DARZALEX®
(daratumumab)
injection for intravenous infusion
100 mg/5 mL, 400 mg/20 mL

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

DARZALEX *FASPRO*® AND DARZALEX®

Reimbursement & Access Guide

Important Information for the Reimbursement Process

DARZALEX *FASPRO*® UPDATE INSIDE

The information provided in this reimbursement guide is valid as of November 2025 and is subject to change.

Please see Important Safety Information for DARZALEX *FASPRO*® on pages 31-32 and click here to see full Prescribing Information.
Please see Important Safety Information for DARZALEX® on pages 59-60 and click here to see full Prescribing Information.

Johnson & Johnson is pleased to provide you with this detailed information to assist you in obtaining reimbursement for **DARZALEX *FASPRO*®** for subcutaneous injection and **DARZALEX®** for intravenous infusion on behalf of your patients. We have developed this Reimbursement and Access Guide to provide coding information, a list of specialty distributors, and important product information that we hope will be helpful to you and your practice.

- 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®*) and Healthcare Common Procedure Coding System (HCPCS) codes are supplied for informational purposes only and represent no statement, promise, or guarantee by Johnson & Johnson 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 every 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 the payer organization for its reimbursement policies.

DARZALEX *FASPRO*® coding summary

Code Type	Code	Description	CMS-1500 Placement	CMS-1450 Placement
Diagnosis ICD-10-CM*	C90.00 C90.01 C90.02 D47.2	Multiple myeloma not having achieved remission Multiple myeloma in remission Multiple myeloma in relapse Monoclonal gammopathy of undetermined significance (MGUS)†	Item 21	Form Locator 67
Procedure CPT®	96401	Chemotherapy administration, subcutaneous or intramuscular; nonhormonal anti-neoplastic	Item 24D	Form Locator 44
Drug HCPCS	J9144	Injection, daratumumab 10 mg and hyaluronidase-fihj	Item 24D	Form Locator 44
Drug FDA-Specified 10-Digit NDC (5-3-2 format)‡	57894-503-01	**1,800 mg daratumumab and 30,000 units hyaluronidase human/15 mL vial** Single-dose vial containing 1,800 mg daratumumab and 30,000 units hyaluronidase per 15 mL	Shaded portion of Item 24	Form Locator 43

*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.

†Smoldering multiple myeloma (SMM) is a plasma cell disorder that has not yet progressed to active multiple myeloma. Code D47.2 should be used when only SMM is documented.

‡Although the FDA uses a 10-digit format when registering NDCs, payers often require an 11-digit NDC format on claim forms for billing purposes. It is important to confirm with your payer if an NDC is needed and the format the payer requires. To convert the 10-digit NDC to the 11-digit format, insert a leading zero into the middle sequence: NDC 57894-0503-01.

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.

FDA, U.S. Food and Drug Administration; mL, milliliter.

DARZALEX® coding summary

Code Type	Code	Description	CMS-1500 Placement	CMS-1450 Placement
Diagnosis ICD-10-CM*	C90.00 C90.01 C90.02	Multiple myeloma not having achieved remission Multiple myeloma in remission Multiple myeloma in relapse	Item 21	Form Locator 67
Procedure CPT®	96413	Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug	Item 24D	Form Locator 44
	96415	Each additional hour (list separately in addition to code for primary procedure)		
Drug HCPCS	J9145	Injection, daratumumab, 10 mg	Item 24D	Form Locator 44
Drug FDA-Specified 10-Digit NDC (5-3-2 format)†	57894-505-05	**100-mg/5-mL vial (20 mg/mL)** Single-dose vial containing 100 mg of daratumumab solution for intravenous infusion	Shaded portion of Item 24	Form Locator 43
	57894-505-20	**400-mg/20-mL vial (20 mg/mL)** Single-dose vial containing 400 mg of daratumumab solution for intravenous infusion		

*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.

†Although the FDA uses a 10-digit format when registering NDCs, payers often require an 11-digit NDC format on claim forms for billing purposes. It is important to confirm with your payer if an NDC is needed and the format the payer requires. To convert the 10-digit NDCs to the 11-digit format, insert a leading zero into the middle sequence:

- NDC 57894-0505-05
- NDC 57894-0505-20

The fact that a drug, device, procedure, or service is assigned an HCPCS code and a payment rate does not imply coverage by the Medicare and/or Medicaid program, but indicates only how the product, procedure, or service may be paid if covered by the program. Fiscal Intermediaries (FIs)/Medicare Administrative Contractors (MACs) and/or state Medicaid administration determine whether a drug, device, procedure, or other service meets all program requirements for coverage.

Table of contents – DARZALEX *FASPRO*® section

Table of contents – DARZALEX® section

DARZALEX *Faspro*®

(daratumumab and hyaluronidase-fihj)

Injection for subcutaneous use | 1,800mg/30,000units

INDICATIONS

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

- In combination with bortezomib, lenalidomide, and dexamethasone for induction and consolidation in newly diagnosed patients who are eligible for autologous stem cell transplant
- 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 (PI)
- 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 PI and an immunomodulatory agent or who are double refractory to a PI and an immunomodulatory agent

DARZALEX *FASPRO*® as monotherapy is indicated for the treatment of adult patients with high-risk smoldering multiple myeloma.

Dosing and Administration

DARZALEX *FASPRO*® is for subcutaneous use only. Do not administer intravenously.

The recommended dose of DARZALEX *FASPRO*® is 1,800 mg/30,000 units (1,800 mg daratumumab and 30,000 units hyaluronidase) administered subcutaneously, over approximately 3-5 minutes, according to the dosing schedule by indication (please see Tables 1 through 6 on pages 10-15).[1] If a planned dose of DARZALEX *FASPRO*® is missed, administer the dose as soon as possible and adjust the dosing schedule to maintain the dosing interval.[1]

DARZALEX *FASPRO*® should be administered by a healthcare professional. Administer medications before and after administration of DARZALEX *FASPRO*® to minimize administration-related reactions.[1]

Pre-medications[1]

Administer the following pre-medications 1-3 hours before each dose of DARZALEX *FASPRO*®:

- Acetaminophen 650 mg to 1,000 mg orally
- Diphenhydramine 25 mg to 50 mg (or equivalent) orally or intravenously
- Corticosteroid (long- or intermediate-acting)

Monotherapy

Administer methylprednisolone 100 mg (or equivalent) orally or intravenously. Consider reducing the dose of methylprednisolone to 60 mg (or equivalent) following the second dose of DARZALEX *FASPRO*®.

In Combination

Administer dexamethasone 20 mg (or equivalent) orally or intravenously prior to every DARZALEX *FASPRO*® administration.

When dexamethasone is the background regimen-specific corticosteroid, the dexamethasone dose that is part of the background regimen will serve as pre-medication on DARZALEX *FASPRO*® administration days.

Do not administer background regimen-specific corticosteroids (eg, prednisone) on DARZALEX *FASPRO*® administration days when patients have received dexamethasone (or equivalent) as a pre-medication.

Post-medications[1]

Administer the following post-medications:

Monotherapy

Administer methylprednisolone 20 mg (or an equivalent dose of an intermediate- or long-acting corticosteroid) orally for 2 days starting the day after the administration of DARZALEX *FASPRO*®.

In Combination

Consider administering oral methylprednisolone at a dose of less than or equal to 20 mg (or an equivalent dose of an intermediate- or long-acting corticosteroid) on the day after administration of DARZALEX *FASPRO*®. If a background regimen-specific corticosteroid (eg, dexamethasone, prednisone) is administered the day after the administration of DARZALEX *FASPRO*®, additional corticosteroids may not be needed.

Note:

- If the patient does not experience a major systemic administration-related reaction after the first 3 doses of DARZALEX *FASPRO*®, consider discontinuing the administration of corticosteroids *(excluding any background regimen-specific corticosteroid)*.
- For patients with a history of chronic obstructive pulmonary disease, consider prescribing short and long-acting bronchodilators and inhaled corticosteroids. Following the first 4 doses of DARZALEX *FASPRO*®, consider discontinuing these additional post-medications, if the patient does not experience a major systemic administration-related reaction.

SELECTED 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 1446 patients with multiple myeloma (N=1235) or light chain (AL) amyloidosis (N=193) who received DARZALEX *FASPRO*® as monotherapy or as part of a combination therapy, 7% of patients experienced a systemic administration-related reaction (Grade 2: 3%, Grade 3: 0.8%, Grade 4: 0.1%). In patients with high-risk smoldering multiple myeloma (N=193), systemic administration-related reactions occurred in 17% of patients in AQUILA (Grade 2: 7%, Grade 3: 1%).

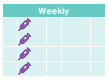
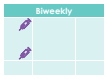
In all patients (N=1639), systemic administration-related reactions occurred in 7% of patients with the first injection, 0.5% with the second injection, and cumulatively 1% with subsequent injections. The median time to onset was 3.2 hours (range: 4 minutes to 3.5 days). Of the 283 systemic administration-related reactions that occurred in 135 patients, 240 (85%) occurred on the day of DARZALEX *FASPRO*® administration. Delayed systemic administration-related reactions have occurred in 1% of the patients.

(Continued on next page.)

DARZALEX *FASPRO*® dosing in multiple myeloma for monotherapy and in combination with lenalidomide and dexamethasone (DRd) or pomalidomide and dexamethasone (DPd) or carfilzomib and dexamethasone (DKd)[1]

- **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 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**
- **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**
- DARZALEX *FASPRO*® (1,800 mg daratumumab/30,000 units hyaluronidase) is administered subcutaneously over approximately 3-5 minutes
- When DARZALEX *FASPRO*® is administered as part of a combination therapy, see the Clinical Studies section (14.2) of the DARZALEX *FASPRO*® Prescribing Information and the prescribing information for dosage recommendations for the other drugs

Table 1: DARZALEX *FASPRO*® Dosing in DRd, DPd, DKd and Monotherapy Regimens

4 Doses Per 28-Day Cycle		given as a **once weekly** dose (4 doses per 4-week cycle; Cycles 1 to 2; Weeks 1 to 8)
2 Doses Per 28-Day Cycle		given as 1 dose **every 2 weeks** (twice per 4-week cycle; Cycles 3 to 6; Weeks 9 to 24)
1 Dose Per 28-Day Cycle		given as 1 dose **every 4 weeks** (once per 4-week cycle; Cycles 7+, Weeks 25+ until disease progression)
23  **Total Doses**		ESTIMATED Year 1

- The dosing schedules for DRd, DPd, DKd, and DARZALEX *FASPRO*® monotherapy are based on a 28-day (4-week) cycle throughout therapy
- Starting at Week 25, administration frequency for DARZALEX *FASPRO*® in combination with Rd, Pd, or Kd, and as monotherapy is once every 4 weeks

SELECTED IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (cont'd)

Hypersensitivity and Other Administration Reactions (cont'd)

Systemic Reactions (cont'd)

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.

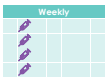
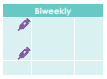
(Continued on next page.)

DARZALEX *FASPRO*® dosing in combination with bortezomib, melphalan, and prednisone (DVMP)[1]

For the treatment of adult patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant

- DARZALEX *FASPRO*® (1,800 mg daratumumab/30,000 units hyaluronidase) is administered subcutaneously over approximately 3-5 minutes
- When DARZALEX *FASPRO*® is administered as part of a combination therapy, see the Clinical Studies section (14.1) of the DARZALEX *FASPRO*® Prescribing Information and the prescribing information for dosage recommendations for the other drugs

Table 2: DARZALEX *FASPRO*® Dosing in DVMP Regimen

6 Doses Per 6-Week Cycle		given as a **once weekly** dose (6 doses per 6-week cycle; Cycle 1; Weeks 1 to 6)
2 Doses Per 6-Week Cycle		given as 1 dose **every 3 weeks** (twice per 6-week cycle; Cycles 2 to 9; Weeks 7 to 54)
1 Dose Per 4-Week Cycle		given as 1 dose **every 4 weeks** (once per 4-week cycle; Cycles 10+; Weeks 55+ until disease progression)
22 Total Doses		ESTIMATED Year 1

- The dosing schedule for DVMP is based on an initial 6-week dosing cycle (Cycles 1 to 9) followed by 28-day (4-week) cycles with DARZALEX *FASPRO*®[1]; VMP administration should be stopped after 9 cycles
- Starting at Cycle 10 (Week 55+), administration frequency for DARZALEX *FASPRO*® in combination with VMP is once every 4 weeks

SELECTED IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (cont'd)

Hypersensitivity and Other Administration Reactions (cont'd)

Systemic Reactions (cont'd)

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.

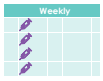
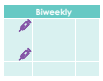
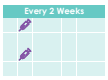
Ocular adverse reactions, including acute myopia and narrowing of the anterior chamber angle due to ciliochoroidal effusions with potential for increased intraocular pressure or glaucoma, have occurred with daratumumab-containing products. If ocular symptoms occur, interrupt DARZALEX *FASPRO*® and seek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

DARZALEX *FASPRO*® dosing in combination with bortezomib, thalidomide, and dexamethasone (DVTd)[1]

For the treatment of adults with newly diagnosed multiple myeloma who are eligible for autologous stem cell transplant (ASCT)

- DARZALEX *FASPRO*® (1,800 mg daratumumab/30,000 units hyaluronidase) is administered subcutaneously over approximately 3-5 minutes
- When DARZALEX *FASPRO*® is administered as part of a combination therapy, see the prescribing information for dosage recommendations for the other drugs

Table 3: DARZALEX *FASPRO*® Dosing in DVTd Regimen

Induction	4 Doses Per 28-Day Cycle		given as a **once weekly** dose (4 doses per 4-week cycle; Cycles 1 to 2; Weeks 1 to 8)
	2 Doses Per 28-Day Cycle		given as 1 dose **every 2 weeks** (twice per 4-week cycle; Cycles 3 to 4; Weeks 9 to 16)
STOP FOR HIGH-DOSE CHEMOTHERAPY AND ASCT			
Consolidation	2 Dose Per 28-Day Cycle		given as 1 dose **every 2 weeks** (twice per 4-week cycle; Cycles 5 and 6; Weeks 1 to 8 of consolidation phase)
	16 Total Doses		23 weeks

- The dosing schedule for DVTd is based on an initial 4-week dosing cycle (Cycles 1 to 2)
- Starting at Week 9, administration frequency of DVTd is once every 2 weeks (Cycles 3 to 4)
- Upon re-initiation of treatment following ASCT, the first dose of the every-2-week dosing schedule is given at Week 1

SELECTED IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (cont'd)

Hypersensitivity and Other Administration Reactions (cont'd)

Local Reactions

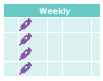
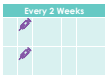
In this pooled safety population of 1446 patients with multiple myeloma (N=1253) or light chain amyloidosis (N=193), injection-site reactions occurred in 8% of patients, including Grade 2 reactions in 1.1%. The most frequent (>1%) injection-site reactions were injection site erythema and injection site rash. In patients with high-risk smoldering multiple myeloma (N=193), injection-site reactions occurred in 28% of patients, including Grade 2 reactions in 3%. These local reactions occurred a median of 6 minutes (range: 0 minutes to 6.5 days) after starting administration of DARZALEX *FASPRO*®. Monitor for local reactions and consider symptomatic management.

