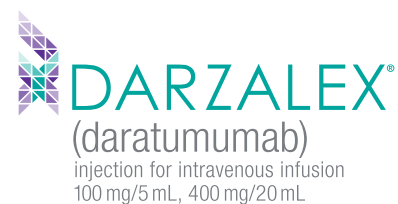


DARZALEX *FASPRO*[®] AND DARZALEX[®]

REIMBURSEMENT & ACCESS GUIDE

IMPORTANT INFORMATION FOR
THE REIMBURSEMENT PROCESS

2023



The information provided in this reimbursement guide is valid as of September 2023 and is subject to change.

Please see Important Safety Information for DARZALEX *FASPRO*[®] on pages [29-30](#) and [click here](#) to see full Prescribing Information.

Please see Important Safety Information for DARZALEX[®] on pages [57-58](#) and [click here](#) to see full Prescribing Information.

Janssen Biotech, Inc. is pleased to provide you with this detailed information to assist you in obtaining reimbursement for **DARZALEX FASPRO**[®] (daratumumab and hyaluronidase-fihj) for subcutaneous injection and **DARZALEX**[®] (daratumumab) 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 Janssen Biotech, Inc., that these codes will be appropriate or that reimbursement will be made. It is not intended to increase or maximize reimbursement by any payer. Laws, regulations, and policies concerning reimbursement are complex and are updated frequently. While we have made 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.

*CPT[®] - Current Procedural Terminology. All rights reserved. CPT[®] is a registered trademark of the American Medical Association, 2021.

Please see Important Safety Information for **DARZALEX FASPRO**[®] on pages [29-30](#) and [click here](#) to see full Prescribing Information.

Please see Important Safety Information for **DARZALEX**[®] on pages [57-58](#) and [click here](#) to see full Prescribing Information.

DARZALEX FASPRO® (daratumumab and hyaluronidase-fihj) 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®	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 human for subcutaneous injection	Shaded portion of Item 24	Form Locator 43

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

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

†This permanent, drug-specific code replaces all HCPCS codes previously used to describe DARZALEX FASPRO®, including any miscellaneous or temporary codes. For claims with dates of service January 1, 2021, and beyond, J9144 is the only code that should be reported in both the hospital outpatient and physician office sites of care.

‡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.

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DARZALEX® (daratumumab) Coding Summary

Code Type	Code	Description	CMS-1500 Placement	CMS-1450 Placement
Diagnosis ICD-10-CM*	C90.00	Multiple myeloma not having achieved remission	Item 21	Form Locator 67
	C90.01	Multiple myeloma in remission		
	C90.02	Multiple myeloma in relapse		
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-use 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-use vial containing 400 mg of daratumumab solution for intravenous infusion		

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.

*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

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Please see Important Safety Information for DARZALEX® on pages [57-58](#) and [click here](#) to see full Prescribing Information.

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Please see Important Safety Information for DARZALEX FASPRO® on pages [29-30](#) and [click here](#) to see full Prescribing Information.

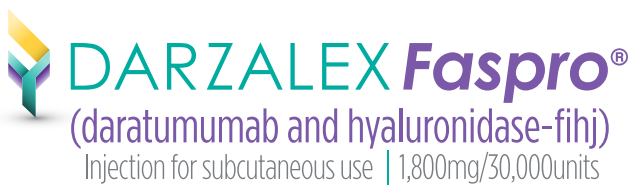
Please see Important Safety Information for DARZALEX® on pages [57-58](#) and [click here](#) to see full Prescribing Information.

Dosing & Administration
for DARZALEX FASPRO®

Coding for
DARZALEX FASPRO®

Sample Claim Forms
for DARZALEX FASPRO®

Important Safety Information
for DARZALEX FASPRO®



INDICATIONS

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

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

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 4 on pages 10-13).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-medications¹

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

- Acetaminophen 650 to 1,000 mg orally
- Diphenhydramine 25 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-medications¹

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

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

(Continued on next page.)

DARZALEX FASPRO® (daratumumab and hyaluronidase-fihj) DOSING FOR MONOTHERAPY AND IN COMBINATION WITH LENALIDOMIDE AND DEXAMETHASONE (DRd) OR POMALIDOMIDE AND DEXAMETHASONE (DPd)¹

- As combination therapy with lenalidomide and low-dose dexamethasone for newly diagnosed patients ineligible for autologous stem cell transplant and in patients with relapsed or refractory multiple myeloma
- As combination therapy with pomalidomide and dexamethasone in patients who have received at least one prior line of therapy including lenalidomide and a proteasome inhibitor
- As monotherapy for patients with relapsed/refractory multiple myeloma
- 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, and Monotherapy Regimens		
4 Doses Per Cycle		given as 1 weekly dose (Cycles 1 to 2; Weeks 1 to 8)
2 Doses Per Cycle		given as 1 dose every 2 weeks (twice per 4-week cycle; Cycles 3 to 6; Weeks 9 to 24)
1 Dose Per Cycle		given as 1 dose every 4 weeks (Cycles 7+, Weeks 25+ until disease progression)
23		Total Doses ESTIMATED year 1

- The dosing schedules for DRd, DPd, 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 or Pd and as monotherapy is once every 4 weeks

SELECTED IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (cont)

Hypersensitivity and Other Administration Reactions (cont)

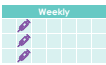
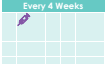

Systemic Reactions (cont)

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
(Continued on next page.)

