DARZALEX® (daratumumab)
REIMBURSEMENT & ACCESS GUIDE

IMPORTANT INFORMATION TO SUPPORT THE REIMBURSEMENT PROCESS

2017 GUIDELINES

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
• Important product information
• Sample claims forms
• 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 DARZALEX® reimbursement-related questions or concerns.

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® is a registered trademark of the American Medical Association (AMA). 2015 American Medical Association. All rights reserved. CPT® policies and determination processes, ICD-10-CM Diagnosis Codes, CMS Discarded Drug Policies, Same-Day Evaluation and Management Services, Partial Additional Hours of Infusion Time, Physician Office Sample Claim Form: CMS 1500, Hospital Outpatient Department Sample Claim Form: CMS 1450 (UB-04), Using the JW Modifier With the CMS 1500, Using the JW Modifier With the CMS 1450 (UB-04), Specialty Distributors, Potential Cost Support Options for DARZALEX®, Sample Claim Forms for DARZALEX®, Important Safe ty Information, Sample Letter of Formulary Exception Request, Sample Letter of Medical Necessity, Sample Letter of Formulary Exception Request, Important Safety Information, References, are updated frequently.

Please click here to see full Prescribing Information or visit www.Darzalexhcp.com.

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Dosing & Administration

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 charts on pages 6 and 7.

For example, a patient with a body weight of 75 kg would require a 1200 mg dose of DARZALEX®.

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

Pre-infusion Medication

Administer the following medications to reduce the risk of infusion reactions to all patients 1-3 hours prior to every DARZALEX® infusion:

- Corticosteroid (long acting or intermediate acting)
  - **Monotherapy:** Methylprednisolone 100 mg, or equivalent, administered intravenously. Following the second infusion, the dose of corticosteroid may be reduced (oral or intravenous methylprednisolone 60 mg).
  - **Combination therapy:** Administer 20 mg dexamethasone prior to every DARZALEX® infusion. Dexamethasone is given intravenously prior to the first DARZALEX® infusion and oral administration may be considered prior to subsequent infusions.
- Antipyretics (oral acetaminophen 650 to 1000 mg)
- Antihistamine (oral or intravenous diphenhydramine 25 to 50 mg or equivalent)

IMPORTANT SAFETY INFORMATION

Contraindications

None

Warnings and Precautions

Infusion Reactions – DARZALEX® can cause severe infusion reactions. Approximately half of all patients experienced a reaction, most during the first infusion, infusion reactions can also occur with subsequent infusions. Nearly all reactions occurred during infusion or within 4 hours of completing an infusion. Prior to the introduction of post-infusion medication in clinical trials, infusion reactions occurred up to 48 hours after infusion. Severe reactions have occurred, including bronchospasm, hypoxia, dyspnea, hypertension, laryngeal edema and pulmonary edema. Signs and symptoms may include respiratory symptoms, such as nasal congestion, cough, throat irritation, as well as chills, vomiting and nausea. Less common symptoms were wheezing, allergic rhinitis, pyrexia, chest discomfort, pruritus, and hypotension.

Please click here to see full Prescribing Information or visit www.Darzalexhcp.com.
### DARZALEX® (daratumumab) DOSING IN BOTH MONOTHERAPY AND IN COMBINATION WITH LENALIDOMIDE AND DEXAMETHASONE

- DARZALEX® is given as an intravenous (IV) infusion after dilution at 16 mg/kg of body weight.
- Lenalidomide is given orally on days 1–21 of each cycle.
- Dexamethasone 40 mg is given orally or IV weekly.

#### DARZALEX® DOSING IN COMBINATION WITH BORTEZOMIB AND DEXAMETHASONE

- DARZALEX® is given as an IV infusion after dilution at 16 mg/kg of body weight.
- Bortezomib is administered by IV or subcutaneous injection on days 1, 4, 8, and 11 of each cycle for a total of 8 cycles.
- Dexamethasone is given orally once daily on days 1, 2, 4, 5, 8, 9, 11, and 12 of each cycle for a total of 8 cycles.

