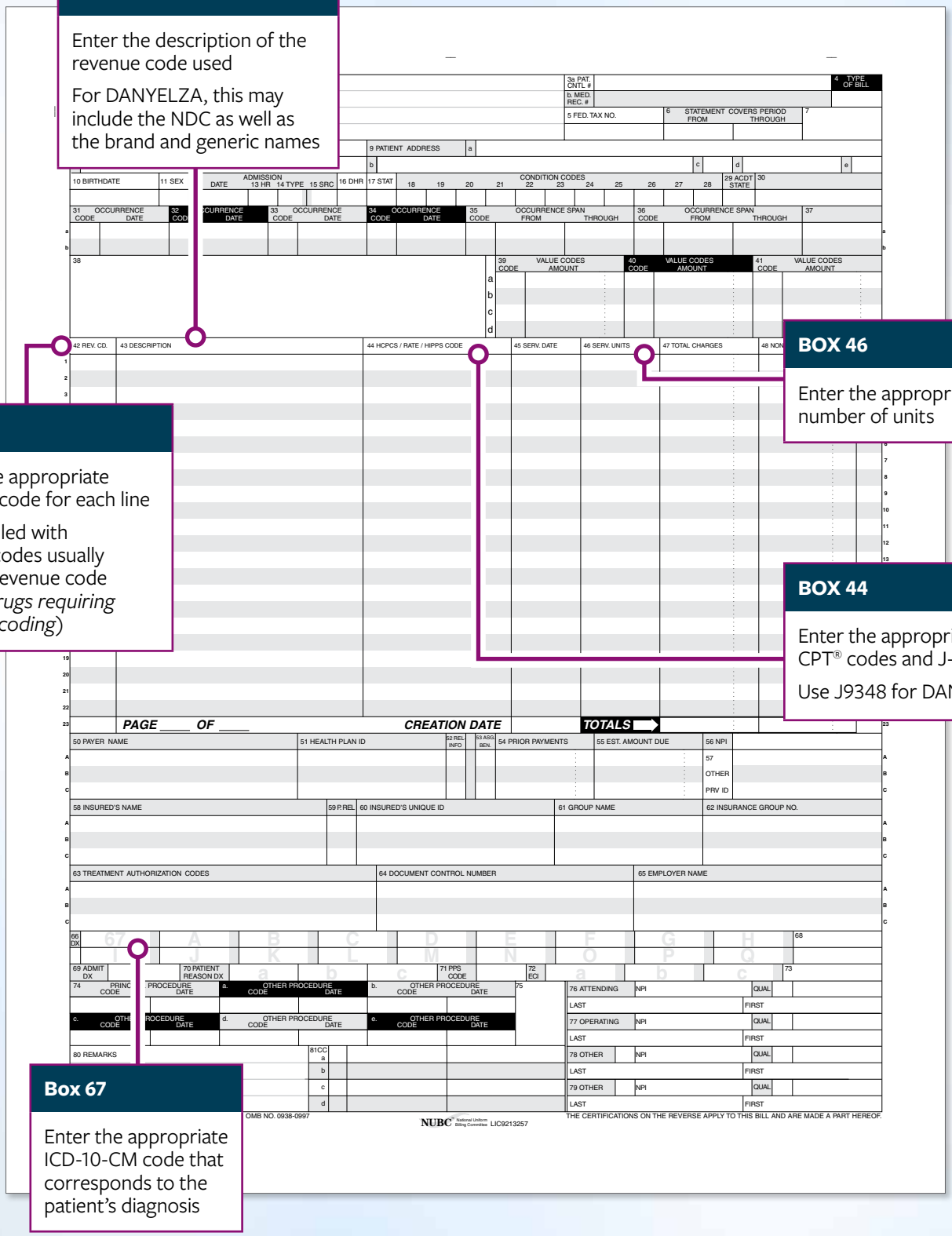
Peripheral neuropathy, including peripheral sensory neuropathy, peripheral motor neuropathy, paresthesia, and neuralgia, occurred in 32% of patients in Study 201 and in 25% of patients in Study 12-230. Most signs and symptoms of neuropathy began on the day of the infusion and neuropathy lasted a median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

Sample UB-04 (CMS-1450) claim form for hospital outpatient billing: DANYELZA® (naxitamab-gqgk) injection

Included below is a sample UB-04 form with tips on DANYELZA claim submissions. Adherence to tips does not guarantee reimbursement.