DARZALEX Faspro® (daratumumab and hyaluronidase-fihj) DOSING IN COMBINATION WITH BORTEZOMIB AND DEXAMETHASONE (DVd)¹

- As combination therapy with bortezomib and dexamethasone for patients with relapsed/refractory multiple myeloma
- 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 2: DARZALEX Faspro® Dosing in DVd Regimen

3	Doses Per Cycle		given as 1 weekly dose (Cycles 1 to 3, Weeks 1 to 9)
1	Dose Per Cycle		given as 1 dose every 3 weeks (once per 3-week cycle; Cycles 4 to 8; Weeks 10 to 24)
1	Dose Per Cycle		given as 1 dose every 4 weeks (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)

Hypersensitivity and Other Administration Reactions (cont)

System Reactions (cont)

and other medications after the administration of DARZALEX Faspro® depending on dosing regimen and medical history to minimize the risk of delayed (defined as occurring the day after administration) systemic administration-related reactions.

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

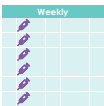
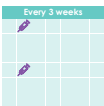
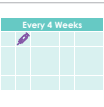

Local Reactions

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

DARZALEX FASPRO® (daratumumab and hyaluronidase-fihj) 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 3: DARZALEX FASPRO® Dosing in DVMP Regimen		
6 Doses Per Cycle		given as 1 weekly dose (Cycle 1, Weeks 1 to 6)
2 Doses Per Cycle		given as 1 dose every 3 weeks (twice per 6-week cycle; Cycles 2 to 9, Weeks 7 to 54)
1 Dose Per Cycle		given as 1 dose every 4 weeks (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)

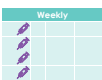
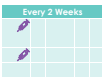
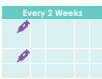

Neutropenia

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.

DARZALEX FASPRO® (daratumumab and hyaluronidase-fihj) DOSING IN COMBINATION WITH BORTEZOMIB, THALIDOMIDE, AND DEXAMETHASONE (D-VTd)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 4: DARZALEX FASPRO® Dosing in D-VTd Regimen	
Induction	<p>4 Doses Per Cycle  given as 1 weekly dose (Cycles 1 to 2; Weeks 1 to 8)</p>
	<p>2 Doses Per Cycle  given as 1 dose every 2 weeks (twice per 4-week cycle; Cycles 3 to 4; Weeks 9 to 16)</p>
STOP FOR HIGH-DOSE CHEMOTHERAPY AND ASCT	
Consolidation	<p>2 Doses Per Cycle  given as 1 dose every 2 weeks (Cycles 5 and 6, upon re-initiation of treatment)</p>
<p>16  Total Doses 23 weeks</p>	

- The dosing schedule for D-VTd is based on an initial 4-week dosing cycle (Cycles 1 to 2)
- Starting at Week 9, administration frequency of D-VTd 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)

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.

CODING FOR DARZALEX FASPRO® (daratumumab and hyaluronidase-fihj)

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 Medicaid fee-for-service 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 5: 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	 <p>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</p>

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 6, 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)

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.

National Drug Codes (NDC) (cont)

Table 6: DARZALEX FASPRO® (daratumumab and hyaluronidase-fihj) 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, UN, ML)
- Reporting the number of NDC units dispensed
- Reporting the qualifier, N4, in front of the NDC³

Using the same DARZALEX FASPRO® example from Table 6, here is how the format would appear on a claim:

N457894050301 ML15

For professional claims (CMS-1500), report the NDC information in the shaded portion of Item 24.² 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 injection⁵

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 7 illustrates the correlation between DARZALEX FASPRO® vials, milligrams, and HCPCS units used for billing.

Table 7: DARZALEX FASPRO® (daratumumab and hyaluronidase-fihj) 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)

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®.

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® (daratumumab and hyaluronidase-fihj) is:

- 96401 - Chemotherapy administration, subcutaneous or intramuscular; non-hormonal anti-neoplastic⁶

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 Janssen CarePath.

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. A 3-character code is to be used only if it is not further subdivided.⁷

Table 8: 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.

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OTHER CODING CONSIDERATIONS

When coding and billing for DARZALEX FASPRO® (daratumumab and hyaluronidase-fihj) 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 9 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)

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 9: 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 ⁹	<ul style="list-style-type: none"> • Patient requires distinct evaluation and management (E/M) service in addition to the infusion procedure⁹ • Must be substantiated with relevant documentation⁹ • Append the modifier to the relevant E/M code⁹ 	✓	✓
PN*	Nonexcepted service provided at an off-campus, outpatient, provider-based department of a hospital ¹⁰	<ul style="list-style-type: none"> • To be reported on each claim line for nonexcepted services furnished in an off-campus, provider-based department of a hospital and billed on an institutional claim¹⁰ 	N/A	✓ Required by Medicare
PO*	Services, procedures, and/or surgeries furnished at excepted off-campus provider-based outpatient departments. ¹⁰	<ul style="list-style-type: none"> • To be reported on each claim line for excepted services furnished in an off-campus, provider-based department of a hospital and billed on an institutional claim¹⁰ 	N/A	✓ Required by Medicare
JG	Drug or biological acquired with 340B Drug Pricing Program Discount ¹⁰	<ul style="list-style-type: none"> • Must be reported by providers that are NOT excepted[†] from the 340B payment policy¹⁰ • To be reported on the same claim line as the drug HCPCS code for all 340B acquired drugs¹⁰ 	N/A	✓ Required by Medicare
TB	Drug or biological acquired with 340B Drug Pricing Program Discount, reported for informational purposes ¹⁰	<ul style="list-style-type: none"> • Must be reported by providers that ARE excepted[†] from the 340B payment policy¹⁰ • To be reported on the same claim line as the drug HCPCS code for all 340B acquired drugs¹⁰ 	N/A	✓ Required by Medicare

*Neither the PO nor the PN modifier is to be reported for dedicated emergency departments, remote locations, or satellite facilities of a hospital, or a provider-based department that is "on campus."¹⁰

†The following provider types are excepted from the 340B payment policy: rural sole community hospitals, children's hospitals, and PPS-exempt cancer hospitals.¹⁰

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.¹¹

Thus, CPT® code 99211 cannot be paid on the same day as an office-based injection of DARZALEX FASPRO® (daratumumab and hyaluronidase-fihj). If a chemotherapy service and a significantly identifiable evaluation and management service are provided on the same day, a different diagnosis is not required.¹¹

Drugs Supplied at No Cost to the Provider

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, it may be necessary to include drug information on the claim and enter "0.01" charges.¹² Payer policies may vary.