#### DARZALEX® DOSING IN BOTH MONOTHERAPY AND IN COMBINATION WITH LENALIDOMIDE AND DEXAMETHASONE

<table>
<thead>
<tr>
<th>Cycle 1–2 (each lasting 28 days)</th>
<th>Total of 8 DARZALEX® doses</th>
<th>Cycle 3–6 (each lasting 28 days)</th>
<th>Total of 8 DARZALEX® doses</th>
<th>Cycle 7+ (each lasting 28 days)</th>
<th>Total of 8 DARZALEX® doses</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Day</strong></td>
<td><strong>1</strong></td>
<td><strong>2</strong></td>
<td><strong>3</strong></td>
<td><strong>4</strong></td>
<td><strong>5</strong></td>
</tr>
<tr>
<td>DARZALEX®</td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>lenalidomide</td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>dexamethasone</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Day</strong></td>
<td><strong>1</strong></td>
<td><strong>2</strong></td>
<td><strong>3</strong></td>
<td><strong>4</strong></td>
<td><strong>5</strong></td>
</tr>
<tr>
<td>DARZALEX®</td>
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<td></td>
</tr>
<tr>
<td>lenalidomide</td>
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<td></td>
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<tr>
<td>dexamethasone</td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td><strong>Day</strong></td>
<td><strong>1</strong></td>
<td><strong>2</strong></td>
<td><strong>3</strong></td>
<td><strong>4</strong></td>
<td><strong>5</strong></td>
</tr>
<tr>
<td>DARZALEX®</td>
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</tr>
<tr>
<td>lenalidomide</td>
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<td></td>
</tr>
<tr>
<td>dexamethasone</td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Cycle 7+ (each lasting 28 days)</strong></td>
<td><strong>Day</strong></td>
<td><strong>1</strong></td>
<td><strong>2</strong></td>
<td><strong>3</strong></td>
<td><strong>4</strong></td>
</tr>
<tr>
<td><strong>DARZALEX®</strong></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td><strong>lenalidomide</strong></td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>dexamethasone</strong></td>
<td></td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

**Note:** Bortezomib and dexamethasone dosing should be stopped after 8 cycles. Dexamethasone 20 mg was continued as a pre-infusion medication after Vd discontinuation.

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### WARNINGS AND PRECAUTIONS

**Infusion Reactions (cont’d)**

- Pre-medicate patients with antihistamines, antipyretics, and corticosteroids.
- Frequently monitor patients during the entire infusion.
- Interrupt infusion for reactions of any severity and institute medical management as needed.
- Permanently discontinue therapy for life-threatening (Grade 4) reactions.
- 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 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.

**Important Safety Information (cont’d)**

**WARNINGS AND PRECAUTIONS**

**Infusion Reactions (cont’d)**

- Pre-medicate patients with antihistamines, antipyretics, and corticosteroids.
- Frequently monitor patients during the entire infusion.
- Interrupt infusion for reactions of any severity and institute medical management as needed.
- Permanently discontinue therapy for life-threatening (Grade 4) reactions.
- 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 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.

---

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INFUSION RATES

Slower rate of infusion for the first DARZALEX® (daratumumab) dose is recommended, as infusion reactions are more likely to occur with the first infusion.\(^1\)

<table>
<thead>
<tr>
<th>Infusion rates for DARZALEX® Administration(^1)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dilution volume</td>
</tr>
<tr>
<td>-----------------</td>
</tr>
<tr>
<td>First infusion</td>
</tr>
<tr>
<td>Second infusion(^1)</td>
</tr>
<tr>
<td>Subsequent infusions(^1)</td>
</tr>
</tbody>
</table>

\(^*\)Consider incremental escalation of the infusion rate only in the absence of infusion reactions.

\(^1\)Use a dilution volume of 500 mL only if there were no Grade 1 (mild) or greater infusion reactions during the first 3 hours of the first infusion. Otherwise, continue to use a dilution volume of 1000 mL and instructions for the first infusion.

\(^2\)Use a modified initial rate for subsequent infusions (ie, third infusion onwards) only if there were no Grade 1 (mild) or greater infusion reactions during a final infusion rate of ≥100 mL/hr in the first 2 infusions. Otherwise, continue to use instructions for the second infusion.

For infusion reactions of any grade/severity, immediately interrupt the DARZALEX® infusion and manage symptoms. Management of infusion reactions may further require reduction in the rate of infusion or treatment discontinuation of DARZALEX®.