DARZALEX *FASPRO*® dosing in combination with bortezomib, lenalidomide, and dexamethasone (DVRd)[1]

For induction and consolidation in newly diagnosed patients who are eligible for autologous stem cell transplant

- DARZALEX *FASPRO*® (1,800 mg daratumumab/30,000 units hyaluronidase) is administered subcutaneously over approximately 3-5 minutes
- When DARZALEX *FASPRO*® is administered as part of a combination therapy, see Clinical Studies (14.1) and the prescribing information for dosage recommendations for the other drugs

Table 4: DARZALEX *FASPRO*® Dosing in DVRd Regimen

Induction	**4** Doses Per 28-Day Cycle		given as a **once weekly** dose (4 doses per 4-week cycle; Cycles 1 to 2; Weeks 1 to 8)
	2 Doses Per 28-Day Cycle		given as 1 dose **every 2 weeks** (twice per 4-week cycle; Cycles 3 to 4; Weeks 9 to 16)
STOP FOR HIGH-DOSE CHEMOTHERAPY AND ASCT			
Consolidation	**2** Dose Per 28-Day Cycle		given as 1 dose **every 2 weeks** (twice per 4-week cycle; Cycles 5 and 6; Weeks 1 to 8 of consolidation phase)
	16 Total Doses		ESTIMATED Year 1

- The dosing schedule for DVRd is based on an initial 4-week dosing cycle (Cycles 1 to 2)
- Starting at Week 9, administration frequency of DVRd is once every 2 weeks (Cycles 3 to 4)
- The consolidation phase starts at Week 1 upon re-initiation of treatment following ASCT; from Week 1 until Week 8, administration frequency is one dose every 2 weeks (Cycles 5 to 6)

SELECTED IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (cont'd)

Infections

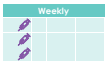
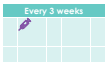
DARZALEX *FASPRO*® can cause serious, life-threatening, or fatal infections. In patients who received DARZALEX *FASPRO*® in a pooled safety population including patients with smoldering multiple myeloma and light chain (AL) amyloidosis (N=1639), serious infections, including opportunistic infections, occurred in 24% of patients, Grade 3 or 4 infections occurred in 22%, and fatal infections occurred in 2.5%. The most common type of serious infection reported was pneumonia (8.5%).

Monitor patients for signs and symptoms of infection prior to and during treatment with DARZALEX *FASPRO*® and treat appropriately. Administer prophylactic antimicrobials according to guidelines.

DARZALEX *FASPRO*® dosing in combination with bortezomib and dexamethasone (DVd)[1]

- **In combination with bortezomib and dexamethasone in patients who have received at least one prior therapy**
- DARZALEX *FASPRO*® (1,800 mg daratumumab/30,000 units hyaluronidase) is administered subcutaneously over approximately 3-5 minutes
- When DARZALEX *FASPRO*® is administered as part of a combination therapy, see the prescribing information for dosage recommendations for the other drugs

Table 5: DARZALEX *FASPRO*® Dosing in DVd Regimen

3 Doses Per 21-Day Cycle		given as a **once weekly** dose (3 doses per 3-week cycle; Cycles 1 to 3; Weeks 1 to 9)
1 Doses Per 21-Day Cycle		given as 1 dose **every 3 weeks** (once per 3-week cycle; Cycles 4 to 8; Weeks 10 to 24)
1 Dose Per 4-Week Cycle		given as 1 dose **every 4 weeks** (once per 4-week cycle; Cycles 9+; Weeks 25+ until disease progression)
21 Total Doses		ESTIMATED Year 1

- The dosing schedule for DVd is based on an initial 21-day (3-week) cycle for Weeks 1 to 24, followed by 28-day (4-week) cycles with DARZALEX *FASPRO*®; bortezomib and dexamethasone should be stopped after 8 cycles
- Starting at Week 25, administration frequency for DARZALEX *FASPRO*® in combination with Vd is once every 4 weeks

SELECTED IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (cont'd)

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.

DARZALEX *FASPRO*® dosing as monotherapy in high-risk smoldering multiple myeloma[1]

- **For the treatment of adults with high-risk smoldering multiple myeloma**
- The recommended dose of DARZALEX *FASPRO*® is 1,800 mg/30,000 units (1,800 mg daratumumab and 30,000 units hyaluronidase) administered subcutaneously over approximately 3-5 minutes

Table 6: DARZALEX *FASPRO*® Dosing High-Risk Smoldering Multiple Myeloma (SMM)

4 Doses Per 4-Week Cycle		given as a **once weekly** dose (4 doses per 4-week cycle; Cycles 1-2; Weeks 1-8)
2 Doses Per 4-Week Cycle		given as one dose **every 2 weeks** (twice per 4-week cycle; Cycles 3 to 6; Weeks 9-24)
1 Dose Per 4-Week Cycle		given as one dose **every 4 weeks** (once per 4-week cycle; Cycles 7+; Weeks 25+ until diagnosis of multiple myeloma or a maximum of 3 years)
23  Total Doses		ESTIMATED Year 1

- The dosing schedule for high-risk SMM is based on a 4-week cycle
- Starting at Week 9, administration is once every 2 weeks
- Starting at Week 25, administration frequency is once every 4 weeks

SELECTED IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (cont'd)

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.

Coding for DARZALEX *FASPRO*®

National Drug Codes (NDC)

The National Drug Code (NDC) is a unique number that identifies a drug's labeler, product, and trade package size. The NDC is most often used on pharmacy claims, including drugs provided for home infusion. However, the NDC is also required on Medicare claims for dual eligible beneficiaries (Medicaid cross-over claims),[2] and by some private payers.[3] Although the FDA uses a 10-digit format when registering NDCs, payers often require an 11-digit NDC format on claim forms for billing purposes. It is important to confirm with your payer if an NDC is needed and the format the payer requires. Electronic data exchange generally requires use of the 11-digit NDC. To convert the 10-digit format to the 11-digit format, insert a leading zero into the middle sequence, as illustrated below:

Table 7: National Drug Codes for DARZALEX *FASPRO*®

FDA-Specified 10-Digit NDC (5-3-2 format)	11-Digit NDC (5-4-2 format)	Description	
57894-503-01	57894-0503-01		**1,800 mg daratumumab and 30,000 units hyaluronidase/15-mL vial** Single dose vial containing 1,800 mg daratumumab and 30,000 units hyaluronidase for subcutaneous injection

FDA, U.S. Food and Drug Administration.

Reporting the NDC on professional or institutional claims requires similar information and formats. The NDC unit of measure is determined by how a drug is supplied. In the outpatient setting, ML (milliliters) applies to drugs supplied in vials in liquid form. The NDC quantity reported is based on the NDC quantity dispensed. If the NDC unit of measure is ML, then the NDC quantity reported will equal the amount of mL given to the patient.[3] Table 8, on the following page, illustrates NDC coding for DARZALEX *FASPRO*® (1,800 mg daratumumab and 30,000 units hyaluronidase).

SELECTED IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (cont'd)

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.

National Drug Codes (NDC) (cont'd)

Table 8: DARZALEX *FASPRO*® NDC Units

Dose to be billed	11-digit NDC (5-4-2 format)	Packaging	NDC Unit of Measure	NDC Units
1,800 mg daratumumab and 30,000 units hyaluronidase	57894-0503-01	**1,800 mg daratumumab and 30,000 units hyaluronidase/ 15 mL vial (liquid)**	ML	15

In this example the drug is supplied as a liquid in 15-mL vials (1,800 mg daratumumab/30,000 units hyaluronidase). One vial = 15 NDC units. The drug is packaged in liquid form so the NDC unit of measure is "ML."

Accurate NDC coding* typically requires the following components:

- Reporting the NDC with 11 digits in a 5-4-2 configuration; this may require converting a 10-digit NDC to an 11-digit NDC
- Reporting the correct NDC unit of measure (ie, ML)
- Reporting the number of NDC units dispensed
- Reporting the qualifier, N4, in front of the NDC[2]

Using the same DARZALEX *FASPRO*® example from Table 8, here is how the format would appear on a professional claim:

N457894050301 ML15

For professional claims (CMS-1500), report the NDC information in the shaded portion of Item 24.[2]

The NDC format for institutional claims varies only with the elimination of a space between the NDC and unit of measure. Here is how the NDC would appear on a facility claim:

N457894050301ML15

For institutional claims (CMS-1450), report the NDC information in Locator Box 43.[4]

*Payer requirements for NDC use and format may vary. Please contact your payers for specific coding policies and more information on correct billing and claims submission.

HCPCS Codes

Drugs are typically reported with Healthcare Common Procedure Coding System (HCPCS) codes assigned by the Centers for Medicare & Medicaid Services (CMS). The HCPCS code for DARZALEX *FASPRO*® is:

- J9144 - Injection, daratumumab 10 mg and hyaluronidase-fihj injection[5]

Each 1,800-mg vial of drug represents 180 units of J9144.

Inaccurate reporting of drug HCPCS units is a common claims error and can result in denied or delayed payment. When coding for J9144, report the total number of 10-mg increments administered. Table 9 illustrates the correlation between DARZALEX *FASPRO*® vials, milligrams, and HCPCS units used for billing.

Table 9: DARZALEX *FASPRO*® HCPCS Billing Units

Number of 1,800-mg vials of DARZALEX *FASPRO*®	Total milligrams (mg)	Number of billing units based on J9144 (10 mg DARZALEX *FASPRO*® per unit)
1	1,800	180

The fact that a drug, device, procedure, or service is assigned an HCPCS code and a payment rate does not imply coverage by the Medicare and/or Medicaid program, but indicates only how the product, procedure, or service may be paid if covered by the program. Fiscal Intermediaries (FIs)/ Medicare Administrative Contractors (MACs) and/or state Medicaid administration determine whether a drug, device, procedure, or other service meets all program requirements for coverage.

SELECTED IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (cont'd)

Interference With Serological Testing (cont'd)

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*®.

CPT® Codes

Current Procedural Terminology (CPT®) codes are the most widely accepted medical nomenclature used to report medical procedures and services under public and private health insurance programs. Drug administration services are reported on claim forms in both the physician office (CMS-1500) and hospital outpatient (CMS-1450) sites of care using the CPT® coding system. Healthcare providers are responsible for selecting appropriate codes for any specific claim based on the patient's condition, the items and services that are furnished, and any specific payer requirements.*

The CPT® code commonly associated with the administration of DARZALEX *FASPRO*® is:

- 96401 - Chemotherapy administration, subcutaneous or intramuscular; non-hormonal anti-neoplastic[6]

Typically, chemotherapy services require advance practice training and competency for staff who provide these services; special considerations for preparation, dosage or disposal; and commonly these services entail significant patient risk and frequent monitoring.[6] When performed to facilitate the injection, preparation of chemotherapy agents is included and not reported separately.[6]

*Payer policies for codes used to describe drug administration services may vary. Consult your payers for guidance. For additional assistance, contact J&J withMe.

ICD-10-CM Diagnosis Codes

All parties covered by the Health Insurance Portability and Accountability Act (HIPAA), not just providers who bill Medicare or Medicaid, are required to use the International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM) codes to document patient diagnoses. ICD-10-CM far exceeds previous coding systems in the number of concepts and codes provided, allowing for greater specificity when describing patient conditions.

ICD-10-CM diagnosis codes use 3 to 7 alpha and numeric characters to achieve this level of detail. Code to the highest level of specificity when supported by the medical record documentation.[7]

Table 10: Diagnosis Codes* for Consideration

ICD-10-CM Codes and Descriptors[8]	
C90.00	Multiple myeloma not having achieved remission
C90.01	Multiple myeloma in remission
C90.02	Multiple myeloma in relapse
D47.2	Monoclonal gammopathy of undetermined significance (MGUS)†

*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.

†Smoldering multiple myeloma (SMM) is a plasma cell disorder that has not yet progressed to active multiple myeloma. Code D47.2 should be used when only SMM is documented.

FDA, U.S. Food and Drug Administration.

Other Coding Considerations

When coding and billing for DARZALEX *FASPRO*® and drug administration services, providers also may need to describe concomitant services or supplies or account for modification to a service. This section reviews some of those additional considerations.

Modifiers

Modifiers are used to report or indicate that a service or procedure has been altered by some specific circumstance but not changed in its definition or code. They provide additional information about a service or procedure and help to eliminate the appearance of duplicate billing and unbundling. Appropriately used, modifiers improve coding and reimbursement accuracy. Table 11 summarizes modifiers that may be applicable to the provision of DARZALEX *FASPRO*® in physician offices and hospital outpatient departments.

SELECTED IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (cont'd)

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.

Table 11: Summary of Code Modifiers

Modifier	Description	Indication and Placement	CMS-1500 Item 24D	CMS-1450 Locator Box 44
25	Significant, separately identifiable evaluation and management service by the same physician or other qualified healthcare professional on the same day of the procedure or other service[6]	• Patient requires distinct evaluation and management (E/M) service in addition to the infusion procedure[6] • Must be substantiated with relevant documentation[6] • Append the modifier to the relevant E/M code[6]	✓	✓
PN*	Non-excepted service provided at an off-campus, outpatient, provider-based department of a hospital[9]	• Non-excepted, off-campus, provider-based departments of a hospital are required to report this modifier on each claim line for non-excepted items and services[9]	N/A	✓ Required by Medicare
PO*	Excepted service provided at an off-campus, outpatient, provider-based department (PBD) of a hospital[9]	• Should be reported with every HCPCS code for all outpatient hospital items and services furnished in an excepted, off-campus, provider-based department of a hospital[9]	N/A	✓ Required by Medicare
TB	Drug or biological acquired with 340B drug pricing[5]	• Must be reported by all 340B covered entities that submit claims for separately payable Part B drugs and biologicals[10] • Report the "TB" modifier on the same claim line as the HCPCS code for 340B acquired drugs[10]	N/A	✓ Required by Medicare
JW	Drug amount discarded/not administered to any patient[11]	• Unused drug remains after applicable dose is administered from single-dose vial[11] • Append the modifier to the HCPCS drug code on a line separate from that reporting the administered dose and document the administered and discarded amounts in the medical record[11]	✓ Required by Medicare	✓ Required by Medicare
JZ	No discarded drug amounts[5]	• Attests that there are no amounts of drugs or biologicals from single-dose containers or packages unused and discarded[11] • Append the modifier to the HCPCS drug code on the claim line with the administered amount[11]	✓ Required by Medicare	✓ Required by Medicare

*Neither the PO nor the PN modifier is to be reported by: a dedicated emergency department; a provider-based department that is "on the campus," or within 250 yards, of the hospital, or a remote location of the hospital.[9]

Same-Day Evaluation and Management Services

It may be necessary to provide evaluation and management (E/M) services on the same day as a drug administration procedure. Depending on the payer, E/M services that are medically necessary, separate and distinct from the drug administration procedure, and documented appropriately, are generally covered.

Please note that CMS has a specific policy regarding use of CPT® code 99211 (level 1 medical visit for an established patient) in the physician office. The policy states:

CPT® code 99211 cannot be paid if it is billed, with or without modifier 25, with a chemotherapy or nonchemotherapy drug administration code.[12]

Thus, CPT® code 99211 cannot be paid on the same day as an office-based injection of DARZALEX *FASPRO*®. If a chemotherapy service and a significantly identifiable evaluation and management service are provided on the same day, a different diagnosis is not required.[12]

Drugs Supplied at No Cost to the Provider

To avoid a chemotherapy or other drug administration code denial, a drug code must be present on the same or prior claim. Under certain circumstances, qualified patients may acquire donated or no-cost drug, or drugs may be covered under a pharmacy benefit and delivered to the administering provider. When the drug was supplied by a third party, at no cost to the provider, it should NOT be billed to Medicare or any other payer. However, the administration of the drug, regardless of the source, is a service that represents an expense to the physician. Therefore, administration of the drug is payable if the drug would have been covered if the physician purchased it. When reporting drug administration services for free-of-charge drugs, include the drug information and enter "0.01" charges. This will allow the claim processing system to register the drug claim as being allowed, which should allow the administration.[13] Payer policies may vary.

Place of Service Codes

The Place of Service (POS) code set provides setting information necessary to appropriately pay professional service claims. The POS is the location of the provider's face-to-face encounter with the beneficiary. POS codes are required on all claims for professional services (billed on CMS-1500). Under the Physician Fee Schedule (PFS), some procedures have separate rates for professional services when provided in facility and nonfacility settings. Therefore, it is important to accurately designate the POS to assure appropriate payment.

The physician practice setting is indicated with POS code 11.[2] To differentiate between on-campus and off-campus provider-based departments, CMS created a new POS code (POS 19) and revised the POS code description for outpatient hospital (POS 22).[2] Professional services delivered in outpatient hospital settings must now specifically include the off-campus or on-campus POS on the claim form.

