

# DARZALEX™ REIMBURSEMENT & ACCESS GUIDE

IMPORTANT INFORMATION TO SUPPORT  
THE REIMBURSEMENT PROCESS

Please see Important Safety Information on pages  
30–31 and accompanying full Prescribing Information.





## INTRODUCTION

**Janssen Biotech, Inc.**, is committed to providing you and your office staff with detailed information to assist you in obtaining reimbursement for DARZALEX™ (daratumumab). This Reimbursement and Access Guide has been developed to provide you with information regarding:

- Essential Coding Considerations
- Sample Claims Forms
- A list of Specialty Distributors
- Important Product Information
- Reimbursement Support Services

Information about access and reimbursement support services for DARZALEX™—for both providers and patients has been made available through Janssen CarePath. Please feel free to call **1-844-55-DARZA (553-2792)** to speak with a Janssen CarePath Case Coordinator about any reimbursement-related questions or concerns.

## Indication

DARZALEX™ is indicated for the treatment of patients with multiple myeloma who have received at least 3 prior lines of therapy, including a proteasome inhibitor (PI) and an immunomodulatory agent (IMiD), or who are double refractory to a PI and IMiD.<sup>1</sup> Please see Important Safety Information on pages 30-31.

## Disclaimer

- This document is presented for informational purposes only and is not intended to provide reimbursement or legal advice
- Laws, regulations, and policies concerning reimbursement are complex and are updated frequently
  - While we have made an effort to be current as of the issue date of this document, the information may not be as current or comprehensive when you view it
  - Similarly, all Current Procedural Terminology (CPT®) and Healthcare Common Procedure Coding System (HCPCS) codes are supplied for informational purposes only, and this information does not represent any statement, promise, or guarantee by Janssen Biotech, Inc., about coverage, levels of reimbursement, payment, or charge
- Please consult your payer organization(s) for local or actual coverage and reimbursement policies and determination processes
- Please consult with your counsel or internal reimbursement specialist for any reimbursement or billing questions specific to your institution. CPT® codes and descriptions are copyright 2015 American Medical Association. All rights reserved. CPT® is a registered trademark of the American Medical Association (AMA)

1. PI/section1/  
all

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1. PI/  
section5.1/  
para1/all

### → Important Safety Information

Infusion-related reactions were reported in approximately half of all patients treated with DARZALEX™. Monitor such patients throughout the infusion and the post-infusion period.

**Please see Important Safety Information on pages 30–31 and accompanying full Prescribing Information.**

## DARZALEX™ (daratumumab) DOSING AND ADMINISTRATION

The recommended dose of DARZALEX™ is 16 mg/kg body weight administered as an intravenous infusion according to the dosing schedule shown in the chart below.<sup>1</sup>

For example, a patient with a body weight of 75 kg would require 1200 mg dose of DARZALEX™. Administer pre-infusion and post-infusion medications to reduce the risk of infusion-related reactions.

### Pre-infusion Medication

Approximately 1 hour prior to every infusion of DARZALEX™ patients should receive:

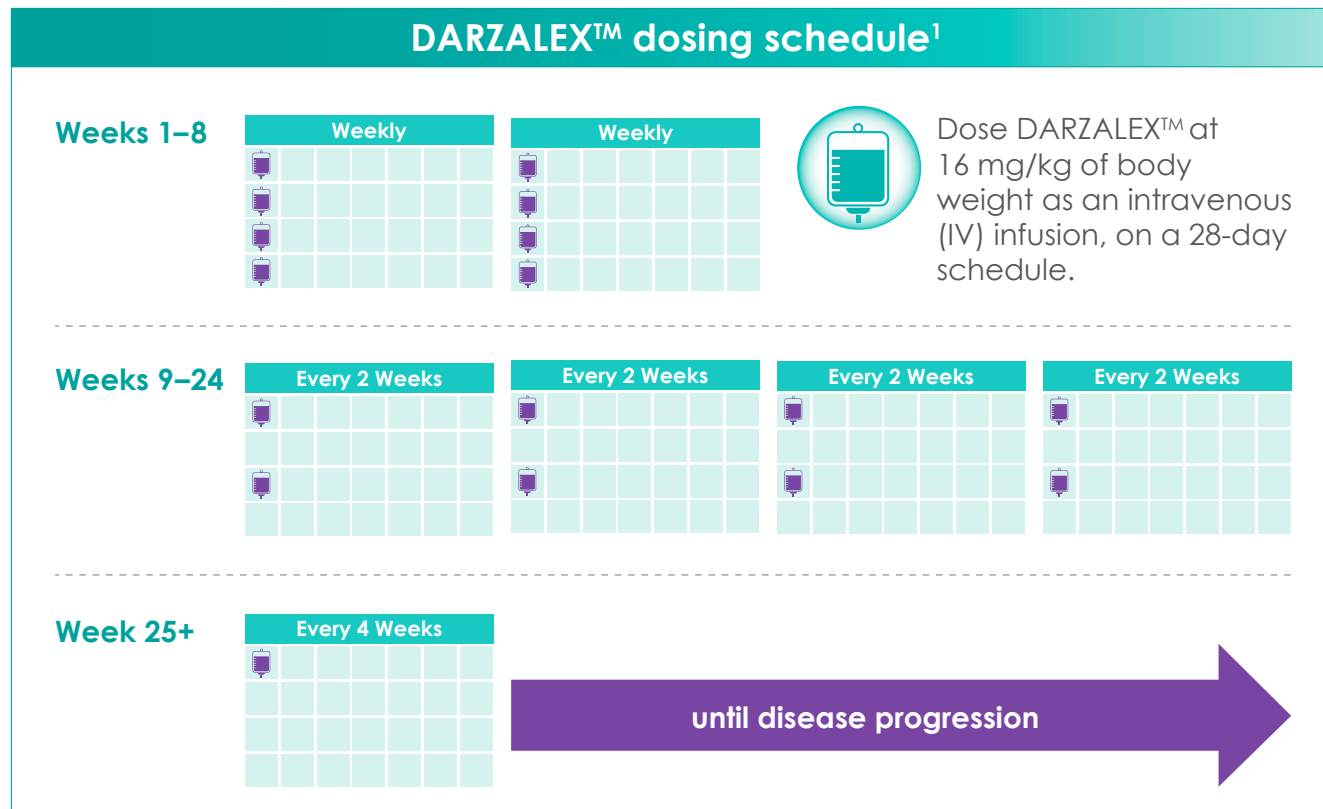
- IV methylprednisolone 100 mg, or equivalent dose of an intermediate-acting or long-acting corticosteroid, plus
- Oral acetaminophen 650 to 1000 mg, plus
- Oral or IV diphenhydramine 25 to 50 mg or equivalent

Following the second infusion, the dose of methylprednisolone may be reduced to 60 mg IV at the discretion of the physician.

### Post-infusion Medication

Administer oral methylprednisolone 20 mg or equivalent dose of a corticosteroid to patients the first and second day after all infusions.

Following dilution with 0.9% sodium chloride USP, administer the DARZALEX™ infusion intravenously at the appropriate infusion rate as presented on the next page. Consider incremental escalation of the infusion rate only if the previous infusion of DARZALEX™ was well-tolerated as defined on the next page.