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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 10 summarizes the potentially applicable place of service codes:

Table 10: 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

SELECTED IMPORTANT SAFETY INFORMATION

ADVERSE REACTIONS

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

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

DARZALEX FASPRO® (daratumumab and hyaluronidase-fihj) Physician Office Sample Claim Form: CMS-1500

A

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

ICD-10 Diagnosis Codes* for Consideration

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

*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

Drug Administration

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

C

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

D

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

DARZALEX FASPRO®

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

Drug Administration


96401 – Enter 1 unit.

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.

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DARZALEX FASPRO® (daratumumab and hyaluronidase-fihj) CMS-1500 Sample Claim Form 2022

CARRIER
PATIENT AND INSURED INFORMATION
PHYSICIAN OR SUPPLIER INFORMATION



HEALTH INSURANCE CLAIM FORM

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

1. MEDICARE <input checked="" type="checkbox"/> (Medicare#) MEDICAID <input type="checkbox"/> (Medicaid#) TRICARE <input type="checkbox"/> (ID#/DoD#) CHAMPVA <input type="checkbox"/> (Member ID#) GROUP HEALTH PLAN <input type="checkbox"/> (ID#) FECA BLK LUNG <input type="checkbox"/> (ID#) OTHER <input type="checkbox"/> (ID#)		1a. INSURED'S ID 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 M <input checked="" type="checkbox"/> F <input type="checkbox"/>	
4. INSURED'S NAME (Last Name, First Name, Middle Initial) Doe, John B		5. INSURED'S ADDRESS (No., Street) 123 Any Street	
6. PATIENT RELATIONSHIP TO INSURED Self <input checked="" type="checkbox"/> Spouse <input type="checkbox"/> Child <input type="checkbox"/> Other <input type="checkbox"/>		7. INSURED'S ADDRESS (No., Street) CITY STATE Any Town AS	
8. RESERVED FOR NUCC USE		9. RESERVED FOR NUCC USE	
9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)		10. IS PATIENT'S CONDITION RELATED TO: a. EMPLOYMENT? (Current or Previous) YES <input type="checkbox"/> NO <input type="checkbox"/> b. AUTO ACCIDENT? YES <input type="checkbox"/> NO <input type="checkbox"/> PLACE (State) _____ c. OTHER ACCIDENT? YES <input type="checkbox"/> NO <input type="checkbox"/> 10d. CLAIM CODES (Designated by NUCC)	
11. INSURED'S POLICY GROUP OR FECA NUMBER		12. IS THERE ANOTHER HEALTH BENEFIT PLAN? YES <input type="checkbox"/> NO <input type="checkbox"/> If yes, complete items 9, 9a, and 9d.	
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 MM DD YY QUAL: _____	
17. NAME OF REFERRING PROVIDER OR OTHER SOURCE Dr. J. Jones		17a. NPI 123-456-7890	
19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)		20. OUTSIDE LAB? YES <input type="checkbox"/> NO <input type="checkbox"/> \$ CHARGES _____	
21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY. Refer to ALL to service line below (24E) ICD-10 Code:		22. RESUBMISSION CODE ORIGINAL REF. NO.	
A. C90.02		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 I. MODIFIER E. DIAGNOSIS POINTER F. \$ CHARGES G. DAYS OR UNITS H. BPOD Family Plan I. ID. QUAL J. RENDERING PROVIDER ID.#		25. FEDERAL TAX I.D. NUMBER SSN EIN	
1 01 01 22 01 01 22 11 B 96401 C A D 1 NPI 123-456-7890		26. PATIENT'S ACCOUNT NO. 27. ACCEPT ASSIGNMENT? (For govt claims, see back) YES <input type="checkbox"/> NO <input type="checkbox"/>	
2 01 01 22 01 01 22 11 J9144 A 180 NPI 123-456-7890		28. TOTAL CHARGE \$ 29. AMOUNT PAID \$ 30. Rev'd 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.)		32. SERVICE FACILITY LOCATION INFORMATION a. NPI b.	
SIGNED: _____ DATE: _____		33. BILLING PROVIDER INFO & PH # (555) 123-5555 Dr. Jones 555 Any Street Anytown, AS 12345	

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

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

A

Locator Box 42 - List revenue codes in ascending order.

B

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

C

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

DARZALEX FASPRO®

J9144 – Injection, daratumumab 10 mg and hyaluronidase-fihj

Drug Administration

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

D

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

DARZALEX FASPRO®

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

Drug Administration

96401 – Enter 1 unit

E

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

ICD-10 Diagnosis Codes* for Consideration

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

*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.

