

DARZALEX FASPRO®

Permanent J-code issued for DARZALEX FASPRO®, effective January 1, 2021

The Centers for Medicare and Medicaid Services (CMS) has issued a permanent, drug-specific code to identify DARZALEX FASPRO® on claims beginning January 1, 2021: **J9144 - injection, daratumumab, 10 mg and hyaluronidase-fihj**. This permanent code replaces all HCPCS codes previously used to describe DARZALEX FASPRO®, including any miscellaneous or temporary codes. For claims with dates of service January 1, 2021, and beyond, J9144 is the only code that should be reported in both the hospital outpatient and physician office sites of care.

CODING & BILLING IN HOSPITAL OUTPATIENT DEPARTMENTS

Sample CMS-1450 (UB-04) Claim Form

INDICATIONS

DARZALEX FASPRO® (daratumumab and hyaluronidase-fihj) is indicated for the treatment of adult patients with multiple myeloma:

- In combination with bortezomib, melphalan, and prednisone in newly diagnosed patients who are ineligible for autologous stem cell transplant
- In combination with lenalidomide and dexamethasone in newly diagnosed patients who are ineligible for autologous stem cell transplant and in patients with relapsed or refractory multiple myeloma who have received at least one prior therapy
- In combination with bortezomib, thalidomide, and dexamethasone in newly diagnosed patients who are eligible for autologous stem cell transplant
- In combination with pomalidomide and dexamethasone in patients who have received at least one prior line of therapy including lenalidomide and a proteasome inhibitor
- In combination with carfilzomib and dexamethasone in patients with relapsed or refractory multiple myeloma who have received one to three prior lines of therapy
- In combination with bortezomib and dexamethasone in patients who have received at least one prior therapy
- As monotherapy in patients who have received at least three prior lines of therapy including a proteasome inhibitor (PI) and an immunomodulatory agent or who are double-refractory to a PI and an immunomodulatory agent

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

DARZALEX FASPRO® is contraindicated in patients with a history of severe hypersensitivity to daratumumab, hyaluronidase, or any of the components of the formulation.

WARNINGS AND PRECAUTIONS

Hypersensitivity and Other Administration Reactions

Both systemic administration-related reactions, including severe or life-threatening reactions, and local injection-site reactions can occur with DARZALEX FASPRO®. Fatal reactions have been reported with daratumumab-containing products, including DARZALEX FASPRO®.

Please see Important Safety Information on [pages 5-6](#) and [click here](#) to see the full Prescribing Information.



The information provided is valid as of August 2021 and is subject to change.

Checklist for Claims

To potentially avoid delays, underpayments, or denials, it may be helpful to perform a review prior to submitting any claim to a payer.

The following may be considered:

- ✓ Insurance was verified
- ✓ This is a covered service
- ✓ If required, prior authorization was obtained
- ✓ Medical necessity is documented*
- ✓ The correct codes (ICD-10, CPT®, and HCPCS) are reported
- ✓ Billed units are accurate and consistent with the code descriptors
- ✓ Specific payer requirements were followed

*A sample letter of medical necessity is available at: www.JanssenCarePath.com.

This document is presented for informational purposes only and is not intended to provide reimbursement or legal advice, nor does it promise or guarantee coverage, levels of reimbursement, payment, or charge. Similarly all Current Procedural Terminology (CPT®¹) and Healthcare Common Procedure Coding System (HCPCS) codes are supplied for informational purposes only and represent no statement, promise, or guarantee by Janssen Biotech, Inc., that these codes will be appropriate or that reimbursement will be made. It is not intended to increase or maximize reimbursement by any payer. Laws, regulations, and policies concerning reimbursement are complex and are updated frequently. While we have made an effort to be current as of the issue date of this document, the information may not be as current or comprehensive when you view it. We strongly recommend you consult your payer organization for its reimbursement policies.

¹CPT® – Current Procedural Terminology. CPT® is a registered trademark of the American Medical Association, 2022.

Consult local payers for coding policies or call a Janssen CarePath Care Coordinator at 877-CarePath (877-227-3728), Monday–Friday, 8:00 AM to 8:00 PM ET

DARZALEX FASPRO® (daratumumab and hyaluronidase-fihj)
Hospital Outpatient Department Sample Claim Form: CMS-1450 (UB-04)

A **Locator Box 42** - List revenue codes in ascending order.

B **Locator Box 43** - Enter narrative description for corresponding revenue code.

C **Locator Box 44** - Indicate appropriate CPT®, HCPCS† codes, and modifiers, as required by payer.

DARZALEX FASPRO®

J9144 - Injection, daratumumab, 10 mg and hyaluronidase-fihj

Drug Administration

96401 - Chemotherapy administration, subcutaneous or intramuscular; non-hormonal anti-neoplastic

D **Locator Box 46** - Enter the units for items/services provided.

DARZALEX FASPRO®

J9144 - Enter the amount of drug in HCPCS units according to the drug-specific descriptor and dose.
 10 mg = 1 unit; each 1,800 mg dose of DARZALEX FASPRO® = 180 units

Drug Administration

96401 - Enter 1 unit

E **Locator Box 67** - Indicate diagnosis using appropriate ICD-10-CM codes. Code to the highest level of specificity for the date of service and enter diagnoses in priority order.