1. PI section 2.1/all

1. PI section 2.2/all

1. PI section 2.1/table1



1. PI/ Patient Information section / para 11: What are possible side effects?/Ins3-4

1. PI section 2.1/table2

1. PI/ section2.3/ paras2-3/all

Slower rate of infusion for the first DARZALEX™ (daratumumab) dose is recommended, as infusion-related reactions are more likely to occur during the first infusion.<sup>1</sup>

Infusion rates for DARZALEX™, <sup>1</sup>				
	Dilution volume	Initial infusion rate (first hour)	Increments of infusion rate	Maximum infusion rate
<b>First infusion</b>	1000 mL	50 mL/hour	50 mL/hour every hour	200 mL/hour
<b>Second infusion*</b>	500 mL	50 mL/hour	50 mL/hour every hour	200 mL/hour
<b>Subsequent infusions<sup>†</sup></b>	500 mL	100 mL/hour	50 mL/hour every hour	200 mL/hour

\*Modified rates should be used only if the first infusion of DARZALEX™ was well tolerated as defined by an absence of >Grade 1 infusion-related reactions during the first 3 hours.

†Modified rates should be used only if the first 2 infusions of DARZALEX™ were well tolerated as defined by an absence of >Grade 1 infusion-related reactions during a final infusion rate of ≥100 mL/hour.

**Note:** For infusion-related reactions of any grade/severity, immediately interrupt the DARZALEX™ infusion and manage symptoms. Management of infusion-related reactions may further require reduction in the rate of infusion or treatment discontinuation of DARZALEX™.

### Important Safety Information

Infusion-related reactions were reported in approximately half of all patients treated with DARZALEX™. Monitor such patients throughout the infusion and the postinfusion period.

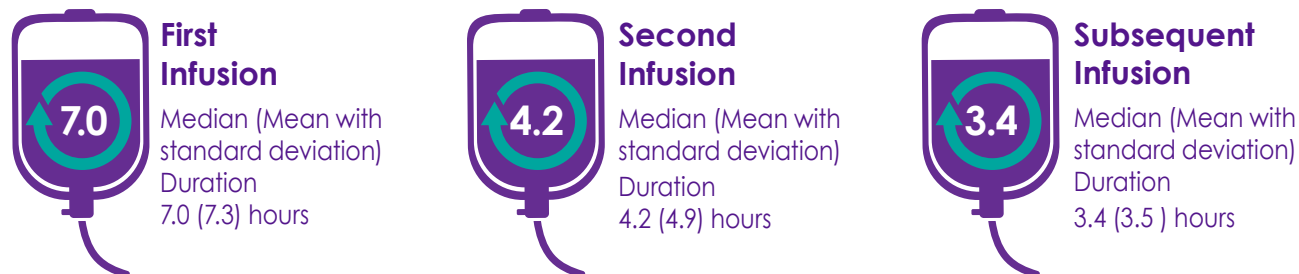
**Please see Important Safety Information on pages 30–31 and accompanying full Prescribing Information.**



2. Data on file.

### Average Length of DARZALEX™ Infusion in a Phase II Study<sup>2</sup>

In a Phase II efficacy and safety study of DARZALEX™ (daratumumab), the median (mean) length of infusion was as follows:



### Important Safety Information (cont'd)

#### Infusion-Related Reactions

#### WARNINGS AND PRECAUTIONS

Infusion-related reactions were reported in approximately half of all patients treated with DARZALEX™. Monitor such patients throughout the infusion and the post-infusion period.

The majority (91%) of IRRs occurred at the first infusion. Seven percent of patients had an IRR at more than one infusion. Common ( $\geq 5\%$ ) symptoms included nasal congestion, chills, cough, allergic rhinitis, throat irritation, dyspnea, and nausea, and were mild to moderate in severity. Severe IRRs (4%) including bronchospasm (1.3%), hypertension (1.3%), and hypoxia (0.6%) were also reported.

Pre-medicate patients with antihistamines, antipyretics and corticosteroids to reduce the risk of IRRs prior to treatment with DARZALEX™. Interrupt DARZALEX™ infusion for IRRs of any severity. Institute medical management/supportive treatment for IRRs as needed. Reduce the infusion rate when re-starting the infusion.

For the prevention of delayed IRRs, administer oral corticosteroids to all patients the first and second day after all infusions. Additionally consider the use of post-infusion medications (e.g. inhaled corticosteroids, short and long acting bronchodilators) for patients with a history of obstructive pulmonary disorder to manage respiratory complications should they occur.

#### Interference with Serological Testing



Daratumumab binds to CD38 found at low levels on red blood cells (RBCs) and may result in a positive indirect Coombs test. Daratumumab-mediated positive indirect Coombs test may persist for up to 6 months after the last daratumumab infusion. It should be recognized that daratumumab bound to RBCs may mask 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.

In the event of a planned transfusion notify blood transfusion centers of this interference with serological testing.

## CODING FOR DARZALEX™ (daratumumab)

### NDC Numbers<sup>1</sup>

In some cases you may be required to include the National Drug Code (NDC) number in the appropriate location on a claim form, especially when reporting with a miscellaneous Healthcare Common Procedure Coding System (HCPCS) code.

NDC Numbers for DARZALEX™,1		
10-digit NDC	11-digit NDC (most commonly used)	Description
57894-502-05	57894-0502-05	 <p><b>100 mg/5 mL vial</b>            Single-use vial containing 100 mg of daratumumab solution for intravenous infusion</p>
57894-502-20	57894-0502-20	 <p><b>400 mg/20 mL vial</b>            Single-use vial containing 400 mg of daratumumab solution for intravenous infusion</p>

1. PI section 16.1/lines3-4

1. PI section 16.1/ line1; section2.5/ bullet1/line1

**Note:** Payer requirements regarding the use of the 10- or 11-digit NDC may vary. Electronic submission generally requires use of the 11-digit NDC. To convert the 10-digit NDC to the 11-digit format, insert a leading zero in the middle sequence, as illustrated in the table above.

Please see Important Safety Information on pages 30–31 and accompanying full Prescribing Information.





### Miscellaneous HCPCS Codes<sup>3</sup>

Drugs are typically reported using product-specific HCPCS codes (eg, J-code) assigned by the Centers for Medicare & Medicaid Services (CMS). J-codes are a subset of the HCPCS Level II code set. Initially, as a new drug, DARZALEX™ (daratumumab) will be reported with a miscellaneous HCPCS code that may vary by payer and treatment setting.

3. CMS. Apha-Numeric HCPCS File, 2015; rows for C9399, J3490, J3590, J9999

Potential Miscellaneous HCPCS Codes for DARZALEX™ <sup>3</sup>			
Code	Description	Relevant Payer Requirements <sup>4</sup>	
		Office Setting	Hospital Outpatient Setting
C9399	Unclassified drugs or biologicals	n/a	For Medicare claims
J9999	Not otherwise classified, antineoplastic drugs	For Medicare or commercial payer claims	For commercial payer claims

4. CMS. Claims Processing Manual, Chapter 17, Sections 90.2-90.3; p 59, para 3; p 62, para 2

5. CMS, HCPCS Coding Procedures, Sep 2012; p3, para 6

**Note:** Unclassified or miscellaneous HCPCS codes are used to allow suppliers to begin billing immediately for an item as soon as the FDA grants marketing approval for a new product, even though no existing national code adequately describes the item being billed. These miscellaneous HCPCS codes can be used during the time when a new code is being considered for a specific product under the HCPCS review process.<sup>5</sup> When listing a miscellaneous HCPCS code, payers may require reporting the drug name, strength, NDC number, dose administered, and route of administration. In addition, for claims with a miscellaneous HCPCS code, some payers may request supplemental information such as the prescribing information, published clinical trials, and/or the purchase invoice. However, specific payer requirements may vary.