Table 12 summarizes the potentially applicable place of service codes:

Table 12: Place of Service Codes[2]

POS Code	POS Name	POS Descriptor
11	Office	Location, other than a hospital, skilled nursing facility (SNF), military treatment facility, community health center, state or local public health clinic, or intermediate care facility (ICF), where the health professional routinely provides health examinations, diagnosis, and treatment of illness or injury on an ambulatory basis.[2]
19	Off Campus – Outpatient Hospital	A portion of an off-campus hospital provider-based department that provides diagnostic, therapeutic (both surgical and nonsurgical), and rehabilitation services to sick or injured persons who do not require hospitalization or institutionalization.[2]
22	On Campus – Outpatient Hospital	A portion of a hospital's main campus that provides diagnostic, therapeutic (both surgical and nonsurgical), and rehabilitation services to sick or injured persons who do not require hospitalization or institutionalization.[2]

SELECTED IMPORTANT SAFETY INFORMATION

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, rash, pyrexia, cough, muscle spasms, back pain, vomiting, hypertension, musculoskeletal pain, upper respiratory tract infection, peripheral neuropathy, peripheral sensory neuropathy, constipation, pneumonia, edema, peripheral edema, and anemia.

The most common adverse reactions (≥20%) in patients with high-risk smoldering multiple myeloma who received DARZALEX *FASPRO*® monotherapy are upper respiratory tract infection, musculoskeletal pain, fatigue, diarrhea, rash, sleep disorder, sensory neuropathy, and injection site reactions.

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

DARZALEX *FASPRO*® 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-CM Diagnosis Codes* for Consideration[8]		
	C90.00	Multiple myeloma not having achieved remission
	C90.01	Multiple myeloma in remission
	C90.02	Multiple myeloma in relapse
	D47.2	Monoclonal gammopathy of undetermined significance (MGUS)

*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.

B

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

DARZALEX *FASPRO*®

- **J9144** - Injection, daratumumab, 10 mg and hyaluronidase-fihj
- **JZ modifier** - No discarded amount from a single-dose container

Drug Administration

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

Note: If the NDC is required, it will be entered in the shaded portion of Item 24.

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*®

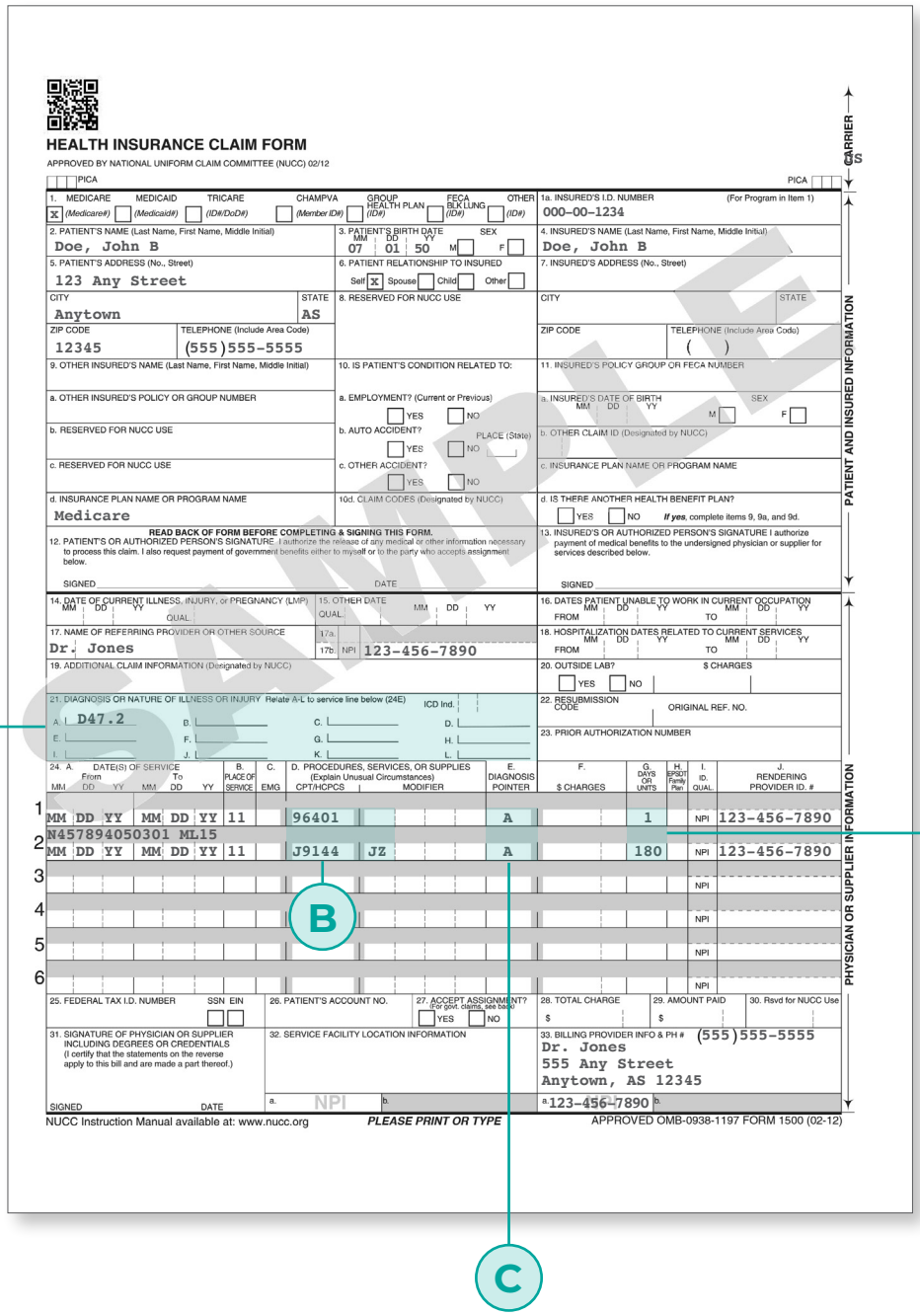
- **J9144** - Enter the amount of drug in HCPCS units according to the drug-specific descriptor and dose: 10 mg, 1 unit; each 1,800 mg dose of DARZALEX *FASPRO*®, 180 units

Drug Administration

- **96401** - Enter 1 unit

The fact that a drug, device, procedure, or service is assigned an HCPCS code and a payment rate does not imply coverage by the Medicare and/or Medicaid program, but indicates only how the product, procedure, or service may be paid if covered by the program. Fiscal Intermediaries (FIs)/Medicare Administrative Contractors (MACs) and/or state Medicaid administration determine whether a drug, device, procedure, or other service meets all program requirements for coverage.

DARZALEX *FASPRO*® CMS-1500 Sample Claim Form



HEALTH INSURANCE CLAIM FORM

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

PICA

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

1a. INSURED'S I.D. NUMBER (For Program in Item 1): 000-00-1234

2. PATIENT'S NAME (Last Name, First Name, Middle Initial): Doe, John B

3. PATIENT'S BIRTH DATE: 07 01 50 | SEX: M

4. INSURED'S NAME (Last Name, First Name, Middle Initial): Doe, John B

5. PATIENT'S ADDRESS (No., Street): 123 Any Street

6. PATIENT RELATIONSHIP TO INSURED: Self [X] Spouse Child Other

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

CITY: Anytown | STATE: AS

8. RESERVED FOR NUCC USE

CITY | STATE

ZIP CODE: 12345 | TELEPHONE (Include Area Code): (555)555-5555

ZIP CODE | TELEPHONE (Include Area Code)

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

10. IS PATIENT'S CONDITION RELATED TO:

11. INSURED'S POLICY GROUP OR FECA NUMBER

a. OTHER INSURED'S POLICY OR GROUP NUMBER

a. EMPLOYMENT? (Current or Previous) YES NO

a. INSURED'S DATE OF BIRTH MM DD YY | SEX M F

b. RESERVED FOR NUCC USE

b. AUTO ACCIDENT? YES NO PLACE (State)

b. OTHER CLAIM ID (Designated by NUCC)

c. RESERVED FOR NUCC USE

c. OTHER ACCIDENT? YES NO

c. INSURANCE PLAN NAME OR PROGRAM NAME

d. INSURANCE PLAN NAME OR PROGRAM NAME: Medicare

10d. CLAIM CODES (Designated by NUCC)

d. IS THERE ANOTHER HEALTH BENEFIT PLAN? YES NO *If yes*, complete items 9, 9a, and 9d.

READ BACK OF FORM BEFORE COMPLETING & SIGNING THIS FORM.

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

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

15. OTHER DATE QUAL. MM DD YY

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

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

17a.

17b. NPI 123-456-7890

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

A. D47.2 B. C. D. E. F. G. H. I. J. K. L.

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	C. EMG	D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS	MODIFIER	E. DIAGNOSIS POINTER	F. $ CHARGES	G. DAYS OR UNITS	H. EPSDT Family Plan	I. ID. QUAL.	J. RENDERING PROVIDER ID. #
1	MM DD YY MM DD YY	11		96401		A		1		NPI	123-456-7890
2	N457894050301 ML15 MM DD YY MM DD YY	11		J9144	JZ	A		180		NPI	123-456-7890
3										NPI	
4										NPI	
5										NPI	
6										NPI	

25. FEDERAL TAX I.D. NUMBER SSN EIN | 26. PATIENT'S ACCOUNT NO. | 27. ACCEPT ASSIGNMENT? (For govt. claims, see back) YES NO | 28. TOTAL CHARGE $ | 29. AMOUNT PAID $ | 30. Rsvd 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

32. SERVICE FACILITY LOCATION INFORMATION

a. NPI b.

33. BILLING PROVIDER INFO & PH # (555)555-5555

Dr. Jones
555 Any Street
Anytown, AS 12345

a. 123-456-7890 b.

NUCC Instruction Manual available at: www.nucc.org

PLEASE PRINT OR TYPE

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

CARRIER

PATIENT AND INSURED INFORMATION

PHYSICIAN OR SUPPLIER INFORMATION

SAMPLE

A

B

C

D

DARZALEX *FASPRO*® 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.

Note: If the NDC is required, it will be entered in Locator Box 43.

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
- **JZ modifier** - No discarded amount from a single-dose container

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

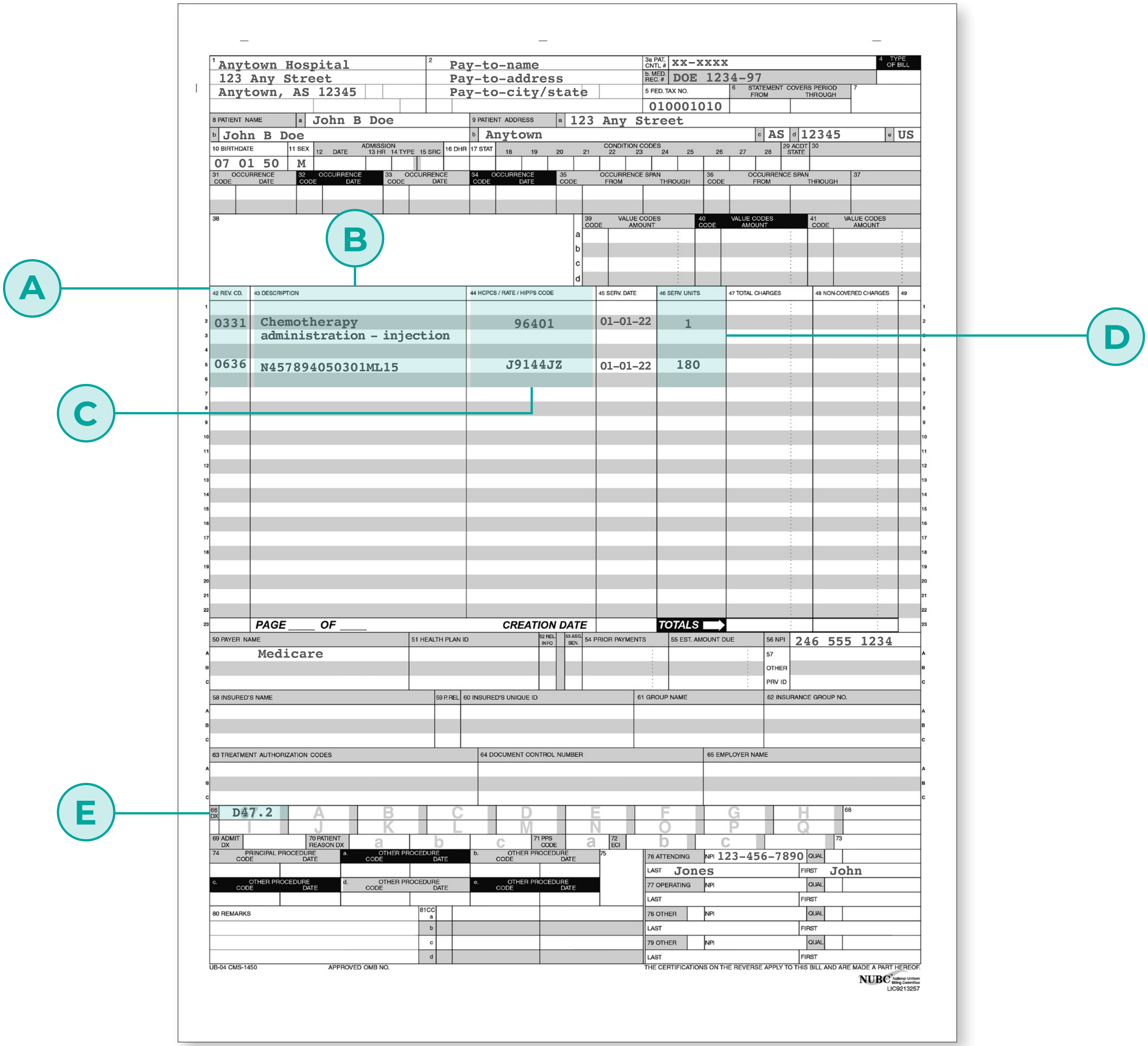
E **Locator Box 67** - Indicate diagnosis using appropriate ICD-10-CM codes. Code to the highest level of specificity for the date of service, and enter diagnoses in priority order.

ICD-10 Diagnosis Codes* for Consideration[8]		
	C90.00	Multiple myeloma not having achieved remission
	C90.01	Multiple myeloma in remission
	C90.02	Multiple myeloma in relapse
	D47.2	Monoclonal gammopathy of undetermined significance (MGUS)

*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.

The fact that a drug, device, procedure, or service is assigned an HCPCS code and a payment rate does not imply coverage by the Medicare and/or Medicaid program, but indicates only how the product, procedure, or service may be paid if covered by the program. Fiscal Intermediaries (FIs)/Medicare Administrative Contractors (MACs) and/or state Medicaid administration determine whether a drug, device, procedure, or other service meets all program requirements for coverage.

DARZALEX *FASPRO*® CMS-1450 (UB-04) Sample Claim Form



Sample Letter of Medical Necessity: DARZALEX *FASPRO*®

Some payers and other formulary decision-makers may require that treating physicians complete a Letter of Medical Necessity or request a formulary exception before patients can receive a specific therapy. We have provided a sample Letter of Medical Necessity and a sample Letter of Formulary Exception Request below.* Please visit **www.JNJwithMe.com/hcp/DARZALEX-FASPRO** for digital sample letter templates.

[Insert Physician Letterhead]

[Insert Name of Medical Director]
[Insert Payer Name]
[Insert Address]
[Insert City, State Zip]

RE: Member Name: [Insert Member Name]
Member Number: [Insert Member Number]
Group Number: [Insert Group Number]

REQUEST: Authorization for treatment with DARZALEX *FASPRO*® (daratumumab and hyaluronidase-fihj) injection for subcutaneous use.

DIAGNOSIS: [Insert Diagnosis] [Insert ICD]

DOSAGE FORM AND STRENGTH: 1,800 mg daratumumab and 30,000 units hyaluronidase per 15 mL

REQUEST TYPE: ☐ Standard ☐ EXPEDITED

Dear [Insert name of Medical Director or name of individual responsible for prior authorization]:

I am writing to support my request for an **authorization** for the above-mentioned patient to receive treatment with DARZALEX *FASPRO*® for [Insert Indication]. My request is supported by the following:

Summary of Patient's Diagnosis

[Insert patient's diagnosis, date of diagnosis, lab results and date, current condition]

Summary of Patient's History

[Insert:

- Previous therapies/procedures, including dose and duration, and response to those interventions
- Description of patient's recent symptoms/condition
- Site of medical service—include site type (eg, inpatient, hospital outpatient, outpatient clinic, private practice, or other) and rationale (eg, compliance or closely monitoring patients)
- Rationale for not using drugs that are on the plan's formulary
- Summary of your professional opinion of the patient's likely prognosis or disease progression without treatment with DARZALEX *FASPRO*®.