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

1 Anytown Hospital 123 Any Street Anytown, AS 12345		2 Pay-to-name Pay-to-address Pay-to-city/state		3a PAT CNTL # 3b MED REC # 010001010	3c XX-XXXX DOE 1234-97	4 TYPE OF BILL
8 PATIENT NAME John B Doe		9 PATIENT ADDRESS 123 Any Street		10 BIRTHDATE 07 01 50		
11 SEX M		12 DATE		13 HR		14 TYPE
15 SRC		16 DHR		17 STAT		18
19		20		21		22
23		24		25		26
27		28		29 ACCT STATE		30
31 OCCURRENCE DATE		32 OCCURRENCE DATE		33 OCCURRENCE DATE		34 OCCURRENCE DATE
35 OCCURRENCE SPAN FROM		36 OCCURRENCE SPAN THROUGH		37 OCCURRENCE SPAN FROM		38 OCCURRENCE SPAN THROUGH
39 VALUE CODES AMOUNT		40 VALUE CODES AMOUNT		41 VALUE CODES AMOUNT		42 VALUE CODES AMOUNT
43 REV CD		44 HCP/PCS RATE / HPPS CODE		45 SERV C		46 SERV UNITS
47 TOTAL CHARGES		48 NON-COVERED CHARGES		49		50
51 HEALTH PLAN ID		52 REL INFO		53 REL BEN		54 PRIOR PAYMENTS
55 EST. AMOUNT DUE		56 NPI		57 OTHER PRV ID		58
59 INSURED'S NAME		60 INSURED'S UNIQUE ID		61 GROUP NAME		62 INSURANCE GROUP NO
63 TREATMENT AUTHORIZATION CODES		64 DOCUMENT CONTROL NUMBER		65 EMPLOYER NAME		66
67		68		69		70
71 PPS CODE		72 ECI		73		74
75		76 ATTENDING		77 OPERATING		78 OTHER
79 OTHER		80		81		82
83		84		85		86
87		88		89		90
91		92		93		94
95		96		97		98
99		100		101		102

Dosing & Administration for DARZALEX FASPRO®

Coding for DARZALEX FASPRO®

Sample Claim Forms for DARZALEX FASPRO®

Important Safety Information for DARZALEX FASPRO®



Please see Important Safety Information for DARZALEX FASPRO® on pages 29-30 and [click here](#) to see full Prescribing Information.

DARZALEX®

Sample Letter of Formulary Exception Request: DARZALEX FASPRO® (daratumumab and hyaluronidase-fihj)

[Insert Physician Letterhead]

[Insert Name of Medical Director] RE: Member Name: [Insert Member Name]
 [Insert Payer Name] Member Number: [Insert Member Number]
 [Insert Address] Group Number: [Insert Group Number]
 [Insert City, State Zip]

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, 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]

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***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® (daratumumab and hyaluronidase-fihj) 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
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
Oncology Supply	1-800-633-7555	1-800-248-8205	https://www.oncologysupply.com

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

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

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

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

Local Reactions

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

Neutropenia

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

IMPORTANT SAFETY INFORMATION (cont)

WARNINGS AND PRECAUTIONS (cont)

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

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


cp-143279v7

Dosing & Administration
for DARZALEX®

Coding for
DARZALEX®

Sample Claim Forms
for DARZALEX®

Important Safety Information
for DARZALEX®

 **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

DARZALEX® 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 11-15 on pages 34-38).¹³ 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.¹³

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.¹³ Administer pre-infusion and post-infusion medications to reduce the risk of infusion-related reactions.¹³

Pre-infusion medications¹³

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 prior to every DARZALEX® infusion. When dexamethasone is the background regimen-specific corticosteroid, the dexamethasone treatment dose will instead serve as pre-medication on DARZALEX® infusion days. IV dexamethasone 20 mg is given prior to the first infusion and IV or oral dexamethasone 20 mg prior to subsequent infusions
- Oral antipyretics (acetaminophen 650 to 1000 mg), plus
- Oral or IV antihistamine (diphenhydramine 25 mg to 50 mg or equivalent)

Note:

- On DARZALEX® infusion days in combination therapy clinical trials, 20 mg of the dexamethasone dose was given as a pre-infusion medication. For patients on a reduced dexamethasone dose, the entire 20-mg dose was given as a DARZALEX® pre-infusion medication.
- Additional background regimen-specific corticosteroids (eg, prednisone) should not be taken on DARZALEX® infusion days when patients receive dexamethasone (or equivalent) as a pre-medication.

Post-infusion medications¹³

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

- Oral corticosteroid
 - ✓ for monotherapy, 20 mg methylprednisolone or equivalent dose of an intermediate-acting or long-acting corticosteroid in accordance with local standards on each of the 2 days following all DARZALEX® (daratumumab) infusions (beginning the day after the infusion)
 - ✓ for combination therapy, ≤20 mg of methylprednisolone or equivalent 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 infusions, if the patient experiences no major infusion-related reactions, these additional inhaled post-infusion medications may be discontinued.

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.

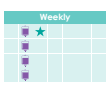
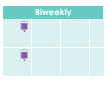
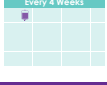

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DARZALEX® (daratumumab) DOSING FOR MONOTHERAPY AND IN COMBINATION WITH LENALIDOMIDE AND DEXAMETHASONE (DRd) OR POMALIDOMIDE AND DEXAMETHASONE (DPd)¹³

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 11: DARZALEX® Dosing in DRd, DPd, and Monotherapy Regimens

4 Doses Per Cycle		given as 1 weekly infusion (Cycles 1 to 2; Weeks 1 to 8)
2 Doses Per Cycle		given as 1 infusion every 2 weeks (twice per 4-week cycle; Cycles 3 to 6; Weeks 9 to 24)
1 Dose Per Cycle		given as 1 infusion every 4 weeks (Cycles 7+, Weeks 25+ until disease progression)
23		ESTIMATED year 1 infusion visits

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

- The dosing schedules for DRd, DPd, and DARZALEX® monotherapy are based on a 28-day (4-week) cycle throughout therapy¹³
- Starting at Week 25, administration frequency for DARZALEX® regimens is once every 4 weeks and median duration averages 3.4 hours¹³

Note: For DARZALEX® infusion rates, please see Table 16 on page 39.