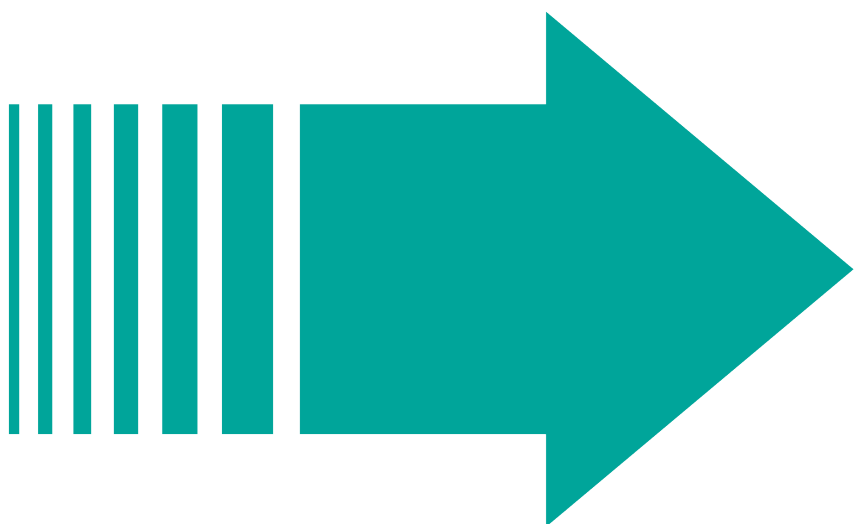
5. CMS, HCPCS Coding Procedures, Sep 2012; p3, para 6

### Transition to Temporary and Permanent HCPCS Codes<sup>5</sup>

A temporary C-code for DARZALEX™ (daratumumab) is expected by April 2016. Once effective, the DARZALEX™ temporary C-code will replace the miscellaneous code C9399 when it is provided for billing Medicare in the hospital outpatient setting.

A permanent J-code for DARZALEX™ is expected by January 2017. The DARZALEX™ permanent J-code will replace miscellaneous and/or temporary codes used across all settings of care.

Expected Changes in HCPCS Codes for DARZALEX™ <sup>5</sup>			
Setting of Care	Miscellaneous Code	Temporary Code	Permanent Code
Office Setting	J9999	n/a	January 2017
Hospital Outpatient Setting	C9399	April 2016	



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## CPT® Codes

CPT codes (Current Procedural Terminology) are the most widely accepted medical nomenclature used to report medical procedures and services under public and private health insurance programs. CPT® is a registered trademark of the American Medical Association.<sup>6</sup>

Consider using the following CPT codes for the administration of the DARZALEX™ (daratumumab) infusion<sup>7</sup>:

Potential CPT Codes for DARZALEX™ Administration <sup>7</sup>	
Code	Description
96413	Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug
96415	Chemotherapy administration, intravenous infusion technique; each additional hour (list separately in addition to code for primary procedure)

**Note:** These chemotherapy administration codes apply to parenteral administration of non-radionuclide anti-neoplastic drugs. CMS policy for chemotherapy administration codes states that if performed to facilitate the chemotherapy infusion, professional services and items described by these CPT codes include use of local anesthesia, IV access, access to indwelling IV, flush at conclusion of infusion, standard tubing, syringes and supplies, and preparation of chemotherapy agent(s).<sup>8</sup>

6. AMA, CPT; p1, para 1

7. AMA Code Manager; Results for 96413, 96415

8. CMS. Claims Processing Manual, Chapter 12, Section 30.5D; p 36, para 7; p 37, para 3.

## ICD-9-CM and ICD-10-CM Potential Diagnosis Codes<sup>9</sup>

The Department of Health & Human Services requires all entities covered by the Health Insurance Portability and Accountability Act (HIPAA) to transition from the ICD-9-CM diagnosis coding system to the ICD-10-CM diagnosis coding system for services performed on or after October 1, 2015. The transition to the ICD-10 coding system does not affect CPT coding for outpatient procedures and physician services.

The table below lists the ICD-9-CM and ICD-10-CM potential diagnosis codes for multiple myeloma, which you can consider for patients treated with DARZALEX™ (daratumumab).

Multiple Myeloma Diagnosis Codes for Consideration			
ICD-9-CM <sup>10</sup>		ICD-10-CM <sup>11</sup>	
<b>203.00</b>	Multiple myeloma, without mention of having achieved remission	<b>C90.00</b>	Multiple myeloma, not having achieved remission
<b>203.01</b>	Multiple myeloma, in remission	<b>C90.01</b>	Multiple myeloma, in remission
<b>203.02</b>	Multiple myeloma, in relapse	<b>C90.02</b>	Multiple myeloma in relapse

**Note:** The ICD-10-CM diagnosis code C90.0 includes multiple myeloma with failed remission and multiple myeloma not otherwise specified (NOS).<sup>11</sup>

**Please see Important Safety Information on pages 30–31 and accompanying full Prescribing Information.**

9. CMS. ICD-10 Myths and Facts, June 2015; p2, para 2; p6, para 2-3

10. ICD9Data; p1

11. CMS. ICD-10 Index Table 2015; p102-103



## 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<sup>4,12,13</sup>

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. The following table summarizes modifiers that may be applicable to the provision of DARZALEX™ in physician offices and hospital outpatient departments.



4. CMS, Claims Processing Manual, Chapter 17, Section 40; p 25, para 6-8; p26,

12. AMA. Coding Manager Online. Modifiers; p2, para 2 & 6;

13. CMS, Claims Processing Manual, Chapter 4, Section 20.6.11; p 62, para 4-6.

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	<ul style="list-style-type: none"> <li>• Patient requires distinct evaluation and management (E/M) service in addition to the infusion procedure</li> <li>• Must be substantiated with relevant documentation</li> <li>• Append the modifier to the relevant E/M code</li> </ul>	✓	✓
JW	Drug amount discarded/not administered to any patient	<ul style="list-style-type: none"> <li>• Unused drug remains after applicable dose is administered from single-use vial</li> <li>• CMS has issued a discarded drug policy; local maximum allowable cost (MAC)/other payer requirements may vary</li> <li>• Append the modifier to the drug code on a line separate from that reporting the administered dose</li> </ul>	If required by payer	If required by payer
PO	Services, procedures, and/or surgeries furnished at off-campus provider-based outpatient departments	<ul style="list-style-type: none"> <li>• Outpatient hospital items and services furnished in an off-campus provider-based department of a hospital*</li> <li>• CMS has issued a policy for off-campus outpatient hospital departments; other payer requirements may vary</li> <li>• Append the modifier to the relevant HCPCS/CPT code(s)</li> </ul>		Required by Medicare in 2016 <sup>†</sup>

13. CMS, Claims Processing Manual, Chapter 4, Section 20.6.11; p 62, para 4-6.

MAC (Maximum Allowable Cost)/other payer

\*The PO modifier should not be reported for remote locations of a hospital satellite, facilities of a hospital, or for services furnished in an emergency department.<sup>13</sup>

<sup>†</sup>In 2015, reporting of the PO modifier in Medicare claims is voluntary.<sup>13</sup>

**Please see Important Safety Information on pages 30–31 and accompanying full Prescribing Information.**



4. CMS, Claims Processing Manual, Chapter 17, Section 40; p 25, para 6-8.



## CMS Discarded Drug Policies<sup>4</sup>

When it is necessary to 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.

