DARZALEX® REIMBURSEMENT & ACCESS GUIDE

IMPORTANT INFORMATION TO SUPPORT THE REIMBURSEMENT PROCESS

2018 GUIDELINES

Permanent J-Code J9145

The information provided in this reimbursement guide is valid as of July 2018 and is subject to change.

Please see Important Safety Information on pages 30-31 and click here to see full Prescribing Information.

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Janssen Biotec, Inc. is pleased to provide you and your office staff with detailed information to assist you in obtaining reimbursement for DARZALEX® (daratumumab) on behalf of your patients. We have developed this Reimbursement and Access Guide to provide coding information, a list of specialty distributors, and important product information that we hope will be helpful to you and your practice.

- This document is presented for informational purposes only and is not intended to provide reimbursement or legal advice.
- Laws, regulations, and policies concerning reimbursement are complex and 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 Biotec, Inc., about coverage, levels of reimbursement, payment, or charge.
- Please consult with your payer organization(s) for local or actual coverage and reimbursement policies and with your internal reimbursement specialist for any reimbursement or billing questions.

At Janssen CarePath, we are committed to helping you get your patients started on the Janssen medications they may need, finding financial assistance options, and providing ongoing support to help them stay on prescribed therapy. Janssen CarePath can provide the following support for your patients: conduct benefits investigations, provide prior authorization support if needed, review and explain insurance coverage information and out-of-pocket cost for the medication, help identify financial assistance options, and support them with a dedicated care coordinator and educational resources.

Call 877-CarePath (877-227-3728) Monday – Friday, 8 AM – 8 PM ET
Visit us online: JanssenCarePath.com

We appreciate your interest in DARZALEX®. Please feel free to call 877-CarePath (877-227-3728) to speak with a Janssen CarePath Care Coordinator if you have any questions.

Please see Important Safety Information on pages 30-31 and click here to see full prescribing information.

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INDICATION

DARZALEX® is indicated:

• in combination with bortezomib, melphalan, and prednisone for the treatment of patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant.

• in combination with lenalidomide and dexamethasone, or bortezomib and dexamethasone, for the treatment of patients with multiple myeloma who have received at least one prior therapy

• in combination with pomalidomide and dexamethasone for the treatment of patients with multiple myeloma who have received at least two prior therapies including lenalidomide and a proteasome inhibitor

• as monotherapy, for the treatment of patients with multiple myeloma who have received at least three prior lines of therapy including a proteasome inhibitor (PI) and an immunomodulatory agent or who are double-refractory to a PI and an immunomodulatory agent

DARZALEX® (DARATUMUMAB) DOSING AND ADMINISTRATION

The recommended dose of DARZALEX® is 16 mg/kg actual body weight administered as an intravenous infusion according to the dosing schedule shown in the charts on pages 6 and 7.1 For example, a patient with a body weight of 75 kg would require a 1200-mg dose of DARZALEX®.

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

Note:

• Oral or IV antihistamine (diphenhydramine 25 mg to 50 mg or equivalent)

• Oral antipyretics (acetaminophen 650 to 1000 mg), plus

• Corticosteroid (long-acting or intermediate-acting)

• Additional background regimen-specific corticosteroids (eg, dexamethasone, prednisone) should not be taken on DARZALEX® infusion.

• On DARZALEX® infusion days in combination therapy clinical trials, 20 mg of the dexamethasone dose was given as a pre-infusion medication.

• Additional background regimen-specific corticosteroids (eg, prednisone) should not be taken on DARZALEX® infusion days when patients receive dexamethasone (or equivalent) as a pre-medication.

