

Billing and coding guide

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

IMPORTANT BILLING CODES

Health care providers can use this guide, in addition to other sources of information, to determine 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 health care 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).

DANYELZA²:	
J9348	Injection, naxitamab-gqgk, 1 mg
GM-CSF²:	
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 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

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

CPT=Current Procedural Terminology.

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

ICD-10-CM=International Classification of Diseases, Tenth Revision, Clinical Modification.

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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DANYELZA[®] (naxitamab-gqgk) information

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

NDC=National Drug Code.

Premedications and supportive medications

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

To order DANYELZA:

DANYELZA can be ordered through a distribution network consisting of 3 specialty distributors:

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

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.

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.

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

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 health care 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

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 health care setting and to submit true and correct claims for the products and services rendered.

HEALTH INSURANCE CLAIM FORM
APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12

PICA PICA

1. MEDICARE MEDICAID TRICARE CHAMPVA GROUP HEALTH PLAN FECA BLK LUNG OTHER
(Medicare#) (Medicaid#) (ID#/DoD#) (Member ID#) (ID#)

2. PATIENT'S NAME (Last Name, First Name, Middle Initial) 3. PATIENT'S BIRTH DATE MM DD YY SEX M F

4. INSURED'S NAME (Last Name, First Name, Middle Initial)

5. PATIENT'S ADDRESS (No., Street) 6. PATIENT RELATIONSHIP TO INSURED
Self Spouse Child Other

7. INSURED'S ADDRESS (No., Street)

8. RESERVED FOR NUCC USE 9. CITY STATE

10. IS PATIENT'S CONDITION RELATED TO:
a. EMPLOYMENT? (Current or Previous) YES NO
b. AUTO ACCIDENT? YES NO PLACE (State) _____
c. OTHER ACCIDENT? YES NO

11. INSURED'S POLICY GROUP OR FECA NUMBER
a. INSURED'S DATE OF BIRTH MM DD YY SEX M F
b. OTHER CLAIM ID (Designated by NUCC) _____
c. INSURANCE PLAN NAME OR PROGRAM NAME _____

12. PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE I authorize the release of any medical or other information necessary to process this claim. I also request payment of government benefits either to myself or to the party who accepts assignment below.
SIGNED _____ DATE _____

13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE I authorize payment of medical benefits to the undersigned physician or supplier for services described below.
SIGNED _____ DATE _____

14. DATE OF CURRENT ILLNESS, INJURY, or PREGNANCY (LMP) MM DD YY QUAL _____ 15. OTHER DATE MM DD YY

16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION FROM MM DD YY TO MM DD YY

17. NAME OF REFERRING PROVIDER OR OTHER SOURCE 17a. NPI 17b. NPI

18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES FROM MM DD YY TO MM DD YY

19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)

20. OUTSIDE LAB? YES NO \$ CHARGES _____

21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E) ICD Ind. _____

22. RESUBMISSION CODE ORIGINAL REF. NO.

23. PRIOR AUTHORIZATION NUMBER

24. A. DATE(S) OF SERVICE From MM DD YY To MM DD YY B. PLACE OF SERVICE EMG C. D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CP PCS MODIFIER E. DIAGNOSIS POINTER F. \$ CHARGES G. DAYS OR UNITS H. I. QUAL. J. PROVIDER ID, NPI

25. FEDERAL TAX I.D. NUMBER SSN 27. ACCEPT ASSIGNMENT (For gov't. claims, see bar) YES NO

28. TOTAL CHARGE \$ 29. AMOUNT PAID \$ 30. Rvld for NUCC Use

31. SIGNATURE OF PHYSICIAN OR SUPPLIER INCLUDING DEGREES OR CREDENTIALS (I certify that the statements on the reverse apply to this bill and are made a part thereof)
SIGNED _____ DATE _____

33. BILLING PROVIDER INFO & PH # ()

NUCC Instruction Manual available at www.nucc.org MMB-0938-1197 FORM 1500 (02-12)

BOX 19
Some payers may require the drug name, NDC, route of administration, and/or dosage. Verify requirements with the payer

BOX 21
Enter appropriate diagnosis code(s)

BOX 24 D
Enter the appropriate CPT® codes and J-codes
Use J9348 for DANYELZA

BOX 24 E
Record the diagnosis pointer from Box 21 that corresponds with the procedure in Box 24 D

BOX 24 G
Enter the number of units

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.

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.

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.

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.

ADVERSE REACTIONS

The most common adverse reactions in Studies 201 and 12-230 ($\geq 25\%$ 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 ($\geq 5\%$ 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 accompanying full Prescribing Information and Patient Information for DANYELZA including Boxed Warning on serious infusion-related reactions and neurotoxicity. This is also available at labeling.ymabs.com/danyelza

References: 1. 2021 HCPCS Codes > J Codes. HCPCScodes.org. 2021. Accessed May 27, 2021. <https://hcpcs.org/jcodes> 2. HCPCS release & code sets. Centers for Medicare & Medicaid Services; Medicare Coverage Database. Updated May 5, 2021. Accessed June 8, 2021. <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/medical-coding/cpt.aspx> 4. SUPERSEDED local coverage article: billing and coding: chemotherapy administration (A52991). Centers for Medicare & Medicaid Services; Medicare Coverage Database. Updated October 18, 2020. Accessed May 27, 2021. <https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=52991&ver=101&SearchType=Advanced&CoverageSelection=Local&Arti%E2%80%A6> 5. ICD-10-CM fiscal year: C74.0. Centers for Disease Control and Prevention. Accessed May 27, 2021. <https://icd10cmtool.cdc.gov/?fy=FY2021&q=C74.0> 6. ICD-10-CM fiscal year: C79.5. Centers for Disease Control and Prevention. Accessed May 27, 2021. <https://icd10cmtool.cdc.gov/?fy=FY2021&q=C79.5> 7. Danyelza. Prescribing information. Y-mAbs Therapeutics Inc; 2020.