When processing claims for drugs and biologicals, local contractors may require the use of the modifier JW to identify unused drug or biologicals from single-use vials or packages. This modifier, billed on a separate line, will provide 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 is billed on another line using the JW modifier. Both line items are processed for payment. The JW modifier is applied only to the amount of drug or biological that is discarded.

### Summary

- Both the administered and discarded drug amounts should be clearly documented in the medical record
- Payment for discarded amounts of drug or biologicals 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 may choose to require the JW modifier on claims for discarded drug or biological. Check with your local contractor for specific requirements





8. CMS Manual, Chapter 12, Section 30.5(F); p38, para 4-5; p39, para 1  
14. CMS Transmittal 2845; p3, para 6.

### → Same-Day Evaluation and Management Services<sup>8,14</sup>

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 infusion procedure (CPT codes 99201-99205 and 99211-99215 in the physician office and HCPCS code G0463 in the hospital outpatient setting), 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:

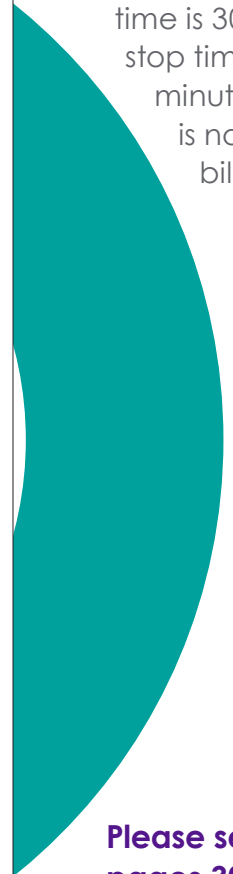
**For services furnished on or after January 1, 2004, do not allow payment for CPT code 99211, with or without modifier 25, if it is billed with a nonchemotherapy drug infusion code or a chemotherapy administration code.**

Because Medicare payment for a chemotherapy infusion is assumed to already cover nursing services related to a Level 1 visit for an established patient, CPT code 99211 cannot be billed on the same day as an office-based infusion of DARZALEX™.

8. CMS Manual, Chapter 12, Section 30.5(E); p38, para 4

### → Partial Additional Hours of Infusion Time<sup>8</sup>

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.” 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.



**Please see Important Safety Information on pages 30–31 and accompanying full Prescribing Information.**

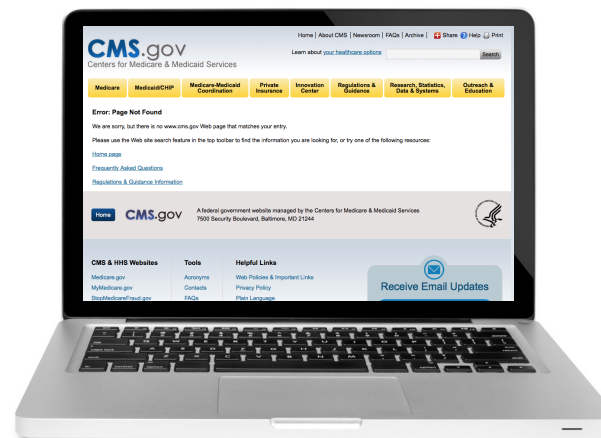
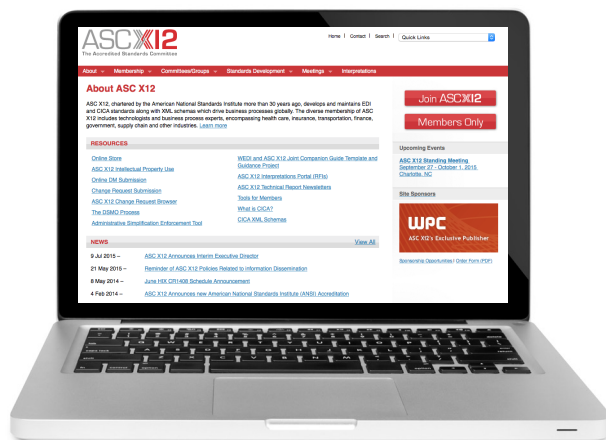




## SAMPLE CLAIM FORMS FOR DARZALEX™ (daratumumab)

The Form CMS-1500 is prescribed by CMS for Medicare and Medicaid claims from noninstitutional providers and suppliers that qualify for a waiver submitted by the Administrative Simplification Compliance Act (ASCA) requirement for electronic submission. This form is also used in the TRICARE Program. For detailed guidance on completing the CMS-1500 items, please see the Medicare Claims Processing Manual, Pub. 100-04, Chap 26, available at: [www.cms.gov/Regulationsand-Guidance/Guidance/Manuals/index.html](http://www.cms.gov/Regulationsand-Guidance/Guidance/Manuals/index.html).

The 837P (Professional) is the standard format used by healthcare professionals and suppliers to transmit healthcare claims electronically. The American National Standards Institute (ANSI) Accredited Standards Committee (ASC) X12N 837P (Professional) Version 5010A1 is the current electronic claim version. Data elements in the CMS uniform electronic billing specifications are consistent with the hard copy data set to the extent that one processing system can handle both. For more information on electronic claims, please see the ASC website at: [www.x12.org](http://www.x12.org). To view a crosswalk between the electronic and hard copy claim form, please see: [www.nucc.org/images/stories/PDF/1500\\_form\\_map\\_to\\_837p\\_5010\\_v2-0\\_112011.pdf](http://www.nucc.org/images/stories/PDF/1500_form_map_to_837p_5010_v2-0_112011.pdf).





The Form CMS-1450, also known as the UB-04, is a uniform institutional provider bill suitable for use in billing multiple third-party payers. It is prescribed by CMS for the Medicare and Medicaid claims from hospitals, including hospital outpatient departments. Because it serves many different types of payers, a particular payer may not need some data elements. For detailed guidance on completing the CMS-1450 items, please see the Medicare Claims Processing Manual, Pub. 100-04, Chap 25, available at: [www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/index.html](http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/index.html).