**Median Duration of DARZALEX® Infusion\(^1\)**

In clinical trials, the median durations of infusions were as follows:

- **First Infusion**: Median Duration 7.0 hours
- **Second Infusion**: Median Duration 4.3 hours
- **Subsequent Infusions**: Median Duration 3.5 hours

**IMPORTANT SAFETY INFORMATION**

**WARNINGS AND PRECAUTIONS**

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 are 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®.

**CODING FOR DARZALEX®**

**NDC Numbers\(^1\)**

In some cases, you may be required to include the National Drug Code (NDC) number in the appropriate location on a claim form.

**NDC Numbers for DARZALEX®\(^3\)**

<table>
<thead>
<tr>
<th>Description</th>
<th>10-digit NDC</th>
<th>11-digit NDC (most commonly used)</th>
</tr>
</thead>
<tbody>
<tr>
<td>100 mg/5 mL vial (20 mg/mL) Single-use vial containing 100 mg of daratumumab solution for intravenous infusion</td>
<td>57894-502-05</td>
<td>57894-0502-05</td>
</tr>
<tr>
<td>400 mg/20 mL vial (20 mg/mL) Single-use vial containing 400 mg of daratumumab solution for intravenous infusion</td>
<td>57894-502-20</td>
<td>57894-0502-20</td>
</tr>
</tbody>
</table>

**Note:** Payer requirements regarding the use of the 10- or 11-digit NDC may vary. 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 above. It may be necessary to include the NDC on claims along with the drug Healthcare Common Procedure Coding System (HCPCS) codes. Payer requirements for NDC use and format may vary and should be verified with the payer.

Please click here to see full Prescribing Information or visit www.Darzalexhcp.com.
Please click here to see full Prescribing Information or visit www.Darzalexhcp.com.
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\(^2,5,8\)

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.

### Modifier: 25

**Description:** 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\(^5\)

- Patient requires distinct evaluation and management (E/M) service in addition to the infusion procedure\(^6\)
- Must be substantiated with relevant documentation\(^5\)
- Append the modifier to the relevant E/M code\(^5\)

**Indication and Placement:**

- Required by Medicare
- Required by Medicare

### Modifier: JW

**Description:** Drug amount discarded/not administered to any patient\(^8\)

- Unused drug remains after applicable dose is administered from single-use vial\(^8\)
- CMS has issued a discarded drug policy and requires use of the JW modifier; other payer requirements may vary\(^8\)
- 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 record\(^8\)

**Indication and Placement:**

- Required by Medicare
- Required by Medicare

### Modifier: PN

**Description:** Nonexcepted service* provided at an off-campus, outpatient, provider-based department of a hospital\(^2\)

- Required beginning January 1, 2017
- To be reported with every HCPCS code for all nonexcepted services furnished in off-campus provider-based departments of a hospital and billed on institutional claims\(^2\)
- Should not be reported for remote locations or satellite facilities of a hospital, emergency departments or on-campus, provider based sites of care\(^2\)

**Indication and Placement:**

- N/A
- Required by Medicare

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*Apply the PN modifier to all nonexcepted items and services billed on an institutional claim at an off-campus, provider based site of care (POS 19). Nonexcepted services include drug administration, evaluation and management and others, codes but do not include separately payable drugs and biologicals. The PN modifier does not apply to on campus, provider based sites of care (POS 22).\(^2\)

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IMPORTANT SAFETY INFORMATION

**Adverse Reactions** – In patients who received DARZALEX® in combination with lenalidomide and dexamethasone, the most frequently reported adverse reactions (incidence ≥20%) were: neutropenia (92%), thrombocytopenia (73%), upper respiratory tract infection (65%), infusion reactions (48%), diarrhea (43%), fatigue (35%), cough (30%), muscle spasms (26%), nausea (24%), dyspnea (21%) and pyrexia (20%). The overall incidence of serious adverse reactions was 49%. Serious adverse reactions were pneumonia (12%), upper respiratory tract infection (7%), influenza (3%) and pyrexia (3%).