It is always the provider's responsibility to determine the appropriate healthcare setting and to submit true and correct claims for the products and services rendered.



BOX 43

Enter the description of the revenue code used

For DANYELZA, this may include the NDC as well as the brand and generic names

BOX 42

Enter the appropriate revenue code for each line

Drugs billed with HCPCS codes usually require revenue code 0636 (*Drugs requiring detailed coding*)

BOX 46

Enter the appropriate number of units

BOX 44

Enter the appropriate CPT® codes and J-codes

Use J9348 for DANYELZA

Box 67

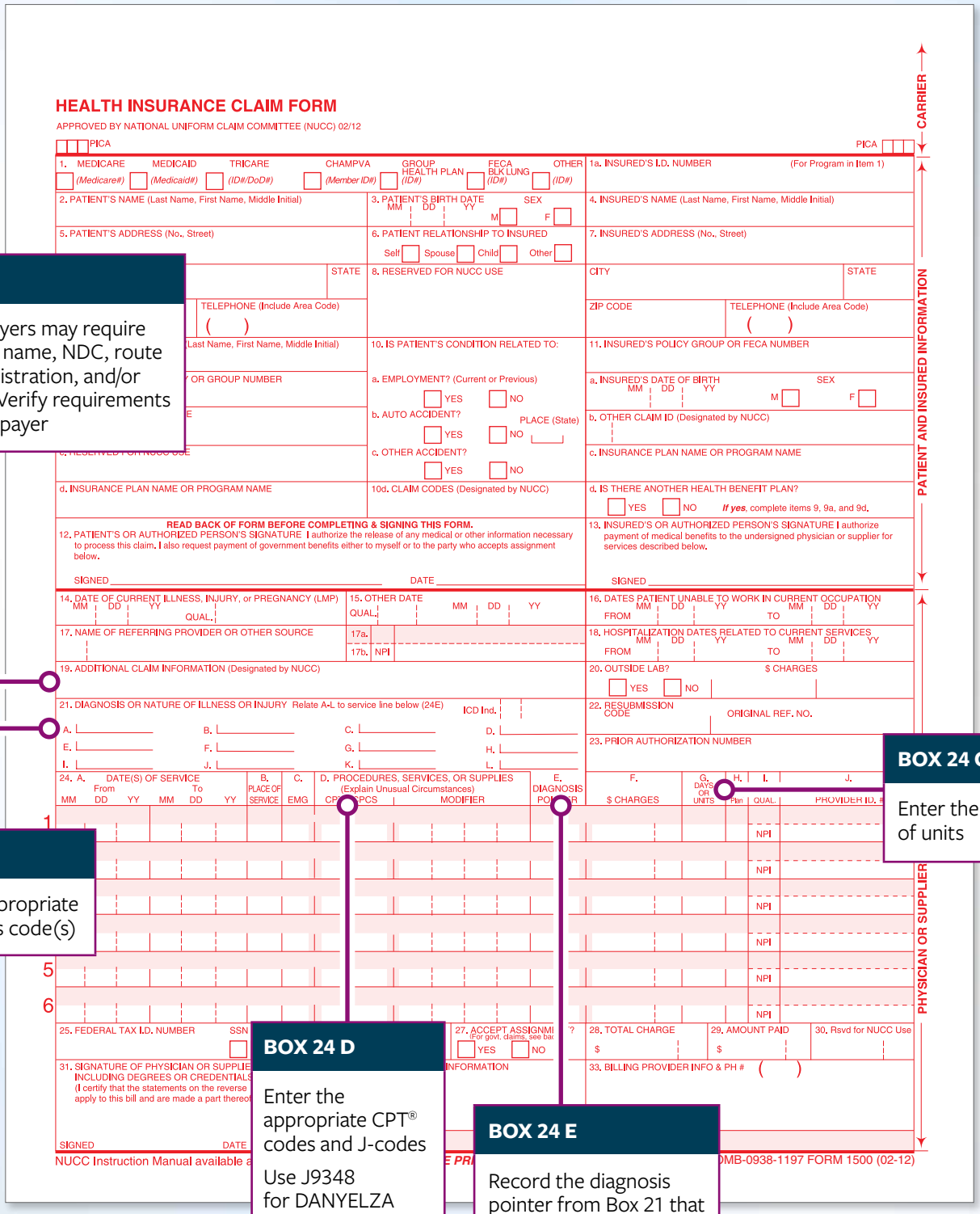
Enter the appropriate ICD-10-CM code that corresponds to the patient's diagnosis