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

1. MEDICARE MEDICAID TRICARE CHAMPVA (For Program in Item 1)  
 Medicare  Medicaid  Other  CHAMPVA  Other  Other

2. PATIENT'S NAME (Last Name, First Name, Middle Initial)  
 3. PATIENT'S BIRTH DATE  
 4. INSURED'S NAME (Last Name, First Name, Middle Initial)  
 5. PATIENT'S ADDRESS (No. Street)  
 6. PATIENT RELATIONSHIP TO INSURED  
 7. INSURED'S ADDRESS (No. Street)  
 8. RESERVED FOR NUCC USE  
 9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)  
 10. IS PATIENT'S CONDITION RELATED TO:  
 11. INSURED'S POLICY GROUP OR FECA NUMBER  
 12. PATIENTS OR AUTHORIZED PERSONS SIGNATURE (Authorized signatory of a valid benefit to the insured person or supplier for services rendered)  
 13. INSURED'S SIGNATURE (Authorized signatory of a valid benefit to the insured person or supplier for services rendered)  
 14. DATE OF SERVICE (MM/DD/YYYY)  
 15. DATE OF REFERENCE (MM/DD/YYYY)  
 16. HOSPITALIZATION DATES (FROM TO)  
 17. NAME OF REFERRING PHYSICIAN OR OTHER SOURCE  
 18. ADDITIONAL CLAIM INFORMATION (Assigned by NUCC)  
 19. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY (Public A to service line below (24E))  
 20. CHARGES  
 21. PRIOR AUTHORIZATION NUMBER  
 22. SIGNATURE OF PHYSICIAN OR SUPPLIER (Including address or credentials if applicable)  
 23. SERVICE FACILITY LOCATION INFORMATION  
 24. BILLING PROVIDER ICP & PH #

25. FEDERAL TAX ID NUMBER  
 26. PATIENT'S ACCOUNT NO.  
 27. ACCOUNT ASSIGNMENT  
 28. TOTAL CHARGE  
 29. AMOUNT PAID  
 30. PAID FOR NUCC USE

31. TREATMENT AUTHORIZATION CODES  
 32. DOCUMENT CONTROL NUMBER  
 33. EMPLOYER NAME

34. PROCEDURE CODES  
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Please see Important Safety Information on pages 30–31 and accompanying full Prescribing Information.



## Physician Office Sample Claim Form: CMS-1500

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.

11. CMS. ICD-10 Index Table 2015; p102-103

### A Item 21 - Indicate diagnosis using appropriate ICD-10-CM code(s).

Potential codes for consideration<sup>11</sup>:

- **C90.00** (Multiple myeloma, not having achieved remission)
- **C90.01** (Multiple myeloma, in remission)
- **C90.02** (Multiple myeloma, in relapse)

3. CMS. Apha-Numeric HCPCS File, 2015; rows for J9999

### B Item 24D - Indicate appropriate CPT and HCPCS codes and modifiers, if required.

**Drug** - Miscellaneous HCPCS code for consideration<sup>3,\*</sup>:

- **J9999** (Not otherwise classified, antineoplastic drugs)

**Infusion Services** - Potential CPT codes for consideration<sup>7</sup>:

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

7. AMA Code Manager; Results for 96413, 96415

### C Item 24G - Indicate appropriate billing units for the listed CPT and HCPCS codes.

**Drug** - Report 1 unit with a miscellaneous HCPCS code regardless of the dose and number of vials used.

**Infusion Services** - For the CPT code 96413, indicate 1 unit of service. For the CPT code 96415, indicate appropriate units of service, based on the duration of DARZALEX™ (daratumumab) infusion.

### D Item 19 - Report additional information required by the payer for claims with a miscellaneous HCPCS code.\*

Potential information required by the payer may include drug name, NDC, dose administered, and route of administration.†

**NDC for DARZALEX™ (11-digit format)<sup>1</sup>:**

- **57894-0502-05** (100 mg/5 mL vial)
- **57894-0502-20** (400 mg/20 mL vial)

1. PI section 16.1/lines3-4

\*Specific payer requirements for DARZALEX™ may vary.

†If the information exceeds the capacity of Item 19, attach additional documentation to the claim.

## CMS 1500 Sample Claim Form (7-Hour Sample Infusion)



### HEALTH INSURANCE CLAIM FORM

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

PICA <input type="checkbox"/>		PICA <input type="checkbox"/>	
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 I.D. NUMBER (For Program in Item 1) <b>000-00-1234</b>	
2. PATIENT'S NAME (Last Name, First Name, Middle Initial) <b>Doe, John B</b>		3. PATIENT'S BIRTH DATE    SEX MM DD YY    M <input checked="" type="checkbox"/> F <input type="checkbox"/> <b>07 01 45</b> M <input checked="" type="checkbox"/> F <input type="checkbox"/>	
5. PATIENT'S ADDRESS (No., Street) <b>123 Any Street</b>		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: <b>Any Town</b> STATE: <b>AS</b>		8. RESERVED FOR NUCC USE	
9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)		10. IS PATIENT'S CONDITION RELATED TO:	
a. OTHER INSURED'S POLICY OR GROUP NUMBER		a. EMPLOYMENT? (Current or Previous) <input type="checkbox"/> YES <input type="checkbox"/> NO	
b. RESERVED FOR NUCC USE		b. AUTO ACCIDENT?    PLACE (State) <input type="checkbox"/> YES <input type="checkbox"/> NO	
c. RESERVED FOR NUCC USE		c. OTHER ACCIDENT? <input type="checkbox"/> YES <input type="checkbox"/> NO	
d. INSURANCE PLAN NAME OR PROGRAM NAME <b>Medicare</b>		10d. CLAIM CODES (Designated by NUCC)	
READ BACK OF FORM BEFORE COMPLETING & SIGNING THIS FORM.			
12. PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE I authorize the release of any medical or other information necessary to process this claim. I also request payment of government benefits either to myself or to the party who accepts assignment below.		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 _____		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 <b>Dr. Jones</b>		17a. NPI    17b. NPI <b>123-456-7890</b>	
19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC) <b>D Darzalex (daratumumab) 57894-0502-20, 1200 mg IV</b>		20. OUTSIDE LAB?    \$ CHARGES <input type="checkbox"/> YES <input type="checkbox"/> NO	
21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY. Refer to 19 for service line below (24E)		22. RESUBMISSION CODE    ORIGINAL REF. NO.	
A. <b>C90.02</b> B. _____    C. _____    D. _____ E. _____    F. _____    G. _____    H. _____ I. _____    J. _____    K. _____		23. PRIOR AUTHORIZATION NUMBER	
24. A. DATE(S) OF SERVICE    B. PLACE OF SERVICE    C. EMG    D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances)    E. DIAGNOSIS POINTER    F. \$ CHARGES    G. DAYS OR UNITS    H. EPSON Family Plan    I. ID. QUAL.    J. RENDERING PROVIDER ID. #			
1    From MM DD YY To MM DD YY    11 <b>B 96413</b> A <b>C 1</b> NPI <b>123-456-7890</b>			
2    10 01 15    11 <b>96415</b> A <b>6</b> NPI <b>123-456-7890</b>			
3    10 01 15    11 <b>J9999</b> A <b>1</b> NPI <b>123-456-7890</b>			
4			
5			
6			
25. FEDERAL TAX I.D. NUMBER    SSN EIN    26. PATIENT'S ACCOUNT NO.    27. ACCEPT ASSIGNMENT? (For gov. claims, see back)    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.)		32. SERVICE FACILITY LOCATION INFORMATION    33. BILLING PROVIDER INFO & PH # <b>(555) 123-5555</b> <b>Dr. Jones</b> <b>555 Any Street</b> <b>Anytown, AS 12345</b>	
SIGNED _____ DATE _____		a. <b>NPI</b> b. <b>123-456-7890</b>	

NUCC Instruction Manual available at: [www.nucc.org](http://www.nucc.org)

PLEASE PRINT OR TYPE

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

CARRIER  
PATIENT AND INSURED INFORMATION  
PHYSICIAN OR SUPPLIER INFORMATION

Sample Claim Forms  
Specialty Distributors  
Janssen Care Path  
Appendix  
Important Safety Information  
References

Please see Important Safety Information on pages 30–31 and accompanying full Prescribing Information.