ICD-10 Diagnosis Codes† for Consideration

C90.00	Multiple myeloma not having achieved remission
C90.01	Multiple myeloma in remission
C90.02	Multiple myeloma in relapse

*CPT® - Current Procedural Terminology. CPT® is a registered trademark of the American Medical Association, 2022.

†The fact that a drug, device, procedure, or service is assigned an HCPCS code and a payment rate does not imply coverage for any specific service by the Medicare and/or Medicaid program. HCPCS codes are used to describe a product, procedure, or service on an insurance claim. Payers such as Medicare Administrative Contractors (MACs) and/or state Medicaid programs use HCPCS codes in conjunction with other information to determine whether a drug, device, procedure, or other service meets all program requirements for coverage, and what payment rules are to be applied to such claims.

‡These codes are not intended to be promotional or to encourage or suggest a use of drug that is inconsistent with FDA-approved use. The codes provided are not intended to be exhaustive and, depending on the patient, additional codes may apply.

DARZALEX FASPRO® (daratumumab and hyaluronidase-fihj)
CMS-1450 (UB-04) Sample Claim Form: 2022

The form is a CMS-1450 (UB-04) claim form. It includes the following sections:

- Header:** 1. Anytown Hospital, 123 Any Street, Anytown, AS 12345. 2. Pay-to-name: Pay-to-address, Pay-to-city/state. 3a. PAT. CNTL. #: XX-XXXX. 3b. MED. REG. #: DOE 1234-97. 4. TYPE OF BILL. 5. FED. TAX NO. 6. STATEMENT COVERS PERIOD FROM TO. 7. 8. PATIENT NAME: John B Doe. 9. PATIENT ADDRESS: 123 Any Street. 10. BIRTHDATE: 07 01 50. 11. SEX: M. 12. DATE OF SERVICE: 01 01 22. 13. HR. 14. TYPE. 15. SRC. 16. DHR. 17. STAT. 18. 19. 20. 21. 22. 23. 24. 25. 26. 27. 28. 29. ACCT. STATE. 30. US.
- Table of Services:**

42 REV. CD.	43 DESCRIPTION	44 HCPCS / RATE / HIPPS CODE	45 SERV. DATE	46 SERV. UNITS	47 TOTAL CHARGES	48 NON-COVERED CHARGES	49
0331	Chemotherapy administration - injection	96401	01-01-22	1			
0636	DARZALEX FASPRO® (daratumumab and hyaluronidase-fihj)	J9144	01-01-22	180			
- Summary:** PAGE OF, CREATION DATE, TOTALS.
- Payer Information:** 50 PAYER NAME: Medicare. 51 HEALTH PLAN ID. 52 REL. INFO. 53 ASGN. BEN. 54 PRIOR PAYMENTS. 55 EST. AMOUNT DUE. 56 NPI: 246 555 1234. 57 OTHER PRV ID.
- Insured Information:** 58 INSURED'S NAME. 59 P.PREL. 60 INSURED'S UNIQUE ID. 61 GROUP NAME. 62 INSURANCE GROUP NO.
- Authorization:** 63 TREATMENT AUTHORIZATION CODES. 64 DOCUMENT CONTROL NUMBER. 65 EMPLOYER NAME.
- Diagnosis:** 66 ICD-10 CODE: C90.02. 67 ICD-10 CODE. 68 ICD-10 CODE.
- Procedure:** 69 ADMIT. DX. 70 PATIENT REASON DX. 71 PRS. CODE. 72 ECI. 73.
- Attending:** 74 PRINCIPAL PROCEDURE CODE. 75 OTHER PROCEDURE CODE. 76 ATTENDING NPI: 123-456-7890. 77 OPERATING NPI. 78 OTHER NPI. 79 OTHER NPI.
- Remarks:** 80 REMARKS. 81CC a, b, c, d.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

DARZALEX FASPRO® is contraindicated in patients with a history of severe hypersensitivity to daratumumab, hyaluronidase, or any of the components of the formulation.

WARNINGS AND PRECAUTIONS

Hypersensitivity and Other Administration Reactions

Both systemic administration-related reactions, including severe or life-threatening reactions, and local injection-site reactions can occur with DARZALEX FASPRO®. Fatal reactions have been reported with daratumumab-containing products, including DARZALEX FASPRO®.

Systemic Reactions

In a pooled safety population of 898 patients with multiple myeloma (N=705) or light chain (AL) amyloidosis (N=193) who received DARZALEX FASPRO® as monotherapy or in combination, 9% of patients experienced a systemic administration-related reaction (Grade 2: 3.2%, Grade 3: 1%). Systemic administration-related reactions occurred in 8% of patients with the first injection, 0.3% with the second injection, and cumulatively 1% with subsequent injections. The median time to onset was 3.2 hours (range: 4 minutes to 3.5 days). Of the 140 systemic administration-related reactions that occurred in 77 patients, 121 (86%) occurred on the day of DARZALEX FASPRO® administration. Delayed systemic administration-related reactions have occurred in 1% of the patients.