SELECTED IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (cont)

Infusion-Related Reactions (cont)

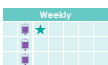
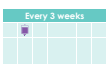
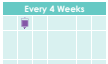

When DARZALEX® dosing was interrupted in the setting of ASCT (CASSIOPEIA) for a median of 3.75 months (range: 2.4 to 6.9 months), upon re-initiation of DARZALEX®, the incidence of infusion-related reactions was 11% for the first infusion following ASCT. *(Continued on next page.)*

DARZALEX® (daratumumab) DOSING IN COMBINATION WITH BORTEZOMIB AND DEXAMETHASONE (DvD)¹³

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 12: DARZALEX® Dosing in DVd Regimen

3 Doses Per Cycle		given as 1 weekly infusion (Cycles 1 to 3, Weeks 1 to 9)
1 Dose Per Cycle		given as 1 infusion every 3 weeks (once per 3-week cycle; Cycles 4 to 8; Weeks 10 to 24)
1 Dose Per Cycle		given as 1 infusion every 4 weeks (Cycles 9+, Weeks 25+ until disease progression)
21		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 cycles¹³
- Starting at Week 25, administration frequency for DARZALEX® regimens is once every 4 weeks, and median duration averages 3.4 hours¹³

Note: For DARZALEX® infusion rates, please see Table 16 on page 39.

SELECTED IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (cont)

Infusion-Related Reactions (cont)

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.

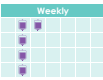
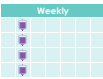
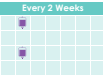


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DARZALEX® (daratumumab) DOSING IN COMBINATION WITH CARFILZOMIB AND DEXAMETHASONE (DKd)¹³

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 13: DARZALEX® Dosing in DKd Regimen

5 Doses Per Cycle		Week 1: given as split dose infusion over 2 consecutive days Weeks 2-4: given as 1 weekly infusion
4 Doses Per Cycle		Weeks 5 to 8: given as 1 weekly infusion (Cycle 2)
2 Doses Per Cycle		Weeks 9-24: given as 1 infusion every 2 weeks (Cycles 3-6)
1 Dose Per Cycle		Weeks 25+ until disease progression: given as 1 infusion every 4 weeks (Cycles 7+)
24		ESTIMATED year 1 infusion visits

- The dosing schedule for DKd is based on 28-day (4 week) cycles. Two initial doses are given Week 1, followed by weekly doses Weeks 2 to 8 and doses every 2 weeks Weeks 9 to 24.¹³
- Starting at Week 25, administration frequency for DARZALEX® regimens is once every 4 weeks, and median duration averages 3.4 hours¹³

Note: For DARZALEX® infusion rates, please see Table 16 on page 39.

SELECTED IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (cont)

Infusion-Related Reactions (cont)

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.





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DARZALEX® (daratumumab) DOSING IN COMBINATION WITH BORTEZOMIB, THALIDOMIDE, AND DEXAMETHASONE (DVTd)¹³

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 trial¹³

Table 14: DARZALEX® Dosing in DVTd Regimen	
Induction	4 Doses Per Cycle  given as 1 weekly infusion (Cycles 1 to 2; Weeks 1 to 8)
	2 Doses Per 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 Doses 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  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)¹³
- DARZALEX® is then stopped for high-dose chemotherapy and ASCT¹³
- During consolidation, the administration frequency for DARZALEX® is once every 2 weeks for 8 weeks (Cycles 5 and 6)¹³

Note: For DARZALEX® infusion rates, please see Table 16 on page 39.

SELECTED IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (cont)


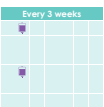


Infusion-Related Reactions (cont)

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.

DARZALEX® (daratumumab) DOSING IN COMBINATION WITH BORTEZOMIB, MELPHALAN, AND PREDNISONE (DVMP)¹³

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 15 : DARZALEX® Dosing in DVMP Regimen		
6 Doses Per Cycle		given as 1 weekly infusion (Cycle 1, Weeks 1 to 6)
2 Doses Per Cycle		given as 1 infusion every 3 weeks (twice per 6-week cycle; Cycles 2 to 9, Weeks 7 to 54)
1 Dose Per Cycle		given as 1 infusion every 4 weeks (Cycles 10+, Weeks 55+ until disease progression)
22		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 cycles¹³
- Starting at Cycle 10 (Week 55+), administration frequency for DARZALEX® is once every 4 weeks and median duration of infusion averages 3.4 hours¹³

Note: For DARZALEX® infusion rates, please see Table 16 on page 39.