## Hospital Outpatient Department Sample Claim Form: CMS-1450 (UB-04)

### **A** Locator Box 67 - Indicate diagnosis using appropriate ICD-10-CM code(s).

11. CMS. ICD-10 Index Table 2015; p102-103

Potential codes for consideration<sup>11</sup>:

- **C90.00** (Multiple myeloma, not having achieved remission)
- **C90.01** (Multiple myeloma, in remission)
- **C90.02** (Multiple myeloma, in relapse)

### **B** Locator Box 44 - Indicate appropriate CPT and HCPCS codes and modifiers, if required.

3. CMS. Apha-Numeric HCPCS File, 2015; rows for C9399, J9999

**Drug** - Miscellaneous HCPCS codes for consideration<sup>3</sup>:  
MEDICARE - **C9399** (Unclassified drugs or biologicals)  
COMMERCIAL PAYERS - **J9999** (Not otherwise classified, antineoplastic drugs)

7. AMA Code Manager; Results for 96413, 96415

**Infusion Services** - Potential CPT codes for consideration<sup>7,\*</sup>:

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

### **C** Locator Box 46 - Indicate appropriate billing units for the listed CPT and HCPCS codes.

**Drug** - Report 1 unit with a miscellaneous HCPCS code regardless of the dose and number of vials used.

**Infusion Services** - For the CPT code 96413, indicate 1 unit of service. For the CPT code 96415, indicate appropriate units of service, based on the duration of DARZALEX™ (daratumumab) infusion.

### **D** Locator Box 80 - Report additional information required by the payer for claims with a miscellaneous HCPCS code.†

Potential information required by the payer may include drug name, NDC, dose administered, and route of administration.†

**NDC for DARZALEX™ (11-digit format)<sup>1</sup>:**

- **57894-0502-05** (100 mg/5 mL vial)
- **57894-0502-20** (400 mg/20 mL vial)

1. PI section 16.1/lines3-4

13. CMS, Claims Processing Manual, Chapter 4, Section 20.6.11; p 62, para 4-6.

\*For 2016, Medicare requires reporting the PO modifier for all outpatient hospital items and services furnished in an off-campus provider-based department of a hospital.<sup>13</sup>  
†Specific payer requirements for DARZALEX™ may vary.  
‡If the information exceeds the capacity of Locator Box 80, attach additional documentation to the claim.

## CMS 1450 (UB-04) Sample Claim Form (7-Hour Sample Infusion)

1 <b>Anytown Hospital</b> 123 Any Street Anytown, AS 12345		2 <b>Pay-to-name</b> <b>Pay-to-address</b> <b>Pay-to-city/state</b>		3a PAT. CNTRL # <b>XX-XXXX</b>	4 TYPE OF BILL
				b. MED. REC. # <b>DOE 1234-97</b>	
				5 FED. TAX NO. <b>010001010</b>	6 STATEMENT COVERS PERIOD FROM THROUGH
8 PATIENT NAME <b>John B Doe</b>		9 PATIENT ADDRESS <b>123 Any Street</b>			
b <b>John B Doe</b>		b <b>Any Town</b>		c <b>AS</b>	d <b>12345</b>
10 BIRTHDATE <b>07 01 45</b>		11 SEX <b>M</b>		12 DATE	
13 HR		14 TYPE		15 SRC	
16 DHR		17 STAT		18	
19		20		21	
22		23		24	
25		26		27	
28		29 ACDT STATE		30	
31 OCCURRENCE DATE		32 OCCURRENCE DATE		33 OCCURRENCE DATE	
34 OCCURRENCE DATE		35 OCCURRENCE DATE		36 OCCURRENCE SPAN FROM THROUGH	
37		38		39	
39 CODE		40 VALUE CODES AMOUNT		41 VALUE CODES AMOUNT	
42 REV. CD.		43 DESCRIPTION		44 HCPCS / RATE / HIPPS CODE	
				45 SERV	
				46 SERV. UNITS	
				47 TOTAL CHARGES	
				48 NON-COVERED CHARGES	
				49	
PAGE <b>OF</b>		CREATION DATE		TOTALS	
50 PAYER NAME <b>Medicare</b>		51 HEALTH PLAN ID		52 REL INFO	
				53 ASSI BEN.	
				54 PRIOR PAYMENTS	
				55 EST. AMOUNT DUE <b>246 555 1234</b>	
				56 NPI	
				57 OTHER PRV ID	
58 INSURED'S NAME		59 P.REL		60 INSURED'S UNIQUE ID	
				61 GROUP NAME	
				62 INSURANCE GROUP NO.	
63 TREATMENT AUTHORIZATION CODES		64 DOCUMENT CONTROL NUMBER		65 EMPLOYER NAME	
66 DX <b>C90.02</b>		67		68	
69 ADMIT DX		70 PATIENT REASON DX		71 PPS CODE	
72 ECI		73		74	
74 PRINCIPAL PROCEDURE CODE		75 OTHER PROCEDURE CODE		76 ATTENDING <b>123-456-7890</b>	
77 OPERATING NPI		78 OTHER NPI		79 OTHER NPI	
LAST <b>Jones</b>		FIRST <b>John</b>		QUAL	
LAST		FIRST		QUAL	
LAST		FIRST		QUAL	
LAST		FIRST		QUAL	
80 REMARKS <b>D Darzalex (daratumumab) 57894-0502-20, 1200 mg IV</b>		81CC a		82	
		b		83	
		c		84	
		d		85	

SAMPLE

Please see Important Safety Information on pages 30–31 and accompanying full Prescribing Information.



Sample Claim Forms  
 Specialty Distributors  
 Janssen Care Path  
 Appendix  
 Important Safety Information  
 References

NUBC National Uniform Billing Committee LIC9213257



## **SPECIALTY DISTRIBUTORS**

The following specialty distributors are authorized to sell DARZALEX™ (daratumumab) and are able to service institutions, physician offices, and community oncology practices.

Specialty Distributor	Phone	Fax	Website
ASD Healthcare	1-800-746-6273	1-800-547-9413	<a href="https://www.asdhealthcare.com">https://www.asdhealthcare.com</a>
Cardinal Health Specialty Pharmaceutical Distribution	<b>Product Ordering:</b> 1-855-740-1871 <b>General Inquiries:</b> 1-877-453-3972 <b>All Other:</b> 1-855-855-0708	1-888-345-4916	<a href="https://specialtyonline.cardinalhealth.com">https://specialtyonline.cardinalhealth.com</a>
CuraScript Specialty Distribution (Priority Healthcare)	1-877-599-7748	1-800-862-6208	<a href="https://www.curascriptonline.com">https://www.curascriptonline.com</a>
McKesson Plasma & Biologics	1-877-625-2566	1-888-752-7626	<a href="https://connect.mckesson.com">https://connect.mckesson.com</a> Email: <a href="mailto:plasma@mckesson.com">plasma@mckesson.com</a>
McKesson Specialty Health	<b>Multispecialty:</b> 1-855-477-9800 <b>Oncology:</b> 1-800-482-6700	<b>Multispecialty:</b> 1-800-800-5673 <b>Oncology:</b> 1-800-289-9285	<a href="https://www.mckessonspecialtyhealth.com">https://www.mckessonspecialtyhealth.com</a>
Oncology Supply	1-800-633-7555	1-800-248-8205	<a href="https://www.oncologysupply.com">https://www.oncologysupply.com</a>

**Note:** Janssen Biotech, Inc., does not endorse the use of any of the listed distributors in particular.

Please see Important Safety Information on pages 30–31 and accompanying full Prescribing Information.