Severe reactions included hypoxia, dyspnea, hypertension, tachycardia, and ocular adverse reactions, including choroidal effusion, acute myopia, and acute angle closure glaucoma. Other signs and symptoms of systemic administration-related reactions may include respiratory symptoms, such as bronchospasm, nasal congestion, cough, throat irritation, allergic rhinitis, and wheezing, as well as anaphylactic reaction, pyrexia, chest pain, pruritus, chills, vomiting, nausea, hypotension, and blurred vision.

Pre-medicate patients with histamine-1 receptor antagonist, acetaminophen, and corticosteroids. Monitor patients for systemic administration-related reactions, especially following the first and second injections. For anaphylactic reaction or life-threatening (Grade 4) administration-related reactions, immediately and permanently discontinue DARZALEX FASPRO®. Consider administering corticosteroids and other medications after the administration of DARZALEX FASPRO® depending on dosing regimen and medical history to minimize the risk of delayed (defined as occurring the day after administration) systemic administration-related reactions.

Ocular adverse reactions, including acute myopia and narrowing of the anterior chamber angle due to ciliochoroidal effusions with potential for increased intraocular pressure or glaucoma, have occurred with daratumumab-containing products. If ocular symptoms occur, interrupt DARZALEX FASPRO® and seek immediate ophthalmologic evaluation prior to restarting DARZALEX FASPRO®.

Local Reactions

In this pooled safety population, injection-site reactions occurred in 8% of patients, including Grade 2 reactions in 0.7%. The most frequent (>1%) injection-site reaction was injection-site erythema. These local reactions occurred a median of 5 minutes (range: 0 minutes to 6.5 days) after starting administration of DARZALEX FASPRO®. Monitor for local reactions and consider symptomatic management.

Neutropenia

Daratumumab may increase neutropenia induced by background therapy. Monitor complete blood cell counts periodically during treatment according to manufacturer's prescribing information for background therapies. Monitor patients with neutropenia for signs of infection. Consider withholding DARZALEX FASPRO® until recovery of neutrophils. In lower body weight patients receiving DARZALEX FASPRO®, higher rates of Grade 3-4 neutropenia were observed.

Thrombocytopenia

Daratumumab may increase thrombocytopenia induced by background therapy. Monitor complete blood cell counts periodically during treatment according to manufacturer's prescribing information for background therapies. Consider withholding DARZALEX FASPRO® until recovery of platelets.

Embryo-Fetal Toxicity

Based on the mechanism of action, DARZALEX FASPRO® can cause fetal harm when administered to a pregnant woman. DARZALEX FASPRO® may cause depletion of fetal immune cells and decreased bone density. Advise pregnant women of the potential risk to a fetus. Advise females with reproductive potential to use effective contraception during treatment with DARZALEX FASPRO® and for 3 months after the last dose.

The combination of DARZALEX FASPRO® with lenalidomide, thalidomide, or pomalidomide is contraindicated in pregnant women because lenalidomide, thalidomide, and pomalidomide may cause birth defects and death of the unborn child. Refer to the lenalidomide, thalidomide, or pomalidomide prescribing information on use during pregnancy.

Interference With Serological Testing

Daratumumab binds to CD38 on red blood cells (RBCs) and results in a positive indirect antiglobulin test (indirect Coombs test). Daratumumab-mediated positive indirect antiglobulin test may persist for up to 6 months after the last daratumumab administration. Daratumumab bound to RBCs masks detection of antibodies to minor antigens in the patient's serum. The determination of a patient's ABO and Rh blood type are not impacted.

Notify blood transfusion centers of this interference with serological testing and inform blood banks that a patient has received DARZALEX FASPRO®. Type and screen patients prior to starting DARZALEX FASPRO®.

Interference With Determination of Complete Response

Daratumumab is a human immunoglobulin G (IgG) kappa monoclonal antibody that can be detected on both the serum protein electrophoresis (SPE) and immunofixation (IFE) assays used for the clinical monitoring of endogenous M-protein. This interference can impact the determination of complete response and of disease progression in some DARZALEX FASPRO®-treated patients with IgG kappa myeloma protein.

ADVERSE REACTIONS

In multiple myeloma, the most common adverse reaction (≥20%) with DARZALEX FASPRO® monotherapy is upper respiratory tract infection. The most common adverse reactions with combination therapy (≥20% for any combination) include fatigue, nausea, diarrhea, dyspnea, insomnia, headache, pyrexia, cough, muscle spasms, back pain, vomiting, hypertension, upper respiratory tract infection, peripheral sensory neuropathy, constipation, pneumonia, and peripheral edema.

The most common hematology laboratory abnormalities (≥40%) with DARZALEX FASPRO® are decreased leukocytes, decreased lymphocytes, decreased neutrophils, decreased platelets, and decreased hemoglobin.

Please [click here](#) to see the full Prescribing Information.

cp-143279v7