

DARZALEX FASPRO™

CODING & BILLING IN PHYSICIAN OFFICES

Sample CMS-1500 Claim Form

DARZALEX FASPRO™ (daratumumab and hyaluronidase-fihj) IS INDICATED FOR ADULT PATIENTS:

- 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 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

This document is presented for informational purposes only and is not intended to provide reimbursement or legal advice. Laws, regulations, and policies concerning reimbursement are complex and 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. Similarly, all Current Procedural Terminology (CPT®) and Healthcare Common Procedure Coding System (HCPCS) codes are supplied for informational purposes only, and this information does not represent any statement, promise, or guarantee by Janssen Biotech, Inc., about coverage, levels of reimbursement, payment, or charge. Please consult with your payer organization(s) for local or actual coverage and reimbursement policies and with your internal reimbursement specialist for any reimbursement or billing questions.

*CPT® – Current Procedural Terminology. CPT® is a registered trademark of the American Medical Association, 2019.

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 include: Hypersensitivity and Other Administration Reactions, Neutropenia, Thrombocytopenia, Embryo-Fetal Toxicity, Interference with Serological Testing, and Interference with Determination of Complete Response.

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 May 2020 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
- ✓ Information to support use of the not otherwise classified (NOC) drug code is included
- ✓ Billed units are accurate and consistent with the code descriptors (Note: NOC drug codes are always billed with 1 unit)
- ✓ Specific payer requirements were followed

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

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)
Physician Office Sample Claim Form: CMS-1500

A **Item 19** - When submitting claims with an unclassified drug code, enter drug name, dose, route of administration, and NDC (payers commonly require 11-digit version) information. Payer requirements may vary and can include requests for additional documentation (eg, Prescribing Information, letter of medical necessity, or other support) to accompany the claim.

National Drug Codes for DARZALEX FASPRO™		
10-digit NDC	11-digit NDC	Description
57894-503-01	57894-0503-01	1,800 mg daratumumab and 30,000 units hyaluronidase-fihj/15 mL vial

B **Item 21** - Indicate diagnosis using appropriate ICD-10-CM codes. Use diagnosis codes to the highest level of specificity for the date of service and enter the 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

*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.

C **Item 24D** - Indicate appropriate CPT®, HCPCS codes, and modifiers (if applicable).

DARZALEX FASPRO™

J9999 - Not otherwise classified anti-neoplastic drug†

Drug Administration

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

D **Item 24E** - Refer to the diagnosis for this service (see Item 21). Enter only 1 diagnosis pointer per line.

E **Item 24G** - Enter the units for items/services provided.

DARZALEX FASPRO™

J9999 - Enter 1 unit and report additional information in Item 19.

Drug Administration

96401 - Enter 1 unit.

†Accurate reporting of miscellaneous drug codes can vary by site of care, payer, and timing after FDA approval. Please contact your payers for specific coding policies and correct claim submission requirements.

DARZALEX FASPRO™ (daratumumab and hyaluronidase-fihj)
CMS-1500 Sample Claim Form

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

1. MEDICARE **MEDICAID** **TRICARE** **CHAMPVA** **GROUP HEALTH PLAN** **FECA BLK LUNG** **OTHER**

1a. INSURED'S I.D. NUMBER 000-00-1234

2. PATIENT'S NAME Doe, John B

3. PATIENT'S BIRTH DATE 07 01 50

4. INSURED'S NAME Doe, John B

5. PATIENT'S ADDRESS 123 Any Street

6. PATIENT RELATIONSHIP TO INSURED Self Spouse Child Other

7. INSURED'S ADDRESS Any Town, AS

8. RESERVED FOR NUCC USE

9. OTHER INSURED'S NAME

10. IS PATIENT'S CONDITION RELATED TO:

11. INSURED'S POLICY GROUP OR FECA NUMBER

12. PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE Dr. Jones

13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE

14. DATE OF CURRENT ILLNESS, INJURY, or PREGNANCY (LMP)

15. OTHER DATE

16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION

17. NAME OF REFERRING PROVIDER OR OTHER SOURCE Dr. Jones

18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES

19. ADDITIONAL CLAIM INFORMATION 15 mL DARZALEX FASPRO™ (1,800 mg daratumumab and 30,000 Units hyaluronidase-fihj) SC; NDC 57894-0503-01

20. OUTSIDE LAB? YES NO

21. ICD-10 CODE C90.02

22. RESUBMISSION CODE

23. PRIOR AUTHORIZATION NUMBER

A	B	C	D	E	F	G	H	I	J
DATE OF SERVICE	DATE OF SERVICE	PLACE OF SERVICE	PROCEDURES, SERVICES, OR SUPPLIES	DIAGNOSIS POINTER	\$ CHARGES	DAYS OR UNITS	ESRD Family Plan	ID. QUAL.	RENDERING PROVIDER ID. #
05 01 20	05 01 20	11	96401	A		1		NPI	123-456-7890
05 01 20	05 01 20	11	J9999	A		1		NPI	123-456-7890
								NPI	
								NPI	
								NPI	
								NPI	

25. FEDERAL TAX I.D. NUMBER SSN EIN

26. PATIENT'S ACCOUNT NO.

27. ACCEPT ASSIGNMENT? YES NO

28. TOTAL CHARGE \$

29. AMOUNT PAID \$

30. Rsvd for NUCC Use

31. SIGNATURE OF PHYSICIAN OR SUPPLIER Dr. Jones

32. SERVICE FACILITY LOCATION INFORMATION NPI

33. BILLING PROVIDER INFO & PH # 555 133-5555

SIGNED DATE

PLEASE PRINT OR TYPE

NUCC Instruction Manual available at: www.nucc.org

APPROVED OMB-0938-1197 FORM 1500 (02-12)

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

DARZALEX FASPRO™ (daratumumab and hyaluronidase-fihj) 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™.

Systemic Reactions

In a pooled safety population of 490 patients who received DARZALEX FASPRO™ as monotherapy or in combination, 11% of patients experienced a systemic administration-related reaction (Grade 2: 3.9%, Grade 3: 1.4%). Systemic administration-related reactions occurred in 10% of patients with the first injection, 0.2% with the second injection, and cumulatively 0.8% with subsequent injections. The median time to onset was 3.7 hours (range: 9 minutes to 3.5 days). Of the 84 systemic administration-related reactions that occurred in 52 patients, 73 (87%) occurred on the day of DARZALEX FASPRO™ administration. Delayed systemic administration-related reactions have occurred in less than 1% of the patients.

Severe reactions included hypoxia, dyspnea, hypertension and tachycardia. 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, pruritis, chills, vomiting, nausea, and hypotension.

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.

Local Reactions

In this pooled safety population, injection-site reactions occurred in 8% of patients, including Grade 2 reactions in 0.6%. The most frequent (>1%) injection-site reaction was injection site erythema. These local reactions occurred a median of 7 minutes (range: 0 minutes to 4.7 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 is contraindicated in pregnant women, because lenalidomide may cause birth defects and death of the unborn child. Refer to the lenalidomide 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 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

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, pyrexia, cough, muscle spasms, back pain, vomiting, upper respiratory tract infection, peripheral sensory neuropathy, constipation, and pneumonia.

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.