Note: Exercise your medical judgment and discretion when providing a diagnosis and characterization of the patient's medical condition.]

Rationale for Treatment

[Insert summary statement for rationale for treatment such as: Considering the patient's history, condition, and the full Prescribing Information supporting uses of DARZALEX *FASPRO*®, I believe treatment with DARZALEX *FASPRO*® at this time is medically necessary, and should be a covered and reimbursed service.]

[You may consider including documents that provide additional clinical information to support the recommendation for DARZALEX *FASPRO*® for this patient, such as the full Prescribing Information, peer-reviewed journal articles, or clinical guidelines.]

[Given the urgent nature of this request,] please provide a timely authorization. Contact my office at [Insert Phone Number] if I can provide you with any additional information.

Sincerely,

[Insert Physician Name and Participating Provider Number]

Enclosures [Include full Prescribing Information and the additional support noted above]

***PLEASE NOTE:** These are sample letters. Use of these letters does not guarantee reimbursement.

Sample Letter of Formulary Exception Request: DARZALEX *FASPRO*®*

[Insert Physician Letterhead]

[Insert Name of Medical Director]
[Insert Payer Name]
[Insert Address]
[Insert City, State Zip]

RE: Member Name: [Insert Member Name]
Member Number: [Insert Member Number]
Group Number: [Insert Group Number]

REQUEST: Authorization for treatment with DARZALEX *FASPRO*® (daratumumab and hyaluronidase-fihj) injection for subcutaneous use.
DIAGNOSIS: [Insert Diagnosis] [Insert ICD]
DOSAGE FORM AND STRENGTH: 1,800 mg daratumumab and 30,000 Units hyaluronidase per 15 mL
REQUEST TYPE: ☐ Standard ☐ EXPEDITED

Dear [Insert Name of Medical Director]:

I am writing to request a **formulary exception** for the above-mentioned patient to receive treatment with DARZALEX *FASPRO*® for [insert indication]. My request is supported by the following:

Summary of Patient's Diagnosis
[Insert patient's diagnosis, date of diagnosis, lab results and date, current condition]

Summary of Patient's History
[Insert:

- Previous therapies/procedures, including dose and duration, and response to those interventions
- Description of patient's recent symptoms/condition
- Site of medical service—include site type: Inpatient, hospital outpatient, outpatient clinic, private practice, or other
- Rationale for not using drugs that are on the plan's formulary
- Summary of your professional opinion of the patient's likely prognosis or disease progression without treatment with DARZALEX *FASPRO*®.

Note: Exercise your medical judgment and discretion when providing a diagnosis and characterization of the patient's medical condition.]

Rationale for Treatment
[Insert summary statement for rationale for treatment such as: Considering the patient's history, condition, and the full Prescribing Information supporting uses of DARZALEX *FASPRO*®, I believe treatment with DARZALEX *FASPRO*® at this time is medically necessary, and should be a covered and reimbursed service.]

[You may consider including documents that provide additional clinical information to support the recommendation for DARZALEX *FASPRO*® for this patient, such as the full Prescribing Information, peer-reviewed journal articles, or clinical guidelines.]

[Given the urgent nature of this request,] please provide a timely authorization. Contact my office at [Insert Phone Number] if I can provide you with any additional information.

Sincerely,
[Insert Physician Name and Participating Provider Number]

Enclosures [Include full Prescribing Information and the additional support noted above]

***PLEASE NOTE:** These are sample letters. Use of these letters does not guarantee reimbursement.

Specialty Distributors

The following specialty distributors are authorized to sell DARZALEX *FASPRO*® and are able to service institutions and/or physician offices, and community oncology practices.

Specialty Distributor	Phone	Fax	Website
ASD Healthcare	1-800-746-6273	1-800-547-9413	https://www.asdhealthcare.com
BioCareSD	1-800-304-3064	N/A	Email: order@biocaresd.com
Cardinal Health Specialty Pharmaceutical Distribution	**Physician Offices:** 1-877-453-3972 **Hospitals/All Other:** 1-866-677-4844	1-614-652-7043 1-614-652-7043	https://specialtyonline.cardinalhealth.com https://orderexpress.cardinalhealth.com
CuraScript Specialty Distribution (Priority Healthcare)	1-877-599-7748	1-800-862-6208	https://curascriptsd.com/
McKesson Plasma & Biologics	1-877-625-2566	1-888-752-7626	https://connect.mckesson.com Email: mpborders@mckesson.com
McKesson Specialty Health	**Multispecialty:** 1-855-477-9800 **Oncology:** 1-800-482-6700	**Multispecialty:** 1-800-800-5673 **Oncology:** 1-855-824-9489	https://mscs.mckesson.com
Morris & Dickson SD	1-800-710-6100	N/A	https://morrisdickson.com https://mdspecialtydist.com
Oncology Supply	1-800-633-7555	1-800-248-8205	https://www.oncologysupply.com

Note: Johnson & Johnson does not endorse the use of any of the listed distributors in particular.

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 1446 patients with multiple myeloma (N=1235) or light chain (AL) amyloidosis (N=193) who received DARZALEX *FASPRO*® as monotherapy or as part of a combination therapy, 7% of patients experienced a systemic administration-related reaction (Grade 2: 3%, Grade 3: 0.8%, Grade 4: 0.1%). In patients with high-risk smoldering multiple myeloma (N=193), systemic administration-related reactions occurred in 17% of patients in AQUILA (Grade 2: 7%, Grade 3: 1%).

In all patients (N=1639), systemic administration-related reactions occurred in 7% of patients with the first injection, 0.5% 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 283 systemic administration-related reactions that occurred in 135 patients, 240 (85%) 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 of 1446 patients with multiple myeloma (N=1253) or light chain amyloidosis (N=193), injection-site reactions occurred in 8% of patients, including Grade 2 reactions in 1.1%. The most frequent (>1%) injection-site reactions were injection site erythema and injection site rash. In patients with high-risk smoldering multiple myeloma (N=193), injection-site reactions occurred in 28% of patients, including Grade 2 reactions in 3%. These local reactions occurred a median of 6 minutes (range: 0 minutes to 6.5 days) after starting administration of DARZALEX *FASPRO*®. Monitor for local reactions and consider symptomatic management.

Infections

DARZALEX *FASPRO*® can cause serious, life-threatening, or fatal infections. In patients who received DARZALEX *FASPRO*® in a pooled safety population including patients with smoldering multiple myeloma and light chain (AL) amyloidosis (N=1639), serious infections, including opportunistic infections, occurred in 24% of patients, Grade 3 or 4 infections occurred in 22%, and fatal infections occurred in 2.5%. The most common type of serious infection reported was pneumonia (8.5%).

Monitor patients for signs and symptoms of infection prior to and during treatment with DARZALEX *FASPRO*® and treat appropriately. Administer prophylactic antimicrobials according to guidelines.

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

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, rash, pyrexia, cough, muscle spasms, back pain, vomiting, hypertension, musculoskeletal pain, upper respiratory tract infection, peripheral neuropathy, peripheral sensory neuropathy, constipation, pneumonia, edema, peripheral edema, and anemia.

The most common adverse reactions (≥20%) in patients with high-risk smoldering multiple myeloma who received DARZALEX *FASPRO*® monotherapy are upper respiratory tract infection, musculoskeletal pain, fatigue, diarrhea, rash, sleep disorder, sensory neuropathy, and injection site reactions.

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 read full Prescribing Information for DARZALEX *FASPRO*®.

cp-552204v2

DARZALEX®

(daratumumab)

injection for intravenous infusion
100 mg/5 mL, 400 mg/20 mL

INDICATIONS

DARZALEX® (daratumumab) is indicated for the treatment of adult patients with multiple myeloma:

- 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, melphalan, and prednisone in newly diagnosed patients who are ineligible for autologous stem cell transplant
- 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
- 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 pomalidomide and dexamethasone in patients who have received at least two prior therapies including lenalidomide and a proteasome inhibitor
- 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

Dosing and Administration

The recommended dose of DARZALEX® is 16 mg/kg actual body weight administered as an intravenous infusion according to the dosing schedule by indication (please see Tables 14-18 on pages 37-41).[14] If a planned dose of DARZALEX® is missed, administer the dose as soon as possible and adjust the dosing schedule accordingly, maintaining the treatment interval.[14]

DARZALEX® should be administered by a healthcare professional, with immediate access to emergency equipment and appropriate medical support to manage infusion-related reactions if they occur.[14] Administer pre-infusion and post-infusion medications to reduce the risk of infusion-related reactions.[14]

Pre-infusion medications[14]

Administer the following pre-infusion medications 1 to 3 hours prior to every infusion of DARZALEX®:

- Corticosteroid (long-acting or intermediate-acting)
  - ✓ for monotherapy, intravenous (IV) methylprednisolone 100 mg, or equivalent. Following the second infusion, the dose of corticosteroid may be reduced (oral or IV methylprednisolone 60 mg)
  - ✓ for combination therapy, administer dexamethasone 20 mg (or equivalent) orally or intravenously. When dexamethasone is the background regimen-specific corticosteroid, that dexamethasone dose will serve as the pre-medication on DARZALEX® infusion days. Do not administer background regimen-specific corticosteroids (eg, prednisone) on DARZALEX® infusion days when patients have received dexamethasone (or equivalent) as pre-medication
- Acetaminophen 650 mg to 1,000 mg orally
- Diphenhydramine 25 mg to 50 mg (or equivalent) orally or intravenously

Post-infusion medications[14]

Administer the following post-infusion medication to reduce the risk of delayed infusion-related reactions:

- Oral corticosteroid

✓ for monotherapy, administer methylprednisolone 20 mg (or equivalent dose on an intermediate- or long-acting corticosteroid) orally for 2 days starting the day after the administration of DARZALEX®

✓ for combination therapy, consider administering oral methylprednisolone at a dose ≤20 mg (or an equivalent dose of an intermediate- or long-acting corticosteroid) beginning the day after the DARZALEX® infusion; however, if a background regimen-specific corticosteroid (eg, dexamethasone, prednisone) is administered the day after the DARZALEX® infusion, additional post-infusion medications may not be needed

Note:

- For patients with a history of chronic obstructive pulmonary disease, consider prescribing short- and long-acting bronchodilators and inhaled corticosteroids. Following the first 4 DARZALEX® infusions, if the patient experiences no major infusion-related reactions, consider discontinuing these post-infusion medications

SELECTED IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

DARZALEX® is contraindicated in patients with a history of severe hypersensitivity (eg, anaphylactic reactions) to daratumumab or any of the components of the formulation.

WARNINGS AND PRECAUTIONS

Infusion-Related Reactions

DARZALEX® can cause severe and/or serious infusion-related reactions including anaphylactic reactions. These reactions can be life-threatening, and fatal outcomes have been reported. In clinical trials (monotherapy and combination: N=2066), infusion-related reactions occurred in 37% of patients with the Week 1 (16 mg/kg) infusion, 2% with the Week 2 infusion, and cumulatively 6% with subsequent infusions. Less than 1% of patients had a Grade 3/4 infusion-related reaction at Week 2 or subsequent infusions. The median time to onset was 1.5 hours (range: 0 to 73 hours). Nearly all reactions occurred during infusion or within 4 hours of completing DARZALEX®. Severe reactions have occurred, including bronchospasm, hypoxia, dyspnea, hypertension, tachycardia, headache, laryngeal edema, pulmonary edema, and ocular adverse reactions, including choroidal effusion, acute myopia, and acute angle closure glaucoma. Signs and symptoms may include respiratory symptoms, such as nasal congestion, cough, throat irritation, as well as chills, vomiting, and nausea. Less common signs and symptoms were wheezing, allergic rhinitis, pyrexia, chest discomfort, pruritus, hypotension, and blurred vision.

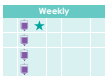
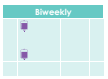
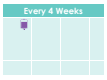
(Continued on next page.)

DARZALEX® dosing for monotherapy and in combination with lenalidomide and dexamethasone (DRd) or pomalidomide and dexamethasone (DPd)[14]

For the treatment of adults with multiple myeloma:

- **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**
- **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 pomalidomide and dexamethasone in patients who have received at least two prior therapies including lenalidomide and a proteasome inhibitor**
- DARZALEX® is given as an intravenous (IV) infusion after dilution at 16 mg/kg of actual body weight, with pre- and post-infusion medications
- Split first dose option: the first prescribed 16-mg/kg dose at Week 1 may be split over 2 consecutive days, ie, 8 mg/kg on Day 1 and Day 2, respectively
- For dosing instructions of combination agents administered with DARZALEX®, see the Clinical Studies (14.1) section of the DARZALEX® Prescribing Information and the respective manufacturers' prescribing information

Table 13: DARZALEX® Dosing in DRd, DPd, and Monotherapy Regimens

4 Doses Per 28-Day Cycle		given as a **once weekly** infusion (4 doses per 4-week cycle; Cycles 1 to 2; Weeks 1 to 8)
2 Doses Per 28-Day Cycle		given as **one dose** every 2 weeks (2 doses per 4-week cycle; Cycles 3 to 6; Weeks 9 to 24)
1 Dose Per 28-Day Cycle		given as 1 infusion **every 4 weeks** (once per 4-week cycle; Cycles 7+, Weeks 25+ until disease progression)
23  **Total Doses**		ESTIMATED Year 1 infusion visits

★ **To facilitate administration, the first prescribed dose at Week 1 may be split over2 consecutive days.**

- The dosing schedules for DRd, DPd, and DARZALEX® monotherapy are based on a 28-day (4-week) cycle throughout therapy[13]
- Starting at Week 25, administration frequency for DARZALEX® regimens is once every 4 weeks and median duration averages 3.4 hours[13]

Note: For DARZALEX® infusion rates, please see Table 18 on page 41.

SELECTED IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (cont'd)

Infusion-Related Reactions (cont'd)

When DARZALEX® dosing was interrupted in the setting of ASCT (CASSIOPEIA) for a median of 3.75 months (range: 2.4 to 6.9 months), upon re-initiation of DARZALEX®, the incidence of infusion-related reactions was 11% for the first infusion following ASCT.

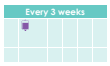
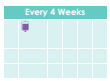
(Continued on next page.)

DARZALEX® dosing in combination with bortezomib and dexamethasone (DVd)[14]

For the treatment of adults with multiple myeloma who have received at least one prior therapy

- DARZALEX® is given as an intravenous (IV) infusion after dilution at 16 mg/kg of actual body weight, with pre- and post-infusion medications
- Split first dose option: the first prescribed 16-mg/kg dose at Week 1 may be split over 2 consecutive days, ie, 8 mg/kg on Day 1 and Day 2, respectively
- For dosing instruction of combination agents administered with DARZALEX®, see the Clinical Studies (14.1) section of the DARZALEX® Prescribing Information and the respective manufacturers' prescribing information

Table 14: DARZALEX® Dosing in DVd Regimen

3 Doses Per 21-Day Cycle		given as a **once weekly** infusion (3 doses per 3-week cycle; Cycles 1 to 3; Weeks 1 to 9)
1 Doses Per 21-Day Cycle		given as 1 infusion **every 3 weeks** (once per 3-week cycle; Cycles 4 to 8; Weeks 10 to 24)
1 Dose Per 4-Week Cycle		given as 1 infusion **every 4 weeks** (3 doses per 3-week cycle; Cycles 9+; Weeks 25+ until disease progression)
21  **Total Doses**		ESTIMATED Year 1 infusion visits

★ **To facilitate administration, the first prescribed dose at Week 1 may be split over 2 consecutive days.**

- The dosing schedule for DVd is based on an initial 21-day cycle for Weeks 1 to 24, followed by 28-day (4-week) cycles with DARZALEX®; bortezomib and dexamethasone should be stopped after 8 cycles[14]
- Starting at Week 25, administration frequency for DARZALEX® regimens is once every 4 weeks, and median duration averages 3.4 hours[14]

Note: For DARZALEX® infusion rates, please see Table 18 on page 41.

