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 PHYSICIAN OFFICES

Sample CMS-1500 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 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 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 May 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.

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)
Physician Office Sample Claim Form: CMS-1500

A

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

B

Item 24D – Indicate appropriate CPT®†, HCPCS‡ codes, and modifiers (if applicable).

DARZALEX *FASPRO*®

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

Drug Administration

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

C

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

D

Item 24G – 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

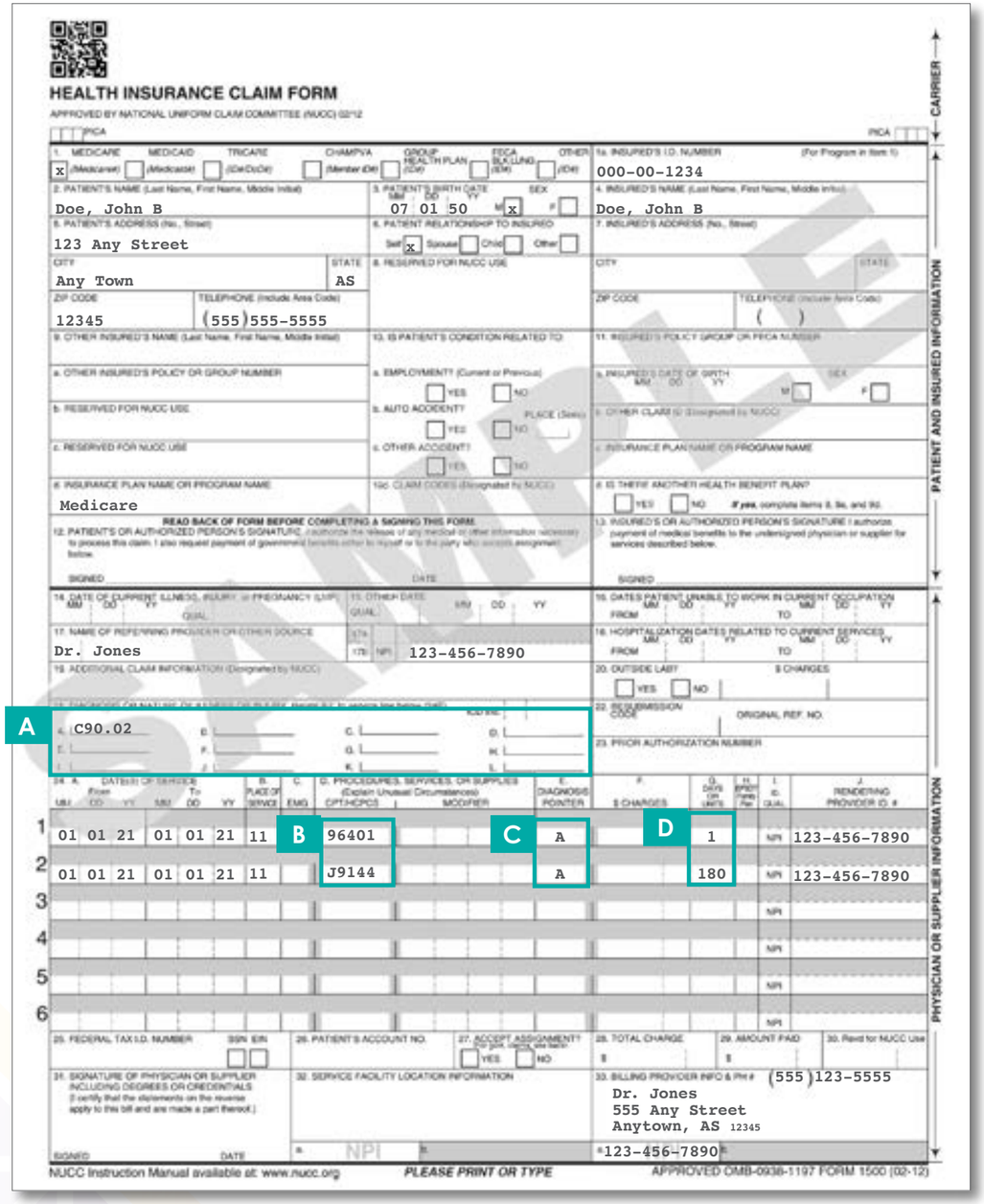
96401 – Enter 1 unit

*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.

†CPT® – Current Procedural Terminology. CPT® is a registered trademark of the American Medical Association, 2021.

‡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.

DARZALEX *FASPRO*® (daratumumab and hyaluronidase-fihj)
CMS-1500 Sample Claim Form 2021



IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

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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 683 patients with multiple myeloma (N=490) or light chain (AL) amyloidosis (N=193) who received DARZALEX *FASPRO*® as monotherapy or in combination, 10% of patients experienced a systemic administration-related reaction (Grade 2: 3.5%, Grade 3: 1%). Systemic administration-related reactions occurred in 9% of patients with the first injection, 0.4% with the second injection, and cumulatively 0.8% with subsequent injections. The median time to onset was 3.2 hours (range: 9 minutes to 3.5 days). Of the 117 systemic administration-related reactions that occurred in 66 patients, 100 (85%) 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, pruritus, 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 9% 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 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 or thalidomide is contraindicated in pregnant women because lenalidomide and thalidomide may cause birth defects and death of the unborn child. Refer to the lenalidomide or thalidomide 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, 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-143279v3

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