DARZALEX *FASPRO*™

New temporary C-code issued for DARZALEX *FASPRO*™ on Medicare hospital outpatient claims, effective October 1, 2020

The Centers for Medicare and Medicaid Services (CMS) has issued a temporary, drug-specific code to identify DARZALEX *FASPRO*™ administered in the Hospital Outpatient Department, and billed to Medicare, on or after October 1, 2020: ***C9062 - Injection, daratumumab 10 mg and hyaluronidase-fihj***

Sample CMS-1450 (UB-04) Claim Form

DARZALEX *FASPRO*™ (daratumumab and hyaluronidase-fihj) IS INDICATED FOR 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 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® 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.

DARZALEX *Faspro*™
(daratumumab and hyaluronidase-fihj)
Injection for subcutaneous use | 1,800mg/30,000units

The information provided is valid as of September 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
- ✔ 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

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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*™

Medicare: C9062 – Injection, daratumumab **10 mg** and hyaluronidase-fihj

This is a temporary, drug-specific code required on Medicare claims submitted by Outpatient Prospective Payment System (OPPS) hospitals until a permanent code is assigned; other payers may accept it at their discretion. Non-Medicare payers will typically continue to require J9999.

Non-Medicare: J9999 – Not otherwise classified anti-neoplastic drug*

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*™

For Medicare and non-Medicare payers that require or accept the temporary C code (C9062)

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 DARAZALEX *FASPRO*™ = 180 units

For non-Medicare payers that do <u>not</u> require or accept the temporary C code (J9999)

Bill 1 unit and enter any additional payer-required information in Form Locator 80*

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.

F

Locator Box 80 - 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

*Accurate reporting of miscellaneous drug codes and requirements for supporting information may vary by payer. Please contact your payers for specific coding policies and correct claim submission requirements.

DARZALEX *FASPRO*™ (daratumumab and hyaluronidase-fihj)
CMS-1450 (UB-04) Sample Claim Form

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 — b. MED REC. # DOE 1234-97 — 4 TYPE OF BILL 010001010 — 5 FED. TAX NO. — 6 STATEMENT COVERS PERIOD FROM THROUGH — 7

8 PATIENT NAME a John B Doe / b John B Doe — 9 PATIENT ADDRESS a 123 Any Street / b Any Town / c AS / d 12345 / e US

10 BIRTHDATE 07 01 50 — 11 SEX M — 12 DATE — ADMISSION 13 HR 14 TYPE 15 SRC — 16 DHR — 17 STAT — 18 19 20 21 CONDITION CODES 22 23 24 25 26 27 28 — 29 ACDT STATE — 30

31 OCCURRENCE CODE DATE — 32 OCCURRENCE CODE DATE — 33 OCCURRENCE CODE DATE — 34 OCCURRENCE CODE DATE — 35 OCCURRENCE SPAN CODE FROM THROUGH — 36 OCCURRENCE SPAN CODE FROM THROUGH — 37

38 — 39 VALUE CODES CODE AMOUNT — 40 VALUE CODES CODE AMOUNT — 41 VALUE CODES CODE AMOUNT (a, b, c, d)

B **A** **C** **D**

42 REV. CD	43 DESCRIPTION	44 HCPCS / RATE / HIPPS CODE	45 SERV. D	46 SERV. UNITS	47 TOTAL CHARGES	48 NON-COVERED CHARGES	49
0331	Chemotherapy administration – injection	96401	10-01-20	1			
0636	Darzalex Faspro	C9062	10-01-20	180			

PAGE ___ OF ___ — CREATION DATE — TOTALS

50 PAYER NAME: Medicare — 51 HEALTH PLAN ID — 52 REL INFO — 53 ASG BEN — 54 PRIOR PAYMENTS — 55 EST. AMOUNT DUE — 56 NPI 246 555 1234 — 57 OTHER PRV ID

58 INSURED'S NAME — 59 P REL — 60 INSURED'S UNIQUE ID — 61 GROUP NAME — 62 INSURANCE GROUP NO.

63 TREATMENT AUTHORIZATION CODES — 64 DOCUMENT CONTROL NUMBER — 65 EMPLOYER NAME

E 66 DX: C90.02 — A B C D E F G H I J K L M N O P Q — 68

69 ADMIT DX — 70 PATIENT REASON DX a b c — 71 PPS CODE — 72 ECI — 73

74 PRINCIPAL PROCEDURE CODE DATE — a. OTHER PROCEDURE CODE DATE — b. OTHER PROCEDURE CODE DATE — 75 — c. OTHER PROCEDURE CODE DATE — d. OTHER PROCEDURE CODE DATE — e. OTHER PROCEDURE CODE DATE

76 ATTENDING NPI 123-456-7890 QUAL — LAST Jones FIRST John — 77 OPERATING NPI QUAL LAST FIRST — 78 OTHER NPI QUAL LAST FIRST — 79 OTHER NPI QUAL LAST FIRST

F 80 REMARKS — ICD a b c d

UB-04 CMS-1450 APPROVED OMB NO. — THE CERTIFICATIONS ON THE REVERSE APPLY TO THIS BILL AND ARE MADE A PART HEREOF.

NUBC National Uniform Billing Committee — UC9213257

SAMPLE

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.

cp-143279v1

DARZALEX *Faspro*™
(daratumumab and hyaluronidase-fihj)
Injection for subcutaneous use | 1,800mg/30,000units

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