In patients who received DARZALEX® in combination with bortezomib and dexamethasone, the most frequently reported adverse reactions (incidence ≥20%) were: thrombocytopenia (90%), neutropenia (68%), peripheral sensory neuropathy (47%), infusion reactions (45%), upper respiratory tract infection (44%), diarrhea (32%), cough (27%), peripheral edema (22%), and dyspnea (21%). The overall incidence of serious adverse reactions was 42%. Serious adverse reactions were upper respiratory tract infection (5%), diarrhea (2%) and atrial fibrillation (2%).

In patients who received DARZALEX® as monotherapy, the most frequently reported adverse reactions (incidence ≥20%) were: neutropenia (60%), thrombocytopenia (48%), infusion reactions (48%), fatigue (39%), nausea (27%), back pain (23%), pyrexia (21%), cough (21%), and upper respiratory tract infection (20%). Serious adverse reactions were reported in 51 (33%) patients. The most frequent serious adverse reactions were pneumonia (6%), general physical health deterioration (5%), and pyrexia (5%).
CMS Discarded Drug Policies

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.

Effective January 1, 2017, when processing claims for drugs and biologicals (except those provided under the Competitive Acquisition Program for Part B drugs and biologicals (CAP)), local contractors shall require the use of 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 line from the administered dose, 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 are billed on another line by using the JW modifier. Both line items would be processed for payment. Effective January 1, 2017, providers must also 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 biological 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

Please see examples of using the JW modifier on pages 20-21.

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 (CPT codes 99201-99205 and 99211-99215 in the physician office and HCPCS code G0463 in the hospital outpatient setting) that are medically necessary, separate, and distinct from the infusion 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:

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® (daratumumab).

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.” 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.

IMPORTANT SAFETY INFORMATION

DRUG INTERACTIONS

Effect of Other Drugs on Daratumumab: The coadministration of lenalidomide or bortezomib with DARZALEX® did not affect the pharmacokinetics of daratumumab.

Effect of Daratumumab on Other Drugs: The coadministration of DARZALEX® with bortezomib did not affect the pharmacokinetics of bortezomib.

Please click here to see full Prescribing Information or visit www.Darzalexhcp.com.
**Physician Office Sample Claim Form: CMS-1500**

**A Item 21 - Indicate diagnosis using appropriate ICD-10-CM code[s].**

Potential code for consideration:
- C90.02 (Multiple myeloma, in relapse)

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

**Infusion Services:**
- 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))

**Drug - HCPCS code:**
- J9145 (Injection, daratumumab, 10 mg)

Medicare requires you to report drug amount discarded/not administered to any patient (see page 20 for an example).

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

**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.

**Drug** - Enter appropriate number of units based on dose administered.

<table>
<thead>
<tr>
<th>Billing Unit Conversion</th>
<th>HCPCS J9145* (Injection, daratumumab, 10 mg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>10 mg</td>
<td>1 Unit</td>
</tr>
<tr>
<td>100 mg vial</td>
<td>10 Units</td>
</tr>
<tr>
<td>400 mg vial</td>
<td>40 Units</td>
</tr>
</tbody>
</table>

**D Item 19 - Reserved for any additional information that may be required by the payer.**

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

---

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

Example below reflects a 1200 mg dose of DARZALEX® (daratumumab)

**Billing Unit Conversion**

<table>
<thead>
<tr>
<th>Drug Dose</th>
<th>Units</th>
</tr>
</thead>
<tbody>
<tr>
<td>10 mg</td>
<td>1 Unit</td>
</tr>
<tr>
<td>100 mg vial</td>
<td>10 Units</td>
</tr>
<tr>
<td>400 mg vial</td>
<td>40 Units</td>
</tr>
</tbody>
</table>

*Insert appropriate number of units based on dose administered. This claim illustrates coding for a 1200 mg dose.
**Hospital Outpatient Department Sample Claim Form: CMS-1450 (UB-04)**

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

Potential codes for consideration:
- C90.02 (Multiple myeloma, in relapse)

**Locator Box 42** - List revenue codes in ascending order. ¹⁰

**Locator Box 43** - Enter narrative description for corresponding revenue code (eg, IV therapy, clinic visit). ¹⁰

**Revenue Codes**¹¹:
- 0260 (IV Therapy)
- 0260 (IV Therapy)
- 0636 DARZALEX® (daratumumab)

**Locator Box 44** - Indicate appropriate CPT and HCPCS codes and modifiers, if required. ¹⁰

**Infusion Services**⁴:
- 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))

**Drug** - HCPCS code²:
- J9145† (Injection, daratumumab, 10 mg)

Medicare requires you to report drug amount discarded/not administered to any patient (see page 21 for an example).