SELECTED IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (cont)

Infusion-Related Reactions (cont)

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® (daratumumab) 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.¹³

Table 16: 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

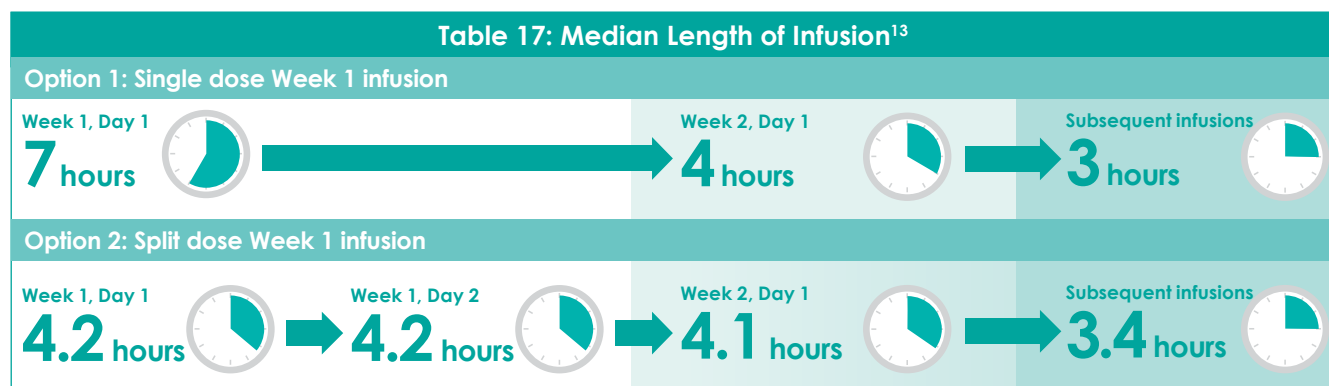
For infusion-related reactions of any grade/severity, immediately interrupt the DARZALEX® infusion and manage symptoms. Depending on the infusion-related reaction severity, management may require further reduction in the infusion rate or discontinuation of the DARZALEX® treatment.¹³

*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.





CODING FOR DARZALEX® (daratumumab)

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 Medicaid fee-for-service 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 18: National Drug Codes for DARZALEX®¹³

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

SELECTED IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (cont)

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)

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 1200 mg dose of DARZALEX® (daratumumab):

Table 19: DARZALEX® NDC Units

Dose to Be Billed	11-Digit NDC (5-4-2 format)	Packaging	NDC Unit of Measure	NDC Units
1200 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 1200 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 1200 mg DARZALEX® example, here is how this format would appear on a claim:

N457894050520 ML60

For professional claims (CMS-1500), report the NDC information in the shaded portion of Item 24.² 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)

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® (daratumumab) is:

- J9145 - Injection, daratumumab, 10 mg¹⁴

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 20 illustrates the correlation between DARZALEX® vials, milligrams, and HCPCS units used for billing.

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	1200	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)

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® (daratumumab) are:

- 96413 - Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug⁶
- 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 Janssen CarePath.

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SELECTED IMPORTANT SAFETY INFORMATION

ADVERSE REACTIONS

The most frequently reported adverse reactions (incidence $\geq 20\%$) 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 ($\geq 40\%$) 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. A 3-character code is to be used only if it is not further subdivided. A code is invalid if it has not been coded to the full number of characters required for that code, including the 7th character, if applicable.⁷

Table 21: 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.

OTHER CODING CONSIDERATIONS

When coding and billing for DARZALEX® (daratumumab) 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 22 summarizes modifiers that may be applicable to the provision of DARZALEX® in physician offices and hospital outpatient departments.

Table 22: 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 ⁹	<ul style="list-style-type: none"> • Patient requires distinct evaluation and management (E/M) service in addition to the infusion procedure⁹ • Must be substantiated with relevant documentation⁹ • Append the modifier to the relevant E/M code⁹ 	✓	✓
JW	Drug amount discarded/not administered to any patient ¹⁵	<ul style="list-style-type: none"> • Unused drug remains after applicable dose is administered from single-use vial¹⁶ • CMS has issued a discarded drug policy and requires use of the JW modifier; other payer requirements may vary¹⁶ • Append the modifier to the drug code on a line separate from that reporting the administered dose, and document administered and discarded amounts in the medical record¹⁶ 	✓ Required by Medicare	✓ Required by Medicare
PN*	Nonexcepted service provided at an off-campus, outpatient, provider-based department of a hospital ¹⁰	<ul style="list-style-type: none"> • To be reported on each claim line for nonexcepted services furnished in an off-campus, provider-based department of a hospital and billed on an institutional claim¹⁰ 	N/A	✓ Required by Medicare
PO*	Services, procedures, and/or surgeries furnished at excepted off-campus provider-based outpatient departments. ¹⁰	<ul style="list-style-type: none"> • To be reported on each claim line for excepted services furnished in an off-campus, provider-based department of a hospital and billed on an institutional claim¹⁰ 	N/A	✓ Required by Medicare
JG	Drug or biological acquired with 340B Drug Pricing Program Discount ¹⁰	<ul style="list-style-type: none"> • Must be reported by providers that are NOT excepted[†] from the 340B payment policy¹⁰ • To be reported on the same claim line as the drug HCPCS code for all 340B acquired drugs¹⁰ 	N/A	✓ Required by Medicare
TB	Drug or biological acquired with 340B Drug Pricing Program Discount, reported for informational purposes ¹⁰	<ul style="list-style-type: none"> • Must be reported by providers that ARE excepted[†] from the 340B payment policy¹⁰ • To be reported on the same claim line as the drug HCPCS code for all 340B acquired drugs¹⁰ 	N/A	✓ Required by Medicare

*Neither the PO nor the PN modifier is to be reported for dedicated emergency departments, remote locations, or satellite facilities of a hospital, or a provider-based department that is "on campus."¹⁰

†The following provider types are excepted from the 340B payment policy: rural sole community hospitals, children's hospitals, and PPS-exempt cancer hospitals.¹⁰

CMS Discarded Drug Policies¹⁶

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.