# Janssen CarePath

## One source for support...

Janssen CarePath is a single point of contact for comprehensive services and support for physicians, office staff, and patients treated with DARZALEX™ (daratumumab).

## ACCESS tools

**Help your patients start therapy** by making treatment accessible with services and resources that include:

- Benefit investigation
- Prior authorization assistance
- Patient cost support options
- Dedicated Case Coordinators that work with you and your patient
- Billing and coding information

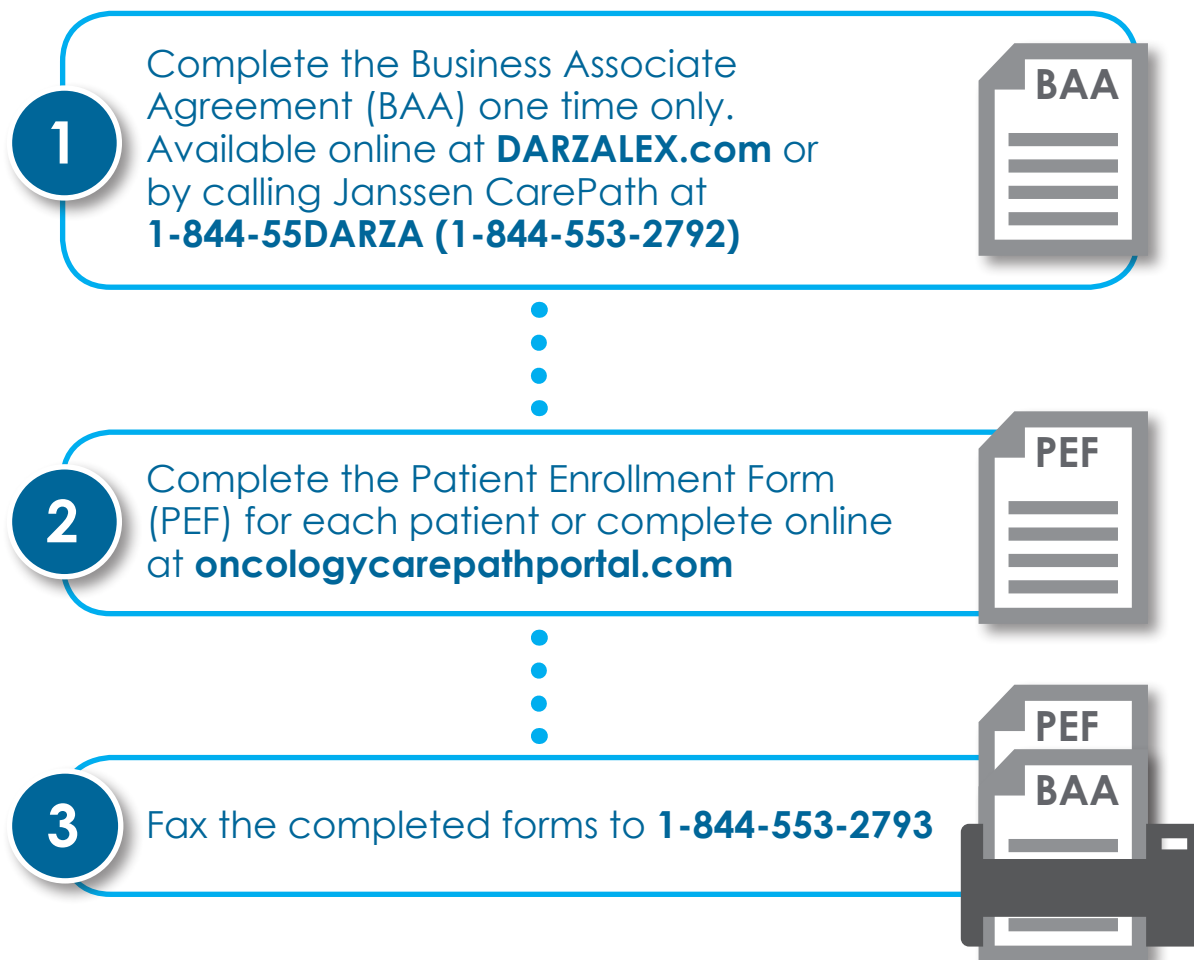
## EDUCATION tools

**Help keep your patients informed** about the disease and their treatment with services and resources that include:

- Access to nurses who can answer questions about the disease and treatment with DARZALEX™
- Education about and referral to independent organizations that provide assistance with costs associated with travel to and from treatment
- A tool that connects patients and caregivers to national and/or state advocacy groups that offer resources relevant to their needs
- Personalized, live appointment reminders



## Getting Started Is Easy



After receiving your completed PEF, Janssen CarePath will research your patient's health coverage and return a Verification of Benefits within 48 hours. Janssen CarePath will also attempt to call your patient to review benefits and discuss potential cost support options.

### For More Information

Please call Janssen CarePath at **1-844-55DARZA (1-844-553-2792), Monday-Friday, 8:00 am-8:00 pm ET**, and speak to a Janssen CarePath Case Coordinator today.

**Please see Important Safety Information on pages 30–31 and accompanying full Prescribing Information.**





## Important Documents

- Business Associate Agreement
- Janssen CarePath Patient Enrollment Form for DARZALEX™
- Janssen CarePath Savings Program Enrollment Form for DARZALEX™
- Sample Letter of Medical Necessity
- Sample Exception Letter

## Potential Cost Support Options for DARZALEX™ (daratumumab)

Your patients may be eligible for programs that can help them afford their treatment with DARZALEX™.

For more information on these programs, please have your patients call Janssen CarePath at **1-844-55DARZA (1-844-553-2792)**, Monday-Friday, 8:00 AM-8:00 PM ET, and speak to a Janssen CarePath Case Coordinator.



### If your patient has commercial insurance



#### Janssen CarePath Savings Program for DARZALEX™

**If eligible, patients pay no more than \$10 for each infusion.** Infusions 1-8 are \$5 per infusion, and infusions 9+ are \$10 per infusion. Subject to a \$15,000 maximum annual program benefit for each calendar year. Not valid for patients enrolled in Medicare or Medicaid. Other restrictions may apply.

Rebates are determined by medication cost only, not the cost associated with IV infusion.

For additional details including complete eligibility and restrictions, please visit [www.carepathsavingsprogram.com](http://www.carepathsavingsprogram.com).