**Locator Box 46** - Indicate appropriate billing units for the listed CPT and HCPCS codes. ¹⁰

<table>
<thead>
<tr>
<th>Billing Unit Conversion</th>
<th>HCPCS J9145² (Injection, daratumumab, 10 mg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>10 mg</td>
<td>1 Unit</td>
</tr>
<tr>
<td>100 mg vial</td>
<td>10 Units</td>
</tr>
<tr>
<td>400 mg vial</td>
<td>40 Units</td>
</tr>
</tbody>
</table>

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.

**Drug** - Enter appropriate number of units based on conversion table.

**Locator Box 80** - Reserved for any additional information that may be required by the payer. ¹⁰

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

Example below reflects a 1200 mg dose of DARZALEX® (daratumumab)

**Locator Box B** - Darzalex 0636

**Locator Box C** - Darzalex 0636

**Locator Box D** - Darzalex 0636

**Locator Box E** - DARZALEX® (daratumumab)

**Billing Unit Conversion**

**Medicare requires the PN modifier to be applied to all nonexcepted items and services billed on an institutional claim at an off-campus, provider based site of care (POS 19). Nonexcepted services include drug administration, evaluation and management and others, but do not include separately payable drugs and biologicals. Note: the PN modifier does not apply to on campus, provider based sites of care (POS 22).²**

Insert appropriate number of units based on dose administered. This claim illustrates a 1200 mg dose.
Example of DARZALEX® dose and CMS 1500 entry.

Example is for 1100 mg dose:
• Requires 3 each, 400 mg vials=1200 mg
• 1100 mg administered, 100 mg discarded
• 10 mg=1 unit (1200 mg=120 units)

Coding: 100 units administered and 10 units discarded; append the JW modifier to the amount discarded.

Using the JW Modifier With Physician Office - CMS-1500 form

Using the JW Modifier in Hospital Outpatient Department - CMS-1450 (UB-04) form

Example of DARZALEX® dose and CMS 1450 entry.

Example is for 1100 mg dose:
• Requires 3 each, 400 mg vials=1200 mg
• 1100 mg administered, 100 mg discarded
• 10 mg=1 unit (1200 mg=120 units)

Coding: 100 units administered and 10 units discarded; append the JW modifier to the amount discarded.

Please click here to see full Prescribing Information or visit www.Darzalexhcp.com.
**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.

<table>
<thead>
<tr>
<th>Specialty Distributor</th>
<th>Phone</th>
<th>Fax</th>
<th>Website</th>
</tr>
</thead>
<tbody>
<tr>
<td>ASD Healthcare</td>
<td>1-800-746-6273</td>
<td>1-800-547-9413</td>
<td><a href="https://www.asdhealthcare.com">https://www.asdhealthcare.com</a></td>
</tr>
<tr>
<td>Specialty Distribution</td>
<td></td>
<td></td>
<td><a href="https://orderexpress.cardinalhealth.com">https://orderexpress.cardinalhealth.com</a></td>
</tr>
<tr>
<td>CuraScript Specialty Distribution (Priority Healthcare)</td>
<td>1-877-599-7748</td>
<td>1-800-862-6208</td>
<td><a href="https://www.curascriptonline.com">https://www.curascriptonline.com</a></td>
</tr>
<tr>
<td>McKesson Plasma &amp; Biologics</td>
<td>1-877-625-2566</td>
<td>1-888-752-7626</td>
<td><a href="https://connect.mckesson.com">https://connect.mckesson.com</a></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Email: <a href="mailto:plasma@mckesson.com">plasma@mckesson.com</a></td>
</tr>
<tr>
<td>Oncology Supply</td>
<td>1-800-633-7555</td>
<td>1-800-248-8205</td>
<td><a href="https://www.oncologysupply.com">https://www.oncologysupply.com</a></td>
</tr>
</tbody>
</table>

**Note:** Janssen Biotech, Inc., does not endorse the use of any of the listed distributors in particular.
Your one source for patient support
Providing resources to help your patients start and stay on the Janssen medications you prescribed

We can help make it simple for you to help your patients
Janssen CarePath is your one source for resources focused on access, affordability, and treatment support for your patients. You, your staff, and your patients have the flexibility to choose which support and resources you may want to use. We can help make it easier for you and your patients to get the resources you both may need.