Pre-infusion medications1

To reduce the risk of infusion reactions, administer approximately 1-3 hours prior to every infusion as follows:

• Oral corticosteroid
  - for monotherapy, intravenous (IV) methylprednisolone 100 mg, or equivalent. Following the second infusion, the dose of corticosteroid may be reduced (oral or IV methylprednisolone 60 mg)
  - for combination therapy, administer dexamethasone 20 mg (or equivalent) prior to every DARZALEX® infusion. IV dexamethasone 20 mg is given prior to the first infusion and IV or oral dexamethasone 20 mg prior to subsequent infusions

• Oral antipyretics (acetaminophen 650 to 1000 mg, plus

• Oral or IV antihistamine (diphenhydramine 25 mg to 50 mg or equivalent)

Note:

• If a planned dose of DARZALEX® is missed, administer the dose as soon as possible and adjust the dosing schedule accordingly, maintaining the treatment interval1

CONTRAINdications

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

WARNINGS AND PRECAUTIONS

Infusion Reactions – DARZALEX® can cause severe and/or serious infusion reactions, including anaphylactic reactions. In clinical trials, approximately half of all patients experienced an infusion reaction. Most infusion reactions occurred during the first infusion and were grade 1-2. 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.

Post-infusion medications1

To reduce the risk of delayed infusion reactions, administer after every infusion as follows:

• Oral corticosteroid
  - for monotherapy, 20 mg methylprednisolone or equivalent dose of an intermediate-acting or long-acting corticosteroid in accordance with local standards on each of the 2 days following at DARZALEX® (daratumumab) infusions (beginning the day after the infusion)
  - for combination therapy, ≤20 mg of methylprednisolone or equivalent the day after the DARZALEX® infusion; however, if a background regimen-specific corticosteroid (eg, dexamethasone, prednisone) is administered the day after the DARZALEX® infusion, additional post-infusion medications may not be needed

Note:

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

SELECT IMPORTANT SAFETY INFORMATION

• DARZALEX® should be administered by a healthcare professional, with immediate access to emergency equipment and appropriate medical support to manage infusion reactions if they occur

• If a planned dose of DARZALEX® is missed, administer the dose as soon as possible and adjust the dosing schedule accordingly, maintaining the treatment interval1

Please see Important Safety Information continued on the next page and on pages 30-31, and click here to see full Prescribing Information.
DARZALEX® (DARATUMUMAB) DOSING IN COMBINATION WITH BORTEZOMIB, MELPHALAN, AND PREDNISONE

- DARZALEX® is given as an intravenous (IV) infusion after dilution at 16 mg/kg of actual body weight, with pre- and post-infusion medications.
- See table on page 10
- Bortezomib 1.3 mg/m² is administered by subcutaneous injection twice weekly at Weeks 1, 2, 4, and 5 (Cycle 1), followed by once weekly at Weeks 1, 2, 4, and 5 (Cycles 2 to 9).*
- Melphalan 9 mg/m² is given orally on Days 1 to 4 of each cycle up to Cycle 9.*
- Prednisone 60 mg/m² is given orally on Days 1 to 4 of each cycle up to Cycle 9.*
- Additional background regimen-specific corticosteroids (eg, prednisone) should not be taken on DARZALEX® infusions days when patients receive dexamethasone (or equivalent) as a pre-medication.

### DARZALEX® Dosing Regimen in NDMM Transplant-Ineligible Patients

<table>
<thead>
<tr>
<th>Cycles</th>
<th>Doses Per Cycle</th>
<th>Dose Per Cycle</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1</td>
<td>(Cycle 10+, Week 55+ until disease progression)</td>
</tr>
<tr>
<td>2</td>
<td>1</td>
<td>(Cycle 2 to 9, Weeks 7 to 54)</td>
</tr>
<tr>
<td>6</td>
<td>1 weekly</td>
<td>(Cycle 1, Weeks 1 to 6)</td>
</tr>
</tbody>
</table>

VMP=bortezomib, melphalan and prednisone.

**Note:** VMP administration should be stopped after 9 cycles.

*For dosing instructions of combination agents administered with DARZALEX®, see the Clinical Studies (14.1) section of the DARZALEX® Prescribing Information.