Please see additional Important Safety Information throughout. Please see full Prescribing Information and Patient Information for DANYELZA including Boxed Warning on serious infusion-related reactions and neurotoxicity.

Sample CMS-1500 claim form for office billing: DANYELZA® (naxitamab-gqgk) injection

Included below is a sample CMS-1500 form with tips on DANYELZA claim submissions. Adherence to tips does not guarantee reimbursement.

It is always the provider's responsibility to determine the appropriate healthcare setting and to submit true and correct claims for the products and services rendered.



Please see additional Important Safety Information throughout. Please see full Prescribing Information and Patient Information for DANYELZA including Boxed Warning on serious infusion-related reactions and neurotoxicity.

IMPORTANT SAFETY INFORMATION (cont)

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.

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.

Myocarditis

Myocarditis has occurred in adolescent patients receiving DANYELZA in clinical trials and expanded access programs. Myocarditis occurred within days of receiving DANYELZA requiring drug interruption. Monitor for signs and symptoms of myocarditis during treatment with DANYELZA. Withhold, reduce the dose, or permanently discontinue DANYELZA based on severity.

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.

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.

Orthostatic Hypotension

Orthostatic hypotension has occurred in patients receiving DANYELZA in clinical trials and expanded access programs. Severe orthostatic hypotension, including cases requiring hospitalization, have occurred. Cases occurred within hours to 6 days of DANYELZA infusions in any cycle.

In patients with symptoms of orthostatic hypotension, monitor postural blood pressure prior to initiating treatment with DANYELZA and as clinically indicated with subsequent dosing. Withhold, reduce dose, or permanently discontinue DANYELZA based on 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 last dose.

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.

Please see full Prescribing Information and Patient Information for DANYELZA including Boxed Warning on serious infusion-related reactions and neurotoxicity.

To review important state-specific disclosure information for licensed healthcare practitioners, please visit https://www.ymabs.com/information-for-prescribers

References: 1. 2023 HCPCS Codes > J Codes. HCPCScodes.org. 2023. Accessed June 20, 2024. https://hcpcscodes.org/jcodes. **2.** HCPCS release & code sets. Centers for Medicare & Medicaid Services; Medicare Coverage Database. Updated May 27, 2021. Accessed June 10, 2024. https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/HCPCS-Quarterly-Update. **3.** What is CPT®? American Academy of Professional Coders. Accessed May 27, 2021. https://www.aapc.com/resources/what-is-cpt. **4.** SUPERSEDED local coverage article: billing and coding: chemotherapy administration (A52991). Centers for Medicare & Medicaid Services; Medicare Coverage Database. Updated October 18, 2020. Accessed July 3, 2024. https://localcoverage.cms.gov/mcd_archive/view/article.aspx?articleInfo=52991:114&. **5.** ICD-10-CM fiscal year: C74.0. Centers for Disease Control and Prevention. Accessed June 20, 2024. https://www.icd10data.com/ICD10CM/Codes/C00-D49/C73-C75/C74-. **6.** ICD-10-CM fiscal year: C79.5. Centers for Disease Control and Prevention. Accessed June 20, 2024. https://www.icd10data.com/ICD10CM/Codes/C00-D49/C76-C80/C79-. **7.** DANYELZA® [package insert]. New York, NY: Y-mAbs Therapeutics, Inc.; 2024. Available online at https://labeling.ymabs.com/danyelza.

Y-mAbs Therapeutics, Inc.™

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Your link to patient support

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(naxitamab-gqgk)
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