ACCESS support to help your patients start on treatment you prescribe
Janssen CarePath helps verify insurance coverage for your patients and provides reimbursement information. Our offerings include:
• Benefits investigation support
• Prior authorization support
• Triage to specialty pharmacy providers, if needed

TREATMENT support to help your patients get informed and stay on prescribed treatment
Janssen CarePath helps keep your patients informed about their condition and the importance of staying on treatment with:

Adherence tools
• Personalized reminders
• Access to the Care4Today® Mobile Health Manager App

Education tools
• Patient education brochures
• Web-based resources
• Education about and referral to independent organizations that provide assistance with costs associated with travel to and from treatment
• AdvocacyConnector.com

With JanssenCarePath.com, convenient support is now at your fingertips.

Getting Started is Easy

1. Complete the Business Associate Agreement (BAA) one time only. Available online at JanssenCarePath.com or by calling Janssen CarePath at 877-CarePath (877-227-3728)

2. Complete the Benefit Investigation Form (BIF) for each patient or complete online at oncologycarepathportal.com

3. Fax the completed forms to 1-844-553-2793

After receiving your completed BIF, 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 877-CarePath (877-227-3728), Monday – Friday, 8:00 AM–8:00 PM ET, and speak to a Janssen CarePath Care Coordinator today. Multilingual phone support available. Visit us online JanssenCarePath.com

Please click here to see full Prescribing Information or visit www.Darzalexhcp.com.
Affordability support to help your patients start and stay on treatment you prescribe

Janssen CarePath can help you find out what affordability assistance may be available for your patients taking Janssen medicines:

- Support for patients using commercial or private insurance
- Support for patients using government insurance
- Support for patients without insurance coverage

If your patients use government-funded insurance such as Medicare, Medicaid, or need supplemental assistance with paying for their medication

Foundation support may be available:

- Good Days from CDF | www.gooddaysfromcdf.org | 1-877-968-7233
- CancerCare | www.cancercare.org | 800-813-4673
- Patient Advocate Foundation | www.paf.org | 1-800-532-5274
- Patient Access Network Foundation | www.panfoundation.org | 1-866-316-7263
- Leukemia & Lymphoma Society | www.lls.org | 1-877-557-2672

Janssen CarePath can refer patients to the Medicare Savings Program to discuss eligibility and program benefits. To determine eligibility, enroll and activate, or get a savings card, visit CarePathSavingsProgram.com or call 844-55DARZA (844-553-2792).

Before the calendar year ends, you will receive information and eligibility requirements for continued participation in the program.

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.

If your patients use 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 medicare.gov/contacts/#resources/msps and select the appropriate state.

Other resources

Johnson & Johnson Patient Assistance Foundation, Inc. (JJPAF), provides free prescription medications to eligible individuals who do not have insurance coverage for their medications and do not have adequate financial resources to pay for them. Please have your patient contact a JJPAF program specialist at 1-800-652-6227 (9 AM to 6 PM ET) or visit the foundation website at JJPAF.org to see if they might qualify for assistance.

For a comprehensive list of cost support programs related to DARZALEX®, visit www.JanssenCarePath.com/DARZALEX.
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]

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®. 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]

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.

Please click here to see full Prescribing Information or visit www.Darzalexhcp.com.
IMPORTANT SAFETY INFORMATION

**CONTRAINDICATIONS**
None

**WARNINGS AND PRECAUTIONS**

Infusion Reactions – DARZALEX® can cause severe infusion reactions. Approximately half of all patients experienced a reaction, most during the first infusion. Infusion reactions can also occur with subsequent infusions. Nearly all reactions occurred during infusion or within 4 hours of completing an infusion. Prior to the introduction of post-infusion medication in clinical trials, infusion reactions occurred up to 48 hours after infusion. Severe reactions have occurred, including bronchospasm, hypoxia, dyspnea, hypertension, laryngeal edema and pulmonary edema. Signs and symptoms may include respiratory symptoms, such as nasal congestion, cough, throat irritation, as well as chills, vomiting and nausea. Less common symptoms were wheezing, allergic rhinitis, pyrexia, chest discomfort, pruritus, and hypotension.