SELECTED IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (cont'd)

Infusion-Related Reactions (cont'd)

Infusion-related reactions occurring at re-initiation of DARZALEX® following ASCT were consistent in terms of symptoms and severity (Grade 3 or 4: <1%) with those reported in previous studies at Week 2 or subsequent infusions. In EQUULEUS, patients receiving combination treatment (n=97) were administered the first 16 mg/kg dose at Week 1 split over two days, ie, 8 mg/kg on Day 1 and Day 2, respectively. The incidence of any grade infusion-related reactions was 42%, with 36% of patients experiencing infusion-related reactions on Day 1 of Week 1, 4% on Day 2 of Week 1, and 8% with subsequent infusions.

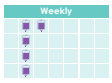
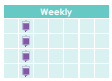
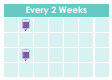
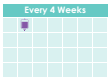
(Continued on next page.)

DARZALEX® dosing in combination with carfilzomib and dexamethasone (DKd)[14]

For the treatment of adults with multiple myeloma who have received one to three lines of prior therapy

- Split first dose: the first prescribed 16-mg/kg dose at Week 1 should be split over 2 consecutive days, ie, 8 mg/kg on Day 1 and Day 2, respectively, with pre- and post-infusion medications
- After the first week, DARZALEX® is given as an intravenous (IV) infusion after dilution at 16 mg/kg of actual body weight, with pre- and post-infusion medications
- For dosing instruction of combination agents administered with DARZALEX®, see the Clinical Studies (14.1) section of the DARZALEX® Prescribing Information and the respective manufacturers' prescribing information

Table 15: DARZALEX® Dosing in DKd Regimen

5 Doses Per 28-Day Cycle		Week 1: given as split dose infusion over **2 consecutive days** Weeks 2-4: given as a **once weekly** infusion (5 doses per 4-week cycle; Cycles 1 to 2)
4 Doses Per 28-Day Cycle		Weeks 5 to 8: given as a **once weekly** infusion (4 doses per 4-week cycle; Cycle 2)
2 Dose Per 28-Day Cycle		Weeks 9 to 24: given as 1 infusion **every 2 weeks** (twice per 4-week cycle; Cycles 3 to 6)
1 Dose Per 28-Day Cycle		Weeks 25+ until disease progression: given as 1 infusion **every 4 weeks** (once per 4-week cycle; Cycles 7+)
24 Total Doses		ESTIMATED Year 1 infusion visits

- The dosing schedule for DKd is based on 28-day (4-week) cycles. Two initial doses are given on Week 1, followed by weekly doses on Weeks 2 to 8 and doses every 2 weeks on Weeks 9 to 24[14]
- Starting at Week 25, administration frequency for DARZALEX® regimens is once every 4 weeks, and median duration averages 3.4 hours[14]

Note: For DARZALEX® infusion rates, please see Table 18 on page 41.

SELECTED IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (cont'd)

Infusion-Related Reactions (cont'd)

Pre-medicate patients with antihistamines, antipyretics, and corticosteroids. Frequently monitor patients during the entire infusion. Interrupt DARZALEX® infusion for reactions of any severity and institute medical management as needed. Permanently discontinue DARZALEX® therapy if an anaphylactic reaction or life-threatening (Grade 4) reaction occurs and institute appropriate emergency care. For patients with Grade 1, 2, or 3 reactions, reduce the infusion rate when re-starting the infusion.

(Continued on next page.)

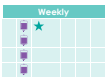
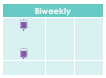
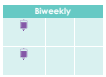
DARZALEX® dosing in combination with bortezomib, thalidomide, and dexamethasone (DVTd)[14]

For the treatment of adults with newly diagnosed multiple myeloma who are eligible for autologous stem cell transplant (ASCT):

- DARZALEX® is given as an intravenous (IV) infusion after dilution at 16 mg/kg of actual body weight, with pre- and post-infusion medications
- Split first dose option: the first prescribed 16-mg/kg dose at Week 1 may be split over 2 consecutive days, ie, 8 mg/kg on Day 1 and Day 2, respectively
- For dosing instruction of combination agents administered with DARZALEX®, see the Clinical Studies (14.1) section of the DARZALEX® Prescribing Information and the respective manufacturers' prescribing information

Dosing schedule based on a phase 3, randomized, active-controlled trial[14]

Table 16: DARZALEX® Dosing in DVTd Regimen

Induction	**4** Doses Per 28-Day Cycle		given as a **once weekly** infusion (4 doses per 4-week cycle; Cycles 1 to 2; Weeks 1 to 8)
	2 Doses Per 28-Day Cycle		given as 1 infusion **every 2 weeks** (twice per 4-week cycle; Cycles 3 to 6; Weeks 9 to 16)
STOP FOR HIGH-DOSE CHEMOTHERAPY AND ASCT			
Consolidation	**2** Dose Per Cycle		given as 1 infusion **every 2 weeks** (twice per 4-week cycle; Cycles 5 and 6; Weeks 1 to 8 of consolidation phase)
	16 Total Doses		ESTIMATED total infusion visits for induction and consolidation

★ **To facilitate administration, the first prescribed dose at Week 1 may be split over 2 consecutive days.**

- During induction, the dosing schedule for DVTd is based on an initial 8-week cycle (Cycles 1 and 2) of weekly infusions, followed by infusions once every 2 weeks for 8 weeks (Cycles 3 and 4)[14]
- DARZALEX® is then stopped for high-dose chemotherapy and ASCT[14]
- During consolidation, the administration frequency for DARZALEX® is once every 2 weeks for 8 weeks (Cycles 5 and 6)[14]

Note: For DARZALEX® infusion rates, please see Table 18 on page 41.

SELECTED IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (cont'd)

Infusion-Related Reactions (cont'd)

To reduce the risk of delayed infusion-related reactions, administer oral corticosteroids to all patients following DARZALEX® infusions. Patients with a history of chronic obstructive pulmonary disease may require additional post-infusion medications to manage respiratory complications. Consider prescribing short- and long-acting bronchodilators and inhaled corticosteroids for patients with chronic obstructive pulmonary disease.

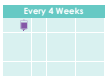
(Continued on next page.)

DARZALEX® dosing in combination with bortezomib, melphalan, and prednisone (DVMP)[14]

For the treatment of adult patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant

- DARZALEX® is given as an intravenous (IV) infusion after dilution at 16 mg/kg of actual body weight, with pre- and post-infusion medications
- Split first dose option: the first prescribed 16 mg/kg dose at Week 1 may be split over 2 consecutive days, ie, 8 mg/kg on Day 1 and Day 2, respectively
- For dosing instruction of combination agents administered with DARZALEX®, see the Clinical Studies (14.1) section of the DARZALEX® Prescribing Information and the respective manufacturers' prescribing information

Table 17: DARZALEX® Dosing in DVMP Regimen

6 Doses Per 6-Week Cycle		given as a **once weekly** infusion (6 doses per 6-week cycle; Cycle 1; Weeks 1 to 6)
2 Doses Per 6-Week Cycle		given as 1 infusion **every 3 weeks** (twice per 6-week cycle; Cycles 2 to 9; Weeks 7 to 54)
1 Dose Per 4-Week Cycle		given as 1 infusion **every 4 weeks** (once per 4-week cycle; Cycles 10+; Weeks 55+ until disease progression)
22  **Total Doses**		ESTIMATED Year 1 infusion visits

★ **To facilitate administration, the first prescribed dose at Week 1 may be split over 2 consecutive days.**

- The dosing schedule for DVMP is based on an initial 6-week dosing cycle (Cycles 1 to 9) followed by 28-day (4-week) cycles with DARZALEX®[1]; VMP administration should be stopped after 9 cycles[14]
- Starting at Cycle 10 (Week 55+), administration frequency for DARZALEX® is once every 4 weeks and median duration of infusion averages 3.4 hours[14]

Note: For DARZALEX® infusion rates, please see Table 18 on page 41.

SELECTED IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (cont'd)

Infusion-Related Reactions (cont'd)

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 DARZALEX® infusion. If ocular symptoms occur, interrupt DARZALEX® infusion and seek immediate ophthalmologic evaluation prior to restarting DARZALEX®.

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 infusion. 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 is not impacted. Notify blood transfusion centers of this interference with serological testing and inform blood banks that a patient has received DARZALEX®. Type and screen patients prior to starting DARZALEX®.

Infusion rates

Administer DARZALEX® infusions intravenously at the rates described in the table below. Consider incremental escalation of the infusion rate only in the absence of infusion-related reactions.[14]

Table 18: Infusion Rates for DARZALEX® Administration[13]

	Dilution volume	Initial rate (first hour)	Rate increment*	Maximum rate
Week 1 Infusion				
Option 1 (single-dose infusion)				
Week 1 **Day 1** (16 mg/kg)	1000 mL	50 mL/hour	50 mL/hour every hour*	200 mL/hour
Option 2 (split-dose infusion)				
Week 1 **Day 1** (8 mg/kg)	500 mL	50 mL/hour	50 mL/hour every hour*	200 mL/hour
Week 1 **Day 2** (8 mg/kg)	500 mL	50 mL/hour	50 mL/hour every hour*	200 mL/hour
Subsequent Infusions				
Week 2 (16 mg/kg) infusion†	500 mL	50 mL/hour	50 mL/hour every hour*	200 mL/hour
Week 3 onwards (16 mg/kg)‡	500 mL	100 mL/hour	50 mL/hour every hour*	200 mL/hour

For infusion-related reactions of any grade/severity, immediately interrupt the DARZALEX® infusion and manage symptoms. Depending on the infusion-related reaction severity, management may require further reduction in the infusion rate or discontinuation of the DARZALEX® treatment.[14]

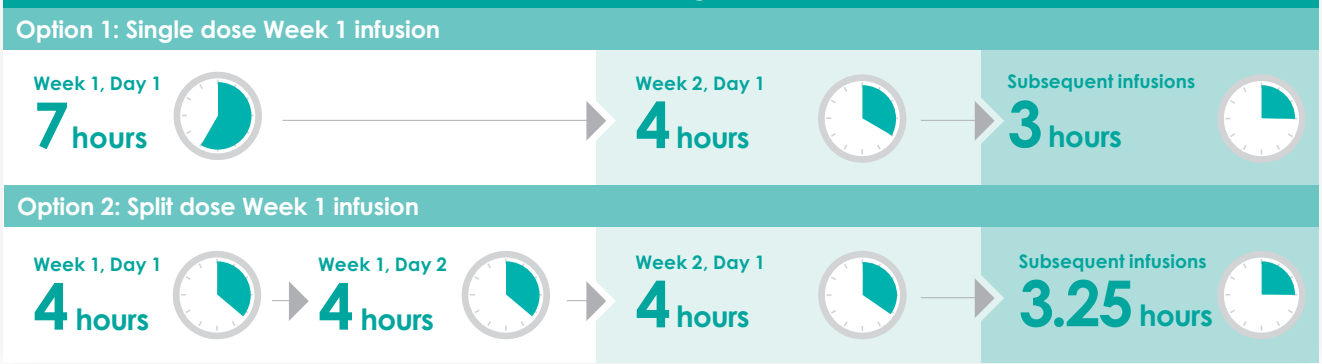
*Consider incremental escalation of the infusion rate only in the absence of infusion-related reactions.

†Use a dilution volume of 500 mL for the 16-mg/kg dose only if there were no infusion-related reactions the previous week. Otherwise, use a dilution volume of 1000 mL.

‡Use a modified initial rate (100 mL/hour) for subsequent infusions (ie, Week 3 onwards) only if there were no infusion-related reactions during the previous infusion. Otherwise, continue to use instructions in the table for the Week 2 infusion rate.

The recommended dose of 16 mg/kg to be administered on Day 1 when DARZALEX® is administered as monotherapy or in combination may be split over two consecutive days, such that an 8-mg/kg dose is administered on Day 1 and Day 2, respectively.

Table 19: Median Length of Infusion[13]

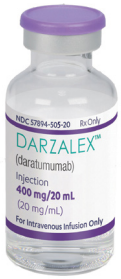


Coding for DARZALEX®

National Drug Codes (NDC)

The National Drug Code (NDC) is a unique number that identifies a drug's labeler, product, and trade package size. The NDC is most often used on pharmacy claims, including drugs provided for home infusion. However, the NDC is also required on Medicare claims for dual-eligible beneficiaries (Medicaid cross-over claims),[2] and by some private payers.[3] Although the FDA uses a 10-digit format when registering NDCs, payers often require an 11-digit NDC format on claim forms for billing purposes. It is important to confirm with your payer if an NDC is needed and the format the payer requires. Electronic data exchange generally requires use of the 11-digit NDC. To convert the 10-digit format to the 11-digit format, insert a leading zero into the middle sequence, as illustrated below:

Table 20: National Drug Codes for DARZALEX®[14]

FDA-Specified 10-Digit NDC (5-3-2 format)	11-Digit NDC (5-4-2 format)	Description
57894-505-05	57894-0505-05	 **100-mg/5-mL vial (20 mg/mL)** Single-use vial containing 100 mg of daratumumab solution for intravenous infusion
57894-505-20	57894-0505-20	 **400-mg/20-mL vial (20 mg/mL)** Single-use vial containing 400 mg of daratumumab solution for intravenous infusion

FDA, U.S. Food and Drug Administration.

SELECTED IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (cont'd)

Neutropenia and Thrombocytopenia

DARZALEX® may increase neutropenia and thrombocytopenia 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® until recovery of neutrophils or for recovery of platelets.

National Drug Codes (NDC) (cont'd)

Reporting the NDC on professional or institutional claims requires similar information and formats. The NDC unit of measure is determined by how a drug is supplied. In the outpatient setting, ML (milliliters) applies to drugs supplied in vials in liquid form. The NDC quantity reported is based on the NDC quantity dispensed. If the NDC unit of measure is ML, then the NDC quantity reported will equal the amount of mL given to the patient.[3] Here is an example for a 1,200-mg dose of DARZALEX®:

Table 21: DARZALEX® NDC Units

Dose to Be Billed	11-Digit NDC (5-4-2 format)	Packaging	NDC Unit of Measure	NDC Units
1,200 mg	57894-0505-20	400-mg/20-mL vial (liquid)	ML	60

In this example the drug is supplied as a liquid in 400-mg/20-mL vials. One 400-mg/20-mL vial = 20 NDC units.

The total dose to be billed is 1,200 mg (3 vials, each containing 400 mg/20 mL = 60 mL), or 60 NDC units. The drug is packaged in liquid form, so the NDC unit of measure is "ML."

Accurate NDC coding* typically requires the following components:

- Reporting the NDC with 11 digits in a 5-4-2 configuration; this may require converting a 10-digit NDC to an 11-digit NDC
- Reporting the correct NDC unit of measure (ie, UN, ML)
- Reporting the number of NDC units dispensed
- Reporting the qualifier, N4, in front of the NDC

Using the same 1,200 mg DARZALEX® example, here is how this format would appear on a professional claim:

N457894050520 ML60

For professional claims (CMS-1500), report the NDC information in the shaded portion of Item 24.[2]

The NDC format for institutional claims varies only with the elimination of a space between the NDC and unit of measure. Here is how the NDC would appear on a facility claim:

N457894050520ML60

For institutional claims (CMS-1450), report the NDC information in Locator Box 43.[4]

*Payer requirements for NDC use and format may vary. Please contact your payers for specific coding policies and more information on correct billing and claims submission.

SELECTED IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (cont'd)

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 patients with IgG kappa myeloma protein.

HCPCS Codes

Drugs are typically reported with Healthcare Common Procedure Coding System (HCPCS) codes assigned by the Centers for Medicare & Medicaid Services (CMS). The HCPCS code for DARZALEX® is:

- J9145 - Injection, daratumumab, 10 mg[5]

Each 100-mg vial of drug represents 10 units of J9145, and each 400-mg vial represents 40 units. Inaccurate reporting of drug HCPCS units is a common claims error and can result in denied or delayed payment. When coding for J9145, report the total number of 10-mg increments administered. Table 22 illustrates the correlation between DARZALEX® vials, milligrams, and HCPCS units used for billing.