## If your patient has Medicare

Janssen CarePath can refer patients to the Medicare Savings Program to discuss eligibility and program benefits. To learn more about eligibility and how the Medicare Savings Program can help patients pay for Medicare Part B products:

- Visit [www.medicare.gov/contacts](http://www.medicare.gov/contacts)
- Click on the link for "Medicare Savings Program (MSPs)" under "Other Helpful Websites"
- Select the appropriate state

## If your patient has Medicare, Medicaid, TRICARE, or commercial insurance

If eligible, patients may be able to receive cost assistance through **independent foundations:**

- CancerCare | [www.cancer.org](http://www.cancer.org) | 1-866-552-6729
- Good Days from CDF | [www.gooddaysfromcdf.org](http://www.gooddaysfromcdf.org) | 1-877-968-7233
- Patient Advocate Foundation | [www.copays.org](http://www.copays.org) | 1-800-532-5274
- Patient Access Network Foundation | [www.panfoundation.org](http://www.panfoundation.org) | 1-866-316-7263
- Leukemia & Lymphoma Society | [www.lls.org](http://www.lls.org) | 1-877-557-2672

## Other resources

**The Johnson & Johnson Patient Assistance Foundation, Inc. (JJPAF)** is committed to providing access to uninsured patients who lack the financial resources to pay for their medicines. If your patients need DARZALEX™ (daratumumab) and are uninsured and unable to pay for their medicine, please contact a JJPAF program specialist at 1-800-652-6227, 9:00 am-6:00 pm ET, or visit the foundation website at [www.jjpf.org](http://www.jjpf.org) to see if they may qualify for assistance.

For a comprehensive list of cost support programs related to DARZALEX™, visit [www.JanssenPrescriptionAssistance.com/DARZALEX](http://www.JanssenPrescriptionAssistance.com/DARZALEX).

**Please see Important Safety Information on pages 30–31 and accompanying full Prescribing Information.**



## APPENDIX

### Sample Letter of Medical Necessity

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.\*

[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 intravenous treatment with DARZALEX™, [insert indication]. This request is consistent with the indication statement for DARZALEX™. 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 History**  
[Insert previous therapies/procedures, response to those interventions, description of patient's recent symptoms/condition. Exercise your medical judgment and discretion when providing a diagnosis and characterization of the patient's medical condition.]

**Rationale for Treatment**  
Considering the patient's history, condition, and the full Prescribing Information supporting uses of DARZALEX™, I believe treatment with DARZALEX™ at this time is warranted, appropriate, and medically necessary, and should be a covered and reimbursed service. The accompanying full Prescribing Information provides the approved clinical information for DARZALEX™.

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]

P.S. –  If this request is denied, I am requesting an expedited Exception reviewed by a "Like" specialist.

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

## Sample Letter of Formulary Exception Request

[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 intravenous treatment with DARZALEX™, [indication]. This request is consistent with the indication statement for DARZALEX™. 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 History

[Insert previous therapies/procedures, response to those interventions, description of patient's recent symptoms/condition. Exercise your medical judgment and discretion when providing a diagnosis and characterization of the patient's medical condition.]

### Rationale for Treatment

Considering the patient's history, condition, and the full Prescribing Information supporting uses of DARZALEX™, I believe treatment with DARZALEX™ at this time is warranted, appropriate, and medically necessary, and should be a covered and reimbursed service. The accompanying full Prescribing Information provides the approved clinical information for DARZALEX™.

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]

P.S. –  If this request is denied, I am requesting an expedited Exception reviewed by a "Like" specialist.

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6/15

035901-150618

Please see Important Safety Information on pages 30–31 and accompanying full Prescribing Information.

 **DARZALEX™**  
daratumumab  
injection for intravenous infusion

| 29

Appendix

Important  
Safety Information

References

## IMPORTANT SAFETY INFORMATION (cont'd)

### LOREM IPSUM DOLOR SIT AMET

Consectetur adipiscing elit. Pellentesque adipiscing rhoncus diam in tincidunt. Integer sit amet sapien at tellus interdum consectetur. Cras accumsan, neque posuere scelerisque blandit, massa augue hendrerit ipsum, id tempus quam tortor sit amet magna. Nam congue lorem nec justo pulvinar placerat. In at erat non tortor fringilla venenatis. Fusce gravida ornare enim sit amet lobortis. Aenean sodales lobortis luctus. Aliquam feugiat pellentesque tortor, a ultrices nisi rhoncus ut. Quisque tristique justo sit amet nibh scelerisque vestibulum.

Aenean et leo eros. In hac habitasse platea dictumst. Nam aliquam, eros eu posuere tempor, quam velit sollicitudin sapien, sit amet auctor diam nulla nec quam. Cras sit amet risus risus. Mauris mattis ipsum eu erat aliquam tempor. Duis lectus nibh, ultricies at pretium ac, fringilla sit amet ipsum. Lorem ipsum dolor sit amet, consectetur adipiscing elit. Aliquam erat volutpat. Pellentesque ultrices porttitor erat, mollis imperdiet ligula suscipit et.

### CURABITUR CURSUS

Lorem ipsum dolor sit amet, consectetur adipiscing elit. Pellentesque adipiscing rhoncus diam in tincidunt. Integer sit amet sapien at tellus.

- Cras accumsan, neque posuere scelerisque blandit, massa augue hendrerit ipsum, id tempus quam tortor sit amet magna. Nam congue lorem nec justo pulvinar placerat. In at erat non tortor fringilla venenatis.
- Fusce gravida ornare enim sit amet lobortis.
- Aenean sodales lobortis luctus.
- Aliquam feugiat pellentesque tortor, a ultrices nisi rhoncus
- Quisque tristique justo sit amet nibh scelerisque vestibulum.

Aenean et leo eros. In hac habitasse platea dictumst. Nam aliquam, eros eu posuere tempor, quam velit sollicitudin sapien, sit amet auctor diam nulla nec quam. Cras sit amet risus risus. Mauris mattis ipsum eu erat aliquam tempor. Duis lectus nibh, ultricies at pretium ac, fringilla sit amet ipsum. Lorem ipsum dolor sit amet, consectetur adipiscing elit. Aliquam erat volutpat. Pellentesque ultrices porttitor erat, mollis imperdiet ligula suscipit et. Phasellus eget lectus elit, sit amet tristique tellus. Curabitur cursus, mauris sit amet euismod sagittis, arcu lorem faucibus purus, in malesuada quam nunc at risus.

Lorem ipsum dolor sit amet, consectetur adipiscing elit. Pellentesque adipiscing rhoncus diam in tincidunt. Integer sit amet sapien at tellus interdum consectetur. Cras accumsan, neque posuere scelerisque blandit, massa augue hendrerit ipsum, id tempus quam tortor sit amet magna. Nam congue lorem nec justo pulvinar placerat. In at erat non tortor fringilla venenatis. Fusce gravida ornare enim sit amet.

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## IMPORTANT SAFETY INFORMATION

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**Please see Important Safety Information on pages 30–31 and accompanying full Prescribing Information.**





## Janssen CarePath

Contact Janssen CarePath at **1-844-55DARZA (1-844-553-2792)**, Monday to Friday, 8:00 AM to 8:00 PM ET, to learn about cost support options.

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Phone: Call **1-800-JANSSEN (1-800-526-7736)**  
E-mail: Submit questions via [www.askjanssenmedinfo.com](http://www.askjanssenmedinfo.com)

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