Pre-medicate patients with antihistamines, antipryretics, and corticosteroids. Frequently monitor patients during the entire infusion. Interrupt infusion for reactions of any severity and institute medical management as needed. Permanently discontinue therapy for life-threatening (Grade 4) reactions. 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 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.

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

**Neutropenia** – DARZALEX® may increase neutropenia induced by background therapy. Monitor complete blood cell counts periodically during treatment according to manufacturer’s prescribing information for background therapies. DARZALEX® dose delay may be required to allow recovery of neutrophils. No dose reduction of DARZALEX® is recommended. Consider supportive care with growth factors.

**Thrombocytopenia** – DARZALEX® may increase thrombocytopenia induced by background therapy. Monitor complete blood cell counts periodically during treatment according to manufacturer’s prescribing information for background therapies. DARZALEX® dose delay may be required to allow recovery of platelets. No dose reduction of DARZALEX® is recommended. Consider supportive care with transfusions.

**Interference with Determination of Complete Response** – Daratumumab is a human IgG kappa monoclonal antibody that can be detected on both the serum protein electrophoresis (SPE) and immunofixation (IFE) assays used for the clinical monitoring of endogenous M-protein. This interference can impact the determination of complete response and of disease progression in some patients with IgG kappa myeloma protein.

**Adverse Reactions** – In patients who received DARZALEX® in combination with lenalidomide and dexamethasone, the most frequently reported adverse reactions (incidence ≥20%) were: neutropenia (92%), thrombocytopenia (73%), upper respiratory tract infection (65%), infusion reactions (48%), diarrhea (43%), fatigue (35%), cough (30%), muscle spasms (26%), nausea (24%), dyspnea (21%) and pyrexia (20%). The overall incidence of serious adverse reactions was 49%. Serious adverse reactions were pneumonia (12%), upper respiratory tract infection (7%), influenza (3%) and pyrexia (3%).

In patients who received DARZALEX® in combination with bortezomib and dexamethasone, the most frequently reported adverse reactions (incidence ≥20%) were: thrombocytopenia (90%), neutropenia (58%), peripheral sensory neuropathy (47%), infusion reactions (45%), upper respiratory tract infection (44%), diarrhea (32%), cough (27%), peripheral edema (22%), and dyspnea (21%). The overall incidence of serious adverse reactions was 42%. Serious adverse reactions were upper respiratory tract infection (5%), diarrhea (2%) and atrial fibrillation (2%).

In patients who received DARZALEX® as monotherapy, the most frequently reported adverse reactions (incidence ≥20%) were: neutropenia (60%), thrombocytopenia (48%), infusion reactions (48%), fatigue (39%), nausea (27%), back pain (23%), pyrexia (21%), cough (21%), and upper respiratory tract infection (20%). Serious adverse reactions were reported in 51 (33%) patients. The most frequent serious adverse reactions were pneumonia (6%), general physical health deterioration (3%), and pyrexia (3%).

**DRUG INTERACTIONS**

Effect of Other Drugs on Daratumumab: The coadministration of lenalidomide or bortezomib with DARZALEX® did not affect the pharmacokinetics of daratumumab. Effect of Daratumumab on Other Drugs: The coadministration of DARZALEX® with bortezomib did not affect the pharmacokinetics of bortezomib.
References:

1. DARZALEX® (daratumumab) [Prescribing Information] Horsham, PA: Janssen Biotech, Inc.


Contact Janssen CarePath at 877-CarePath (877-227-3728), Monday to Friday, 8:00 AM to 8:00 PM ET, to learn about cost support options.

To contact Janssen Medical Information Center
Call: 1-800-JANSSEN (1-800-526-7736)
Monday to Friday, 9:00 AM to 8:00 PM ET
E-mail: Submit questions via our askjanssenmedinfo.com site

Please click here to see full Prescribing Information or visit www.Darzalexhcp.com.