Table 22: DARZALEX® HCPCS Billing Units

Number of 100-mg vials of DARZALEX®	Total milligrams (mg)	Number of billing units based on J9145 (10 mg DARZALEX® per unit)
1	100	10
2	200	20
3	300	30
Number of 400-mg vials of DARZALEX®	**Total milligrams (mg)**	**Number of billing units based on J9145 (10 mg DARZALEX® per unit)**
1	400	40
2	800	80
3	1,200	120

The fact that a drug, device, procedure, or service is assigned an HCPCS code and a payment rate does not imply coverage by the Medicare and/or Medicaid program, but indicates only how the product, procedure, or service may be paid if covered by the program. Fiscal Intermediaries (FIs)/ Medicare Administrative Contractors (MACs) and/or state Medicaid administration determine whether a drug, device, procedure, or other service meets all program requirements for coverage.

SELECTED IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (cont'd)

Embryo-Fetal Toxicity

Based on the mechanism of action, DARZALEX® can cause fetal harm when administered to a pregnant woman. DARZALEX® 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® and for 3 months after the last dose.

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

CPT® Codes

Current Procedural Terminology (CPT®) codes are the most widely accepted medical nomenclature used to report medical procedures and services under public and private health insurance programs. Drug administration services are reported on claim forms in both the physician office (CMS-1500) and hospital outpatient (CMS-1450) sites of care using the CPT® coding system. Healthcare providers are responsible for selecting appropriate codes for any particular claim based on the patient's condition, the items and services that are furnished, and any specific payer requirements.*

The CPT® codes commonly associated with the administration of DARZALEX® are:

- 96413 - Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug[6]
- 96415 - Each additional hour (list separately in addition to code for primary procedure)[6]

These codes, often referred to as "complex" infusion codes, apply to the parenteral administration of chemotherapy and also anti-neoplastic agents provided for treatment of non-cancer diagnoses, or to substances such as certain monoclonal antibodies and other biologic response modifiers.[6] Complex drug administration services require special considerations to prepare, dose, or dispose and typically entail professional skill and patient monitoring significantly beyond that required for therapeutic infusions.[6]

*Payer policies for codes used to describe infusion services may vary. Consult your payers for guidance. For additional assistance, contact J&J withMe.

SELECTED IMPORTANT SAFETY INFORMATION

ADVERSE REACTIONS

The most frequently reported adverse reactions (incidence ≥20%) were upper respiratory infection, neutropenia, infusion-related reactions, thrombocytopenia, diarrhea, constipation, anemia, peripheral sensory neuropathy, fatigue, peripheral edema, nausea, cough, pyrexia, dyspnea, and asthenia. The most common hematologic laboratory abnormalities (≥40%) with DARZALEX® are neutropenia, lymphopenia, thrombocytopenia, leukopenia, and anemia.

ICD-10-CM Diagnosis Codes

All parties covered by the Health Insurance Portability and Accountability Act (HIPAA), not just providers who bill Medicare or Medicaid, are required to use the International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM) codes to document patient diagnoses. ICD-10-CM far exceeds previous coding systems in the number of concepts and codes provided, allowing for greater specificity when describing patient conditions.

ICD-10-CM diagnosis codes use 3 to 7 alpha and numeric characters to achieve this level of detail. Codes with 3 characters are included in ICD-10-CM as the heading of a category of codes that may be further subdivided by use of additional characters to provide greater detail. Code to the highest level of specificity when supported by the medical record documentation.[7]

Table 23: Multiple Myeloma Diagnosis Codes* for Consideration

ICD-10-CM Codes and Descriptors[8]	
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.

FDA, U.S. Food and Drug Administration.

Other Coding Considerations

When coding and billing for DARZALEX® and drug administration services, providers also may need to describe concomitant services or supplies, report discarded drug amount, or account for modification to a service. This section reviews some of those additional considerations.

Modifiers

Modifiers are used to report or indicate that a service or procedure has been altered by some specific circumstance, but not changed in its definition or code. They provide additional information about a service or procedure and help to eliminate the appearance of duplicate billing and unbundling. This could include using modifiers to designate a specific site of service, or to document an interrupted procedure, wasted product, same-day procedure, etc. Appropriately used, modifiers improve coding and reimbursement accuracy. Table 25 summarizes modifiers that may be applicable to the provision of DARZALEX® in physician offices and hospital outpatient departments.

Table 24: Summary of Code Modifiers				
Modifier	**Description**	**Indication and Placement**	**CMS-1500 Item 24D**	**CMS-1450 Locator Box 44**
25	Significant, separately identifiable evaluation and management service by the same physician or other qualified healthcare professional on the same day of the procedure or other service[6]	• Patient requires distinct evaluation and management (E/M) service in addition to the infusion procedure[6] • Must be substantiated with relevant documentation[6] • Append the modifier to the relevant E/M code[6]	✓	✓
PN*	Non-excepted service provided at an off-campus, outpatient, provider-based department of a hospital[9]	• Non-excepted, off-campus, provider-based departments of a hospital are required to report this modifier on each claim line for non-excepted items and services[9]	N/A	✓ Required by Medicare
PO*	Excepted service provided at an off-campus, outpatient, provider-based department (PBD) of a hospital[9]	• Should be reported with every HCPCS code for all outpatient hospital items and services furnished in an excepted, off-campus, provider-based department of a hospital[9]	N/A	✓ Required by Medicare
TB	Drug or biological acquired with 340B drug pricing[5]	• Must be reported by all 340B covered entities that submit claims for separately payable Part B drugs and biologicals[10] • Report the "TB" modifier on the same claim line as the HCPCS code for 340B acquired drugs[10]	N/A	✓ Required by Medicare
JW	Drug amount discarded/not administered to any patient[5]	• Unused drug remains after applicable dose is administered from single-use vial[11] • Append the modifier to the HCPCS drug code on a line separate from that reporting the administered dose and document the administered and discarded amounts in the medical record[11]	✓ Required by Medicare	✓ Required by Medicare
JZ	No discarded drug amounts[5]	• Attests that there are no amounts of drugs or biologicals from single-dose containers or packages unused and discarded[11] • Append the modifier to the HCPCS drug code on the claim line with the administered amount[11]	✓ Required by Medicare	✓ Required by Medicare

*Neither the PO nor the PN modifier is to be reported by: a dedicated emergency department; a provider-based department that is "on the campus," or within 250 yards, of the hospital, or a remote location of the hospital.[9]

JW and JZ Modifiers for Separately Payable Drugs[11]

Medicare's JW and JZ modifier policy applies to all drugs separately payable under Medicare Part B that are described as being supplied in a "single-dose" container or "single-use" package based on FDA-approved labeling. On all claims for single use vials or single use packages payable under Part B, Medicare requires reporting either the JW or the JZ modifier.

Discarded Drug

When a physician, hospital, or other provider or supplier must discard the remainder of a single-use vial or other single-use package after administering a dose/quantity of the drug or biological to a Medicare patient, the program provides payment for the amount of drug or biological discarded as well as the dose administered, up to the amount of the drug or biological as indicated on the vial or package label. Medicare contractors require the modifier JW to identify unused drugs or biologicals from single-use vials or single-use packages that are appropriately discarded. This modifier, billed on a separate claim line, supports payment for the amount of discarded drug or biological. For example, a single-use vial that is labeled to contain 100 units of a drug has 95 units administered to the patient and 5 units discarded. The 95-unit dose is billed on one line, while the discarded 5 units are billed on another line, accompanied by the JW modifier. Both line items will be processed for payment. Providers must record the discarded amounts of drugs and biologicals in the patient's medical record.

No Discarded Amount

To align with the JW modifier policy, the JZ modifier is required when there are no discarded drug amounts from single-use vials or packages for which the JW modifier would be required if there were discarded amounts. The JZ modifier attests the entire contents of the single-use vial or package were administered to a patient and no amount was discarded. For the administered amount, the claim line should include the given drug's HCPCS code and the JZ modifier. When the actual dose of the drug administered is less than the billing unit, the JW modifier is not permitted and the JZ modifier should be used.[11]

Summary of Medicare Policies

- All Medicare Part B claims for single-use vials must include either a JZ or JW modifier
- The JW modifier indicates a discarded amount
- The JZ modifier indicates that no amount was discarded
- Multi-use vials are not subject to this policy

Payer requirements for modifier use can vary. Please contact your payer for specific coding policies and more information on correct billing and claims submission.

Partial Additional Hours of Infusion Time

CMS has a policy for reporting add-on infusion codes when less than a full hour of service is provided. CPT® code 96415[6] (for "each additional hour") is to be used for "infusion intervals of greater than 30 minutes beyond 1-hour increments."[12] If the incremental amount of infusion time is 30 minutes or less, the time is not to be billed separately. Document infusion start and stop times in the medical record. Some payers may require reporting the actual number of minutes on claims. Time associated with interruptions in the infusion process (ie, when drug is not flowing, IV saline to keep a line open with no drug flowing) does not count toward billable infusion time.

Drugs Supplied at No Cost to the Provider

To avoid a chemotherapy or other drug administration code denial, a drug code must be present on the same or prior claim.

Under certain circumstances, qualified patients may acquire donated or no-cost drug, or drugs may be covered under a pharmacy benefit and delivered to the administering provider. When the drug was supplied by a third party, at no cost to the provider, it should NOT be billed to Medicare or any other payer. However, the administration of the drug, regardless of the source, is a service that represents an expense to the physician. Therefore, administration of the drug is payable if the drug would have been covered if the physician purchased it. When reporting drug administration services for free-of-charge drugs, include the drug information and enter "0.01" charges. This will allow the claim processing system to register the drug claim as being allowed, which should allow the administration.[13] Payer policies may vary.

Same-Day Evaluation and Management Services

It may be necessary to provide evaluation and management (E/M) services on the same day as a drug administration procedure. Depending on the payer, E/M services that are medically necessary, separate, distinct from the drug administration procedure, and documented appropriately, are generally covered.

Please note that CMS has a specific policy regarding use of CPT® code 99211 (level 1 medical visit for an established patient) in the physician office. The policy states:

CPT® code 99211 cannot be paid if it is billed, with or without modifier 25, with a chemotherapy or nonchemotherapy drug administration code.[12]

Thus, CPT® code 99211 cannot be paid on the same day as an office-based infusion of DARZALEX®. If a chemotherapy service and a significantly identifiable evaluation and management service are provided on the same day, a different diagnosis is not required.[12]

Place of Service Codes

The Place of Service (POS) code set provides setting information necessary to appropriately pay professional service claims. The POS is the location of the provider's face-to-face encounter with the beneficiary. POS codes are required on all claims for professional services (billed on CMS-1500). Under the Physician Fee Schedule (PFS), some procedures have separate rates for professional services when provided in facility and nonfacility settings. Therefore, it is important to accurately designate the POS to assure appropriate payment.

The physician practice setting is indicated with POS code 11.[2] To differentiate between on-campus and off-campus provider-based departments, CMS created a new POS code (POS 19) and revised the POS code description for outpatient hospital (POS 22).[2] Professional services delivered in outpatient hospital settings must now specifically include the off-campus or on-campus POS on the claim form.

Table 25 summarizes the potentially applicable place of service codes:

Table 25: Place of Service Codes

POS Code	POS Name	POS Descriptor
11	Office	Location, other than a hospital, skilled nursing facility (SNF), military treatment facility, community health center, state or local public health clinic, or intermediate care facility (ICF), where the health professional routinely provides health examinations, diagnosis, and treatment of illness or injury on an ambulatory basis.[2]
19	Off Campus – Outpatient Hospital	A portion of an off-campus hospital provider-based department that provides diagnostic, therapeutic (both surgical and nonsurgical), and rehabilitation services to sick or injured persons who do not require hospitalization or institutionalization.[2]
22	On Campus – Outpatient Hospital	A portion of a hospital's main campus that provides diagnostic, therapeutic (both surgical and nonsurgical), and rehabilitation services to sick or injured persons who do not require hospitalization or institutionalization.[2]

DARZALEX® Physician Office Sample Claim Form: CMS-1500

A

Item 19 - When submitting claims for the initial infusion as a **split dose regimen**, indicate that the initial dose is being delivered on 2 consecutive days. For example: Day 1 of 2, first dose of split dose regimen; Day 2 of 2, final dose of split dose regimen. Payer requirements may vary* and can include requests for additional documentation (eg, Prescribing Information) to accompany the claim.

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.

C

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

DARZALEX®

- **J9145** - Injection, daratumumab, 10 mg

Modifiers

- **JW modifier** - Drug amount discarded from a single-dose container
- **JZ modifier** - No discarded amount from a single-dose container

Infusion Services

- **96413** - Chemotherapy administration, intravenous infusion technique; up to 1 hour
- **96415** - Each additional hour

Payer requirements for drug administration coding may vary.*

D

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

E

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

DARZALEX® - Enter number of HCPCS units based on dose administered (10 mg , 1 unit).

Infusion services

- **96413** - Enter 1 unit for the first hour of infusion
- **96415** - Enter number of units for additional hours based on the duration of the infusion.

Split Dose Regimen

DARZALEX® - The initial dose (16 mg/kg) is divided evenly over 2 consecutive days: Day 1 (8 mg/kg); Day 2 (8 mg/kg); enter the number of units based on the dose administered each day (10 mg , 1 unit).

Infusion services

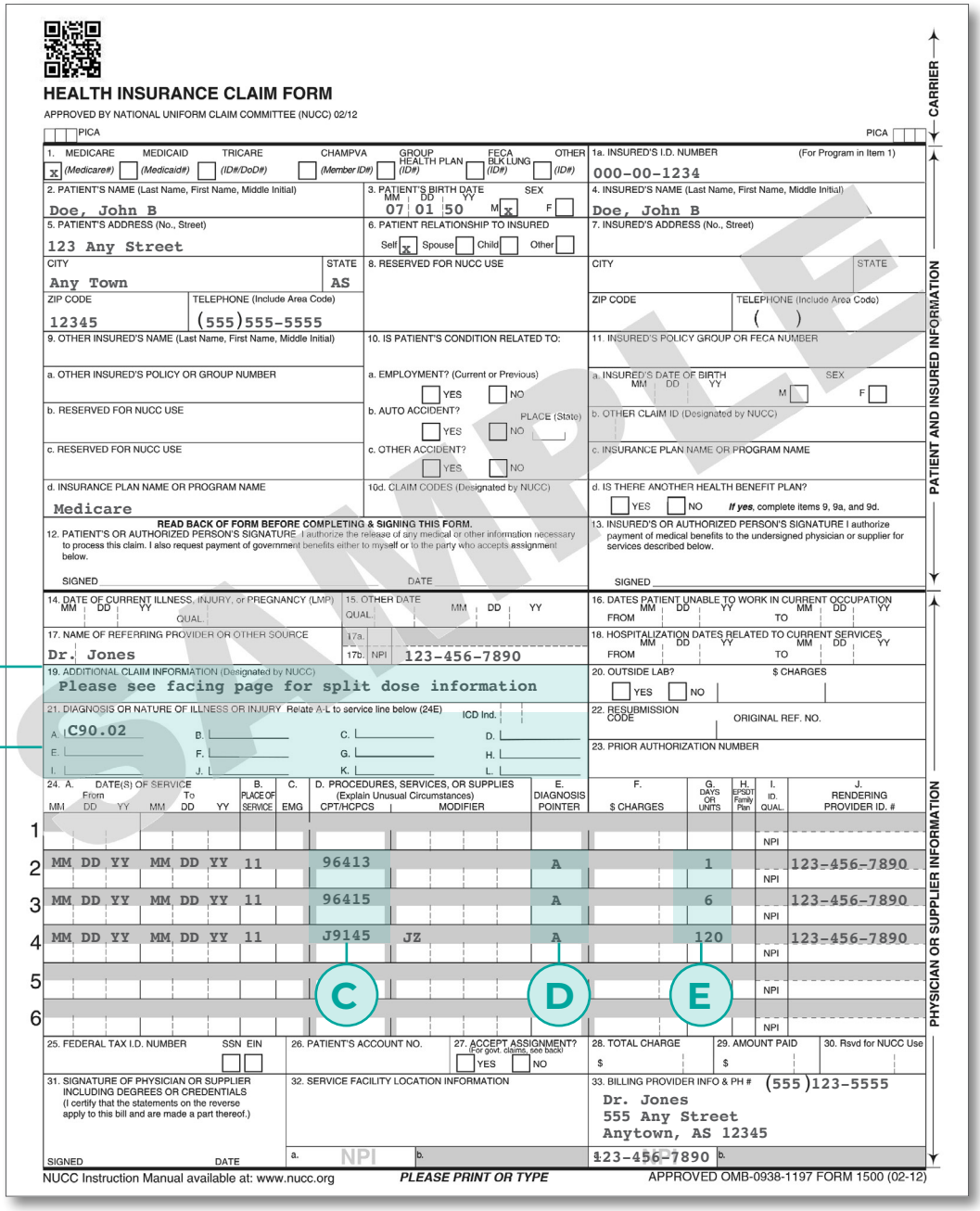
- **96413** - Enter 1 unit for the first hour of infusion
- **96415** - Enter the number of units for additional hours based on the duration

Although the DARZALEX® dose is the same on both days, the length of the infusion may vary.