Summary

- Both the administered and discarded drug amounts should be clearly documented in the medical record
- Payment for discarded amounts of drug or biologics applies only to single-use vials or packages
- Multi-use vials are not subject to payment for discarded amounts of drug or biological
- Medicare contractors require the JW modifier on claims for unused drug or biological. Check with other payers for specific requirements

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 (for “each additional hour”) is to be used for “infusion intervals of greater than 30 minutes beyond 1-hour increments.”¹¹ 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

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, it may be necessary to include drug information on the claim and enter “0.01” charges.¹² 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.¹¹

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.¹¹

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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 23 summarizes the potentially applicable place of service codes:

Table 23: 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® (daratumumab) 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

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			B. PLACE OF SERVICE	C. EMG	D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS	E. DIAGNOSIS POINTER	F. \$ CHARGES	G. DAYS OR UNITS	H. BPSDT PAY PER	I. ID. QUAL	J. RENDERING PROVIDER ID. #	K. SUPPLIER INFORMATION				
	From MM DD YY	To MM DD YY															
1	01	01	22	01	01	22	11		96413			A		1		NPI	123-456-7890
2	01	01	22	01	01	22	11		96415			A		3		NPI	123-456-7890
3	01	01	22	01	01	22	11		J9145			A		60		NPI	123-456-7890

*Please contact your local payer or Janssen CarePath at 877-CarePath (877-227-3728).

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DARZALEX® (daratumumab) CMS-1500 Sample Claim Form: Initial Infusion, Single Dose: 2022

CARRIER
PATIENT AND INSURED INFORMATION
PHYSICIAN OR SUPPLIER INFORMATION



HEALTH INSURANCE CLAIM FORM

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

<input type="checkbox"/> PICA		<input type="checkbox"/> PICA	
1. MEDICARE <input checked="" type="checkbox"/> (Medicare#) <input type="checkbox"/> MEDICAID (Medicaid#) <input type="checkbox"/> TRICARE (ID#/DoD#) <input type="checkbox"/> CHAMPVA (Member ID#) <input type="checkbox"/> GROUP HEALTH PLAN (ID#) <input type="checkbox"/> FECA (Billing (ID#)) <input type="checkbox"/> 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		4. INSURED'S NAME (Last Name, First Name, Middle Initial) Doe, John B	
5. PATIENT'S ADDRESS (No., Street) 123 Any Street		7. INSURED'S ADDRESS (No., Street) ()	
3. PATIENT'S BIRTH DATE MM DD YY 07 01 50		6. PATIENT RELATIONSHIP TO INSURED Self <input checked="" type="checkbox"/> Spouse <input type="checkbox"/> Child <input type="checkbox"/> Other <input type="checkbox"/>	
8. RESERVED FOR NUCC USE		11. INSURED'S POLICY GROUP OR FECA NUMBER	
9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)		10. IS PATIENT'S CONDITION RELATED TO: a. EMPLOYMENT? (Current or Previous) YES <input type="checkbox"/> NO <input type="checkbox"/> b. AUTO ACCIDENT? YES <input type="checkbox"/> NO <input type="checkbox"/> PLACE (State) _____ c. OTHER ACCIDENT? YES <input type="checkbox"/> NO <input type="checkbox"/> d. CLAIM CODE(S) (Designated by NUCC)	
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 _____ DATE _____	
14. DATE OF CURRENT ILLNESS, INJURY, or PREGNANCY (LMP) MM DD YY QUAL: _____		15. OTHER DATE MM DD YY QUAL: _____	
17. NAME OF REFERRING PROVIDER OR OTHER SOURCE Dr. Jones		18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES FROM MM DD YY TO MM DD YY	
19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC) Please see facing page for split dose information		20. OUTSIDE LAB? \$ CHARGES <input type="checkbox"/> YES <input type="checkbox"/> NO	
21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY. Relate to I.C.D. 9-CM service lines below (24E) 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. EPIC/20 Family Plan I. ID. QUAL J. RENDERING PROVIDER ID. #		25. FEDERAL TAX I.D. NUMBER SSN EIN 26. PATIENT'S ACCOUNT NO. 27. ACCEPT ASSIGNMENT? (For prior claims, only check) YES <input type="checkbox"/> NO <input type="checkbox"/> 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	

NUCC Instruction Manual available at: www.nucc.org PLEASE PRINT OR TYPE 123-456789-10 OMB-0938-1197 FORM 1500 (02-12)

DARZALEX® (daratumumab) 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

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 / HPPS CODE	46 SERV. DATE	46 SERV. UNITS	47 TOTAL CHARGES	48 NON-COVERED CHARGES	49
0335	Chemotherapy administration - IV	96413	01-01-22	1			1
0335	Chemotherapy administration - IV	96415	01-01-22	3			2
0636	DARZALEX® (daratumumab)	J9145	01-01-22	60			3

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 Janssen CarePath at 877-CarePath (877-227-3728).

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DARZALEX® (daratumumab) CMS-1450 (UB-04) Sample Claim Form: Initial Infusion, Single Dose: 2022

1 Anytown Hospital 123 Any Street Anytown, AS 12345		2 Pay-to-name Pay-to-address Pay-to-city/state		3a PAT. CTRL. # XX-XXXX	4 TYPE OF BILL
8 PATIENT NAME John B Doe		9 PATIENT ADDRESS 123 Any Street		5 FED. TAX NO. 010001010	7 STATEMENT COVERS PERIOD FROM THROUGH
10 BIRTHDATE 07 01 50	11 SEX M	12 DATE OF BIRTH	13 HR	14 TYPE	15 SRG
16 DHR		17 STAT	18	19	20
21		22	23	24	25
26		27	28	29 ACOT STATE	30
31 OCCURRENCE CODE		32 OCCURRENCE DATE	33 OCCURRENCE CODE	34 OCCURRENCE DATE	35 OCCURRENCE CODE
36 OCCURRENCE DATE		37	38 OCCURRENCE SPAN FROM THROUGH		39
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46		47		48	
49		50		51	
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Sample Letter of Medical Necessity: DARZALEX® (daratumumab)

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.JanssenCarePath.com/hcp/DARZALEX for digital sample letter templates.