	24. A. DATE(S) OF SERVICE From MM	DD	YY	To MM	DD	YY	B. PLACE OF SERVICE	C. EMG	D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS	MODIFIER	E. DIAGNOSIS POINTER	F. $ CHARGES	G. DAYS OR UNITS	H. EPSDT Family Plan	I. ID. QUAL.	J. RENDERING PROVIDER ID. #	
1	MM	DD	YY	MM	DD	YY	11		96413		A		1		NPI	123-456-7890	
2	MM	DD	YY	MM	DD	YY	11		96415		A		3		NPI	123-456-7890	
3	MM	DD	YY	MM	DD	YY	11		J9145	JZ	A		60		NPI	123-456-7890	

*Please contact your local payer or J&J withMe at 833-JNJ-wMe1 (833-565-9631).

DARZALEX® CMS-1500 Sample Claim Form: Initial Infusion, Single Dose



HEALTH INSURANCE CLAIM FORM

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

PICA

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

1a. INSURED'S I.D. NUMBER (For Program in Item 1): 000-00-1234

2. PATIENT'S NAME (Last Name, First Name, Middle Initial): Doe, John B

3. PATIENT'S BIRTH DATE MM DD YY: 07 01 50 | SEX M [x] F [ ]

4. INSURED'S NAME (Last Name, First Name, Middle Initial): Doe, John B

5. PATIENT'S ADDRESS (No., Street): 123 Any Street

6. PATIENT RELATIONSHIP TO INSURED: Self [x] Spouse [ ] Child [ ] Other [ ]

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

CITY: Any Town | STATE: AS

8. RESERVED FOR NUCC USE

CITY | STATE

ZIP CODE: 12345 | TELEPHONE (Include Area Code): (555)555-5555

ZIP CODE | TELEPHONE (Include Area Code)

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

10. IS PATIENT'S CONDITION RELATED TO:

11. INSURED'S POLICY GROUP OR FECA NUMBER

a. OTHER INSURED'S POLICY OR GROUP NUMBER

a. EMPLOYMENT? (Current or Previous) YES [ ] NO [ ]

a. INSURED'S DATE OF BIRTH MM DD YY | SEX M [ ] F [ ]

b. RESERVED FOR NUCC USE

b. AUTO ACCIDENT? YES [ ] NO [ ] PLACE (State)

b. OTHER CLAIM ID (Designated by NUCC)

c. RESERVED FOR NUCC USE

c. OTHER ACCIDENT? YES [ ] NO [ ]

c. INSURANCE PLAN NAME OR PROGRAM NAME

d. INSURANCE PLAN NAME OR PROGRAM NAME: Medicare

10d. CLAIM CODES (Designated by NUCC)

d. IS THERE ANOTHER HEALTH BENEFIT PLAN? YES [ ] NO [ ] *If yes*, complete items 9, 9a, and 9d.

READ BACK OF FORM BEFORE COMPLETING & SIGNING THIS FORM.

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 _____

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

15. OTHER DATE QUAL. MM DD YY

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

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

17a.

17b. NPI: 123-456-7890

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

19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC): Please see facing page for split dose information

20. OUTSIDE LAB? YES [ ] NO [ ] $ CHARGES

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

A. C90.02 B. C. D.

E. F. G. H.

I. J. K. L.

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	C. EMG	D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS	MODIFIER	E. DIAGNOSIS POINTER	F. $ CHARGES	G. DAYS OR UNITS	H. EPSDT Family Plan	I. ID. QUAL	J. RENDERING PROVIDER ID. #
1										NPI	
2	MM DD YY	MM DD YY	11	96413		A		1		NPI	123-456-7890
3	MM DD YY	MM DD YY	11	96415		A		6		NPI	123-456-7890
4	MM DD YY	MM DD YY	11	J9145	JZ	A		120		NPI	123-456-7890
5										NPI	
6										NPI	

25. FEDERAL TAX I.D. NUMBER SSN [ ] EIN [ ]

26. PATIENT'S ACCOUNT NO.

27. ACCEPT ASSIGNMENT? (For govt. claims, see back) YES [ ] NO [ ]

28. TOTAL CHARGE $

29. AMOUNT PAID $

30. Rsvd 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

32. SERVICE FACILITY LOCATION INFORMATION

a. NPI b.

33. BILLING PROVIDER INFO & PH # (555)123-5555

Dr. Jones
555 Any Street
Anytown, AS 12345

a. 123-456-7890 b.

NUCC Instruction Manual available at: www.nucc.org **PLEASE PRINT OR TYPE** APPROVED OMB-0938-1197 FORM 1500 (02-12)

CARRIER

PATIENT AND INSURED INFORMATION

PHYSICIAN OR SUPPLIER INFORMATION

A

B

C

D

E

SAMPLE

DARZALEX® 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 (eg, IV therapy).

C

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

DARZALEX®

- **J9145** - Injection, daratumumab, 10 mg

Modifiers

- **JW modifier** - drug amount discarded from a single-dose container
- **JZ modifier** - no discarded amount from a single-dose container

Infusion Services

- **96413** - Chemotherapy administration, intravenous infusion technique; up to 1 hour
- **96415** - Each additional hour

Payer requirements for drug administration coding may vary.*

D

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

DARZALEX® - Enter number of HCPCS units based on dose administered (10 mg , 1 unit).

Infusion services

- **96413** - Enter 1 unit for the first hour of infusion
- **96415** - Enter number of units for additional hours based on the duration of the infusion

Split Dose Regimen

DARZALEX® - The initial dose (16 mg/kg) is divided evenly over 2 consecutive days: Day 1 (8 mg/kg); Day 2 (8 mg/kg); enter the number of units based on the dose administered each day (10 mg , 1 unit).

- **96413** – Enter 1 unit for the first hour of infusion
- **96415** – Enter the number of units for additional hours based on the duration of the infusion. Although the DARZALEX® dose is the same on both days, the length of the infusion may vary

	42 REV. CD.	43 DESCRIPTION	44 HCPCS / RATE / HIPPS CODE	45 SERV. DATE	46 SERV. UNITS	47 TOTAL CHARGES	48 NON-COVERED CHARGES	49	
1									1
2	0335	Chemotherapy	96413	MM DD YY	1				2
3		administration - IV							3
4	0335	Chemotherapy	96415	MM DD YY	3				4
5		administration - IV							5
6	0636	DARZALEX® (daratumumab)	J9145JZ	MM DD YY	60				6

E

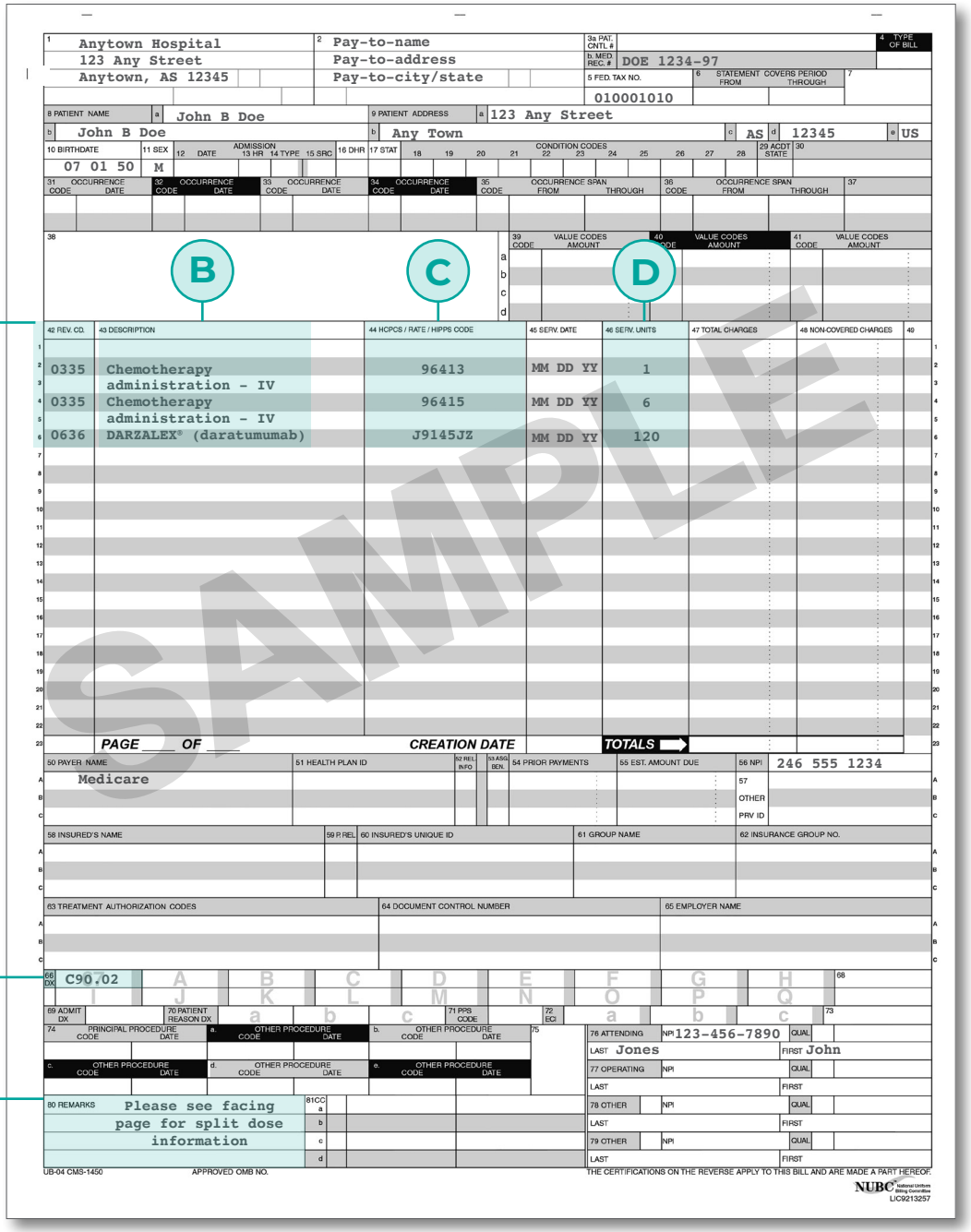
Locator Box 67 - Indicate diagnosis using appropriate ICD-10-CM codes. Code to the highest level of specificity for the date of service and enter diagnoses in priority order.

F

Locator Box 80 - When submitting claims for the initial infusion as a **split dose regimen**, indicate that the initial dose is being delivered on 2 consecutive days. For example: Day 1 of 2, first dose of split dose regimen; Day 2 of 2, final dose of split dose regimen. Payer requirements may vary* and can include requests for additional documentation (eg, Prescribing Information) to accompany the claim.

*Contact your local payer or J&J withMe at 833-JNJ-wMe1 (833-565-9631).

DARZALEX® CMS-1450 (UB-04) Sample Claim Form: Initial Infusion, Single Dose



1 Anytown Hospital
123 Any Street
Anytown, AS 12345

2 Pay-to-name
Pay-to-address
Pay-to-city/state

3a PAT. CNTL #
b. MED REC. # DOE 1234-97

4 TYPE OF BILL

5 FED. TAX NO. 010001010

6 STATEMENT COVERS PERIOD FROM THROUGH

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 ADMISSION DATE 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 C D

A

42 REV. CD.	43 DESCRIPTION	44 HCPCS / RATE / HIPPS CODE	45 SERV. DATE	46 SERV. UNITS	47 TOTAL CHARGES	48 NON-COVERED CHARGES	49
0335	Chemotherapy administration - IV	96413	MM DD YY	1			
0335	Chemotherapy administration - IV	96415	MM DD YY	6			
0636	DARZALEX® (daratumumab)	J9145JZ	MM DD YY	120			
	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 a b c
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

F

80 REMARKS Please see facing page for split dose information
81CC a b c d

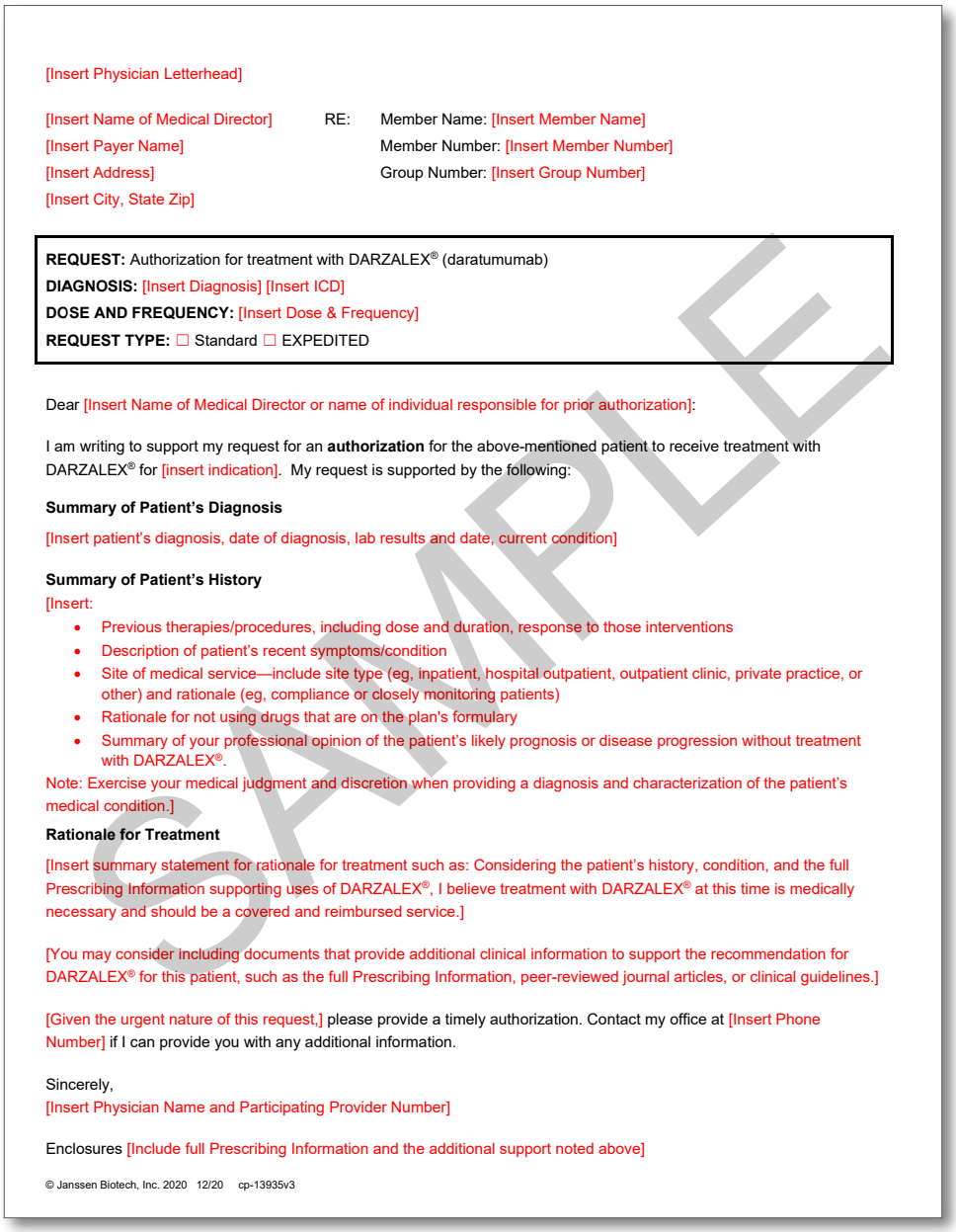
76 ATTENDING NPI 123-456-7890 QUAL LAST Jones FIRST John
77 OPERATING NPI QUAL LAST FIRST
78 OTHER NPI QUAL LAST FIRST
79 OTHER NPI QUAL LAST FIRST

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
LIC9213257

SAMPLE

Sample Letter of Medical Necessity: DARZALEX®

Some payers and other formulary decision-makers may require that treating physicians complete a Letter of Medical Necessity or request a formulary exception before patients can receive a specific therapy. We have provided a sample Letter of Medical Necessity and a sample Letter of Formulary Exception Request below.* Please visit **www.JNJwithMe.com/hcp/DARZALEX** for digital sample letter templates.



[Insert Physician Letterhead]

[Insert Name of Medical Director]
[Insert Payer Name]
[Insert Address]
[Insert City, State Zip]

RE: Member Name: [Insert Member Name]
Member Number: [Insert Member Number]
Group Number: [Insert Group Number]

REQUEST: Authorization for treatment with DARZALEX® (daratumumab)
DIAGNOSIS: [Insert Diagnosis] [Insert ICD]
DOSE AND FREQUENCY: [Insert Dose & Frequency]
REQUEST TYPE: ☐ Standard ☐ EXPEDITED

Dear [Insert Name of Medical Director or name of individual responsible for prior authorization]:

I am writing to support my request for an **authorization** for the above-mentioned patient to receive treatment with DARZALEX® for [insert indication]. My request is supported by the following:

Summary of Patient's Diagnosis

[Insert patient's diagnosis, date of diagnosis, lab results and date, current condition]

Summary of Patient's History

[Insert:

- Previous therapies/procedures, including dose and duration, response to those interventions
- Description of patient's recent symptoms/condition
- Site of medical service—include site type (eg, inpatient, hospital outpatient, outpatient clinic, private practice, or other) and rationale (eg, compliance or closely monitoring patients)
- Rationale for not using drugs that are on the plan's formulary
- Summary of your professional opinion of the patient's likely prognosis or disease progression without treatment with DARZALEX®.

Note: Exercise your medical judgment and discretion when providing a diagnosis and characterization of the patient's medical condition.]

Rationale for Treatment

[Insert summary statement for rationale for treatment such as: Considering the patient's history, condition, and the full Prescribing Information supporting uses of DARZALEX®, I believe treatment with DARZALEX® at this time is medically necessary and should be a covered and reimbursed service.]

[You may consider including documents that provide additional clinical information to support the recommendation for DARZALEX® for this patient, such as the full Prescribing Information, peer-reviewed journal articles, or clinical guidelines.]

[Given the urgent nature of this request,] please provide a timely authorization. Contact my office at [Insert Phone Number] if I can provide you with any additional information.

Sincerely,
[Insert Physician Name and Participating Provider Number]

Enclosures [Include full Prescribing Information and the additional support noted above]

***PLEASE NOTE:** These are sample letters. Use of these letters does not guarantee reimbursement.

Sample Letter of Formulary Exception Request: DARZALEX®*

[Insert Physician Letterhead]

[Insert Name of Medical Director]
[Insert Payer Name]
[Insert Address]
[Insert City, State Zip]

RE: Member Name: [Insert Member Name]
Member Number: [Insert Member Number]
Group Number: [Insert Group Number]

REQUEST: Authorization for treatment with DARZALEX® (daratumumab)
DIAGNOSIS: [Insert Diagnosis] [Insert ICD]
DOSE AND FREQUENCY: [Insert Dose & Frequency]
REQUEST TYPE: ☐ Standard ☐ EXPEDITED

Dear [Insert Name of Medical Director]:

I am writing to request a **formulary exception** for the above-mentioned patient to receive treatment with DARZALEX®, [insert indication]. My request is supported by the following:

Summary of Patient's Diagnosis

[Insert patient's diagnosis, date of diagnosis, lab results and date, current condition]

Summary of Patient's History

[Insert:

- Previous therapies/procedures, including dose and duration, response to those interventions
- Description of patient's recent symptoms/condition
- Site of medical service—include site type: Inpatient, hospital outpatient, outpatient clinic, private practice, or other
- Rationale for not using drugs that are on the plan's formulary
- Summary of your professional opinion of the patient's likely prognosis or disease progression without treatment with DARZALEX®.

Note: Exercise your medical judgment and discretion when providing a diagnosis and characterization of the patient's medical condition.]

Rationale for Treatment

[Insert summary statement for rationale for treatment such as: Considering the patient's history, condition, and the full Prescribing Information supporting uses of DARZALEX®, I believe treatment with DARZALEX® at this time is medically necessary and should be a covered and reimbursed service.]

[You may consider including documents that provide additional clinical information to support the recommendation for DARZALEX® for this patient, such as the full Prescribing Information, peer-reviewed journal articles, or clinical guidelines.]

[Given the urgent nature of this request,] please provide a timely authorization. Contact my office at [Insert Phone Number] if I can provide you with any additional information.

Sincerely,
[Insert Physician Name and Participating Provider Number]

Enclosures [Include full Prescribing Information and the additional support noted above]

***PLEASE NOTE:** These are sample letters. Use of these letters does not guarantee reimbursement.

Specialty Distributors

The following specialty distributors are authorized to sell DARZALEX® and are able to service institutions and/or physician offices, and community oncology practices.

Specialty Distributor	Phone	Fax	Website
ASD Healthcare	1-800-746-6273	1-800-547-9413	https://www.asdhealthcare.com
BioCareSD	1-800-304-3064	N/A	Email: order@biocaresd.com
Cardinal Health Specialty Pharmaceutical Distribution	**Physician Offices:** 1-877-453-3972 **Hospitals/All Other:** 1-866-677-4844	1-614-652-7043 1-614-652-7043	https://specialtyonline.cardinalhealth.com https://orderexpress.cardinalhealth.com
CuraScript Specialty Distribution (Priority Healthcare)	1-877-599-7748	1-800-862-6208	https://curascriptsd.com/
McKesson Plasma & Biologics	1-877-625-2566	1-888-752-7626	https://connect.mckesson.com Email: mpborders@mckesson.com
McKesson Specialty Health	**Multispecialty:** 1-855-477-9800 **Oncology:** 1-800-482-6700	**Multispecialty:** 1-800-800-5673 **Oncology:** 1-855-824-9489	https://mscs.mckesson.com
Morris & Dickson SD	1-800-710-6100	N/A	https://morrisdickson.com https://mdspecialtydist.com
Oncology Supply	1-800-633-7555	1-800-248-8205	https://www.oncologysupply.com

Note: Johnson & Johnson does not endorse the use of any of the listed distributors in particular.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

DARZALEX® is contraindicated in patients with a history of severe hypersensitivity (eg, anaphylactic reactions) to daratumumab or any of the components of the formulation.

WARNINGS AND PRECAUTIONS

Infusion-Related Reactions

DARZALEX® can cause severe and/or serious infusion-related reactions including anaphylactic reactions. These reactions can be life-threatening, and fatal outcomes have been reported. In clinical trials (monotherapy and combination: N=2066), infusion-related reactions occurred in 37% of patients with the Week 1 (16 mg/kg) infusion, 2% with the Week 2 infusion, and cumulatively 6% with subsequent infusions. Less than 1% of patients had a Grade 3/4 infusion-related reaction at Week 2 or subsequent infusions. The median time to onset was 1.5 hours (range: 0 to 73 hours). Nearly all reactions occurred during infusion or within 4 hours of completing DARZALEX®. Severe reactions have occurred, including bronchospasm, hypoxia, dyspnea, hypertension, tachycardia, headache, laryngeal edema, pulmonary edema, and ocular adverse reactions, including choroidal effusion, acute myopia, and acute angle closure glaucoma. Signs and symptoms may include respiratory symptoms, such as nasal congestion, cough, throat irritation, as well as chills, vomiting, and nausea. Less common signs and symptoms were wheezing, allergic rhinitis, pyrexia, chest discomfort, pruritus, hypotension, and blurred vision.

When DARZALEX® dosing was interrupted in the setting of ASCT (CASSIOPEIA) for a median of 3.75 months (range: 2.4 to 6.9 months), upon re-initiation of DARZALEX®, the incidence of infusion-related reactions was 11% for the first infusion following ASCT. Infusion-related reactions occurring at re-initiation of DARZALEX® following ASCT were consistent in terms of symptoms and severity (Grade 3 or 4: <1%) with those reported in previous studies at Week 2 or subsequent infusions. In EQUULEUS, patients receiving combination treatment (n=97) were administered the first 16 mg/kg dose at Week 1 split over two days, ie, 8 mg/kg on Day 1 and Day 2, respectively. The incidence of any grade infusion-related reactions was 42%, with 36% of patients experiencing infusion-related reactions on Day 1 of Week 1, 4% on Day 2 of Week 1, and 8% with subsequent infusions.

Pre-medicate patients with antihistamines, antipyretics, and corticosteroids. Frequently monitor patients during the entire infusion. Interrupt DARZALEX® infusion for reactions of any severity and institute medical management as needed. Permanently discontinue DARZALEX® therapy if an anaphylactic reaction or life-threatening (Grade 4) reaction occurs and institute appropriate emergency care. For patients with Grade 1, 2, or 3 reactions, reduce the infusion rate when re-starting the infusion.

To reduce the risk of delayed infusion-related reactions, administer oral corticosteroids to all patients following DARZALEX® infusions. Patients with a history of chronic obstructive pulmonary disease may require additional post-infusion medications to manage respiratory complications. Consider prescribing short- and long-acting bronchodilators and inhaled corticosteroids for patients with chronic obstructive pulmonary disease.

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 DARZALEX® infusion. If ocular symptoms occur, interrupt DARZALEX® infusion and seek immediate ophthalmologic evaluation prior to restarting DARZALEX®.

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 infusion. 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 is not impacted. Notify blood transfusion centers of this interference with serological testing and inform blood banks that a patient has received DARZALEX®. Type and screen patients prior to starting DARZALEX®.

Neutropenia and Thrombocytopenia

DARZALEX® may increase neutropenia and thrombocytopenia 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® until recovery of neutrophils or for recovery of platelets.

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

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 patients with IgG kappa myeloma protein.

Embryo-Fetal Toxicity

Based on the mechanism of action, DARZALEX® can cause fetal harm when administered to a pregnant woman. DARZALEX® 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® and for 3 months after the last dose.

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

ADVERSE REACTIONS

The most frequently reported adverse reactions (incidence ≥20%) were upper respiratory infection, neutropenia, infusion-related reactions, thrombocytopenia, diarrhea, constipation, anemia, peripheral sensory neuropathy, fatigue, peripheral edema, nausea, cough, pyrexia, dyspnea, and asthenia. The most common hematologic laboratory abnormalities (≥40%) with DARZALEX® are neutropenia, lymphopenia, thrombocytopenia, leukopenia, and anemia.

Please click here to read the full Prescribing Information for DARZALEX®.

cp-60862v8

References

1. DARZALEX *FASPRO*® (daratumumab and hyaluronidase-fihj) [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc.
2. Centers for Medicare & Medicaid Services. Medicare Claims Processing Manual. Chapter 26: Completing and Processing Form CMS-1500 Data Set. Revised August 9, 2024. Accessed November 2, 2025. https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c26pdf.pdf
3. UnitedHealthcare. National Drug Code Requirement Policy, Professional and Facility. Accessed November 2, 2025. https://www.uhcprovider.com/content/dam/provider/docs/public/policies/comm-reimbursement/COMM-National-Drug-Code-Requirement-Policy.pdf
4. Centers for Medicare & Medicaid Services. Medicare Claims Processing Manual. Chapter 25: Completing and Processing the Form CMS-1450 Data Set. Revised December 20, 2023. Accessed November 2, 2025. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c25.pdf
5. Centers for Medicare and Medicaid Services. October 2025 Alpha-numeric HCPCS Files. Accessed November 2, 2025. https://www.cms.gov/medicare/coding-billing/healthcare-common-procedure-system/quarterly-update
6. American Medical Association. Current Procedural Terminology: CPT® 2025: Professional Edition. Chicago, IL: AMA Press; 2024.
7. Centers for Medicare & Medicaid Services. ICD-10-CM Official Guidelines for Coding and Reporting FY 2025. Updated October 1, 2025 (October 1, 2025 -September 30, 2026). Accessed November 2, 2025. https://www.cms.gov/files/document/fy-2026-icd-10-cm-coding-guidelines.pdf
8. National Library of Medicine. Medical Application Platform. Accessed November 2, 2025. https://imagic.nlm.nih.gov/imagic/code/map
9. Centers for Medicare & Medicaid Services. Medicare Claims Processing Manual. Chapter 4: Part B Hospital. Revised November 22, 2024. Accessed November 2, 2025. https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c04.pdf
10. CMS. Revised Part B Inflation Rebate Guidance: Use of the 340B Modifier. (December 14, 2023). Accessed November 2, 2025. https://www.cms.gov/files/document/revised-part-b-inflation-rebate-340b-modifier-guidance.pdf
11. Centers for Medicare & Medicaid Services. Medicare Claims Processing Manual. Chapter 17: Drugs and Biologicals. Revised February 2, 2024. Accessed November 2, 2025. https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c17.pdf
12. Centers for Medicare & Medicaid Services. Medicare Claims Processing Manual. Chapter 12: Physicians/Non-Physician Practitioners. Revised December 19, 2024. Accessed November 2, 2025. https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c12.pdf
13. Article - Billing and Coding: Patients Supplied Donated or Free-of-Charge Drug (A55044). www.cms.gov. Accessed November 2, 2025. https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=55044
14. DARZALEX® (daratumumab) [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc.

Once the clinical decision has been made to prescribe DARZALEX®/DARZALEX *FASPRO*®, Johnson & Johnson has resources to help you support your patients.

J&J withMe

Access and Affordability Resources Plus Personalized Support for Your Patients

J&J withMe is your single source for access, affordability, and treatment support programs from Johnson & Johnson. Your patients will be connected to DARZALEX withMe.

Access support — to help navigate payer processes

Affordability resources — to help patients discover ways to afford their DARZALEX® or DARZALEX *FASPRO*® medicine

Dedicated, free 1-on-1 Care Navigator support for your patients — offered through DARZALEX withMe to support the nonclinical needs that may arise while on DARZALEX® or DARZALEX *FASPRO*®

Get started with J&J withMe

- Visit Portal.JNJwithMe.com to investigate insurance coverage for your patients, enroll your patients in savings, or sign them up for Care Navigator support
- Visit JNJwithMe.com/hcp/ for access and affordability information for the J&J medicine you prescribed
- Bookmark these links for quick and easy access!
- Questions? Call 833-JNJ-wMe1 (833-565-9631), Monday through Friday, 8:00 AM to 8:00 PM ET

The patient support and resources provided by J&J withMe and DARZALEX withMe are not intended to provide medical advice, replace a treatment plan from the patient's doctor or nurse, provide case management services, or serve as a reason to prescribe DARZALEX® or DARZALEX *FASPRO*®.

Johnson&Johnson

DARZALEX® (daratumumab) Injection for intravenous infusion 100 mg/5 mL, 400 mg/20 mL | DARZALEX Faspro® (daratumumab and hyaluronidase-fihj) Injection for subcutaneous use | 1,800 mg/30,000 units

Please see Important Safety Information for DARZALEX *FASPRO*® on pages 31-32 and click here to see full Prescribing Information.

Please see Important Safety Information for DARZALEX® on pages 59-60 and click here to see full Prescribing Information.