[Insert Physician Letterhead]

[Insert Name of Medical Director] RE: Member Name: [Insert Member Name]
 [Insert Payer Name] Member Number: [Insert Member Number]
 [Insert Address] Group Number: [Insert Group Number]
 [Insert City, State Zip]

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 support my request for an **authorization** 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, response to those interventions, description of patient's recent symptoms/condition, 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]

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

Sample Letter of Formulary Exception Request: DARZALEX® (daratumumab)

[Insert Physician Letterhead]

[Insert Name of Medical Director] RE: Member Name: [Insert Member Name]
 [Insert Payer Name] Member Number: [Insert Member Number]
 [Insert Address] Group Number: [Insert Group Number]
 [Insert City, State Zip]

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, response to those interventions, description of patient's recent symptoms/condition, 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]

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***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® (daratumumab) 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
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://mcs.mckesson.com
Oncology Supply	1-800-633-7555	1-800-248-8205	https://www.oncologysupply.com

Note: Janssen Biotech, Inc., 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®.

IMPORTANT SAFETY INFORMATION (cont)

WARNINGS AND PRECAUTIONS (cont)

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.

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 $\geq 20\%$) 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 ($\geq 40\%$) with DARZALEX® are neutropenia, lymphopenia, thrombocytopenia, leukopenia, and anemia.

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 September 4, 2020. Accessed August 30, 2023. <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c26pdf.pdf>
3. UnitedHealthcare. National Drug Code Requirements UnitedHealthcare Commercial and UnitedHealthcare Medicare Advantage Professional and Hospital Outpatient Claims Frequently Asked Questions. Accessed August 30, 2023. <https://www.uhcprovider.com/content/dam/provider/docs/public/complan/wa/forms-and-references/WA-NDC-Requirements-FAQs.pdf>
4. Centers for Medicare & Medicaid Services. Medicare Claims Processing Manual. Chapter 25: Completing and Processing the Form CMS-1450 Data Set. Revised January 11, 2019. Accessed August 30, 2023. <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c25.pdf>
5. HCPCS.codes. HCPCS Codes for Daratumumab, hyaluronidase. Accessed August 30, 2023. <https://hcpcs.codes/j-codes/J9144/>
6. American Medical Association. Current Procedural Terminology: CPT® 2021: Professional Edition. Chicago, IL: AMA Press; 2020.
7. Centers for Medicare & Medicaid Services. ICD-10-CM Official Guidelines for Coding and Reporting FY 2021 (October 1, 2020 -September 30, 2021). Accessed August 30, 2023. <https://www.cms.gov/files/document/2021-coding-guidelines.pdf>
8. American Medical Association. ICD-10-CM 2021: The Complete Official Code Book. Chicago, IL: Optum 360 LLC; 2020.
9. American Medical Association. Current Procedural Terminology: CPT® 2020: Professional Edition. Appendix. Chicago, IL: AMA Press; 2019.
10. Centers for Medicare & Medicaid Services. Medicare Claims Processing Manual. Chapter 4: Part B Hospital. Accessed August 30, 2023. <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c04.pdf>
11. Centers for Medicare & Medicaid Services. Medicare Claims Processing Manual. Chapter 12: Physicians/Non-Physician Practitioners. Accessed August 30, 2023. <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c12.pdf>
12. Article - Billing and Coding: Patients Supplied Donated or Free-of-Charge Drug (A55044). www.cms.gov. Accessed September 7, 2023. <https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=55044>
13. DARZALEX® (daratumumab) [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc.
14. HCPCS.codes. HCPCS Code for Injection, Daratumumab, 10 mg. Accessed August 30, 2023. <https://hcpcs.codes/j-codes/J9145/>
15. American Medical Association. 2020 HCPCS Level 2, Professional Edition. Chicago, IL: AMA Press; 2019.
16. Centers for Medicare & Medicaid Services. Medicare Claims Processing Manual. Chapter 17: Drugs and Biologicals. Accessed August 30, 2023. <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c17.pdf>

Please see Important Safety Information for DARZALEX FASPRO® on pages [29-30](#) and [click here](#) to see full Prescribing Information.

Please see Important Safety Information for DARZALEX® on pages [57-58](#) and [click here](#) to see full Prescribing Information.

Janssen CarePath

Support to help your patients start and stay on medication

Janssen CarePath gives you access and affordability support for your patients to help them start and stay on the Janssen medication you prescribe. We can help:

- ✓ Verify insurance coverage
- ✓ Provide reimbursement information
- ✓ Find affordability options for eligible patients
- ✓ Invite patients to sign up for a dedicated Care Navigator



If you have questions, call Janssen CarePath at 877-CarePath (877-227-3728), Monday–Friday, 8:00 AM–8:00 PM ET.



Sign Up or Log In to the Provider Portal at JanssenCarePathPortal.com

Visit JanssenCarePath.com/hcp/darzalex or JanssenCarePath.com/hcp/darzalex-faspro

To contact Janssen Medical Information Center

Call: **1-800-JANSSEN (1-800-526-7736)**

Monday–Friday, 9:00 AM to 8:00 PM ET

E-mail: Submit questions via our askjanssenmedinfo.com site.

Please see Important Safety Information for DARZALEX FASPRO® on pages [29-30](#) and [click here](#) to see full Prescribing Information.

Please see Important Safety Information for DARZALEX® on pages [57-58](#) and [click here](#) to see full Prescribing Information.