**SELECT IMPORTANT SAFETY INFORMATION**

**WARNINGS AND PRECAUTIONS (cont’d)**

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 if an anaphylactic reaction or life-threatening (Grade 4) reaction occurs and institute appropriate emergency care. For patients with Grade 1, 2, or 3 reactions, reduce the infusion rate when re-starting the infusion. **SELECT IMPORTANT SAFETY INFORMATION**

**WARNINGS AND PRECAUTIONS (cont’d)**

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 if an anaphylactic reaction or life-threatening (Grade 4) reaction occurs and institute appropriate emergency care. For patients with Grade 1, 2, or 3 reactions, reduce the infusion rate when re-starting the infusion.

### DARZALEX® 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 actual body weight, with pre- and post-infusion medications.
- See table on page 10
- For DARZALEX® + Rd Dosing Regimen
- Lenalidomide 25 mg is given orally on days 1–21 of each cycle*
- Dexamethasone 40 mg is given orally or IV once a week†
  - On DARZALEX® infusion days, 20 mg of the dexamethasone dose was given as a pre-infusion medication and the remainder given the day after the infusion.
  - For patients on a reduced dexamethasone dose, the entire 20-mg dose was given as a DARZALEX® pre-infusion medication.

**SELECT IMPORTANT SAFETY INFORMATION**

**WARNINGS AND PRECAUTIONS (cont’d)**

Infusion Reactions (cont’d) – 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.

Please see Important Safety Information on pages 30-31 and click here to see full Prescribing Information.
**DARZALEX® (DARATUMUMAB) DOSING IN COMBINATION WITH BORTEZOMIB AND DEXAMETHASONE**

- DARZALEX® is given as an intravenous (IV) infusion after dilution at 16 mg/kg of actual body weight, with pre- and post-infusion medications.

  See table on page 10

- Bortezomib 1.3 mg/m² is administered by subcutaneous injection or IV infusion on days 1, 4, 8, and 11 of each cycle for a total of 8 cycles.

- Dexamethasone 20 mg is given orally once daily on days 1, 2, 4, 5, 8, 9, 11, and 12 for a total of 8 cycles.
  - On the days of DARZALEX® infusion, 20 mg of the dexamethasone dose was administered as a pre-infusion medication and was continued as a pre-medication after Vd discontinuation.
  - For patients on a reduced dexamethasone dose, the entire 20-mg dose was given as a DARZALEX® pre-infusion medication.

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**SELECT IMPORTANT SAFETY INFORMATION**

**WARNINGS AND PRECAUTIONS (cont'd)**

**Interference with Serological Testing**
- 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. Monitor patients with neutropenia for signs of infection. DARZALEX® dose delay may be required to allow recovery of neutrophils. No dose reduction of DARZALEX® is recommended. Consider supportive care with growth factors.

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**DARZALEX® DOSING IN COMBINATION WITH POMALIDOMIDE AND DEXAMETHASONE**

- DARZALEX® is given as an intravenous (IV) infusion after dilution at 16 mg/kg of actual body weight, with pre- and post-infusion medications.

  See table on page 10

- Pomalidomide 4 mg is given orally on days 1–21 of each cycle.

- Dexamethasone 40 mg is given orally or IV once a week.
  - On DARZALEX® infusion days, 20 mg of the dexamethasone dose was given as a pre-infusion medication and the remainder given the day after the infusion.
  - For patients on a reduced dexamethasone dose, the entire 20-mg dose was given as a DARZALEX® pre-infusion medication.

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**DARZALEX® Dosing Regimen in Dvd Patients With ≥2 Prior Therapies**

<table>
<thead>
<tr>
<th>Cycle</th>
<th>Per Dose</th>
<th>Doses</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>2</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>3</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

- DARZALEX® is given as an intravenous (IV) infusion after dilution at 16 mg/kg of actual body weight, with pre- and post-infusion medications.

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**DARZALEX® Dosing Regimen in Dpd Patients**

<table>
<thead>
<tr>
<th>Cycle</th>
<th>Per Dose</th>
<th>Doses</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>2</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>3</td>
<td>4</td>
<td>4</td>
</tr>
</tbody>
</table>

- DARZALEX® is given as an intravenous (IV) infusion after dilution at 16 mg/kg of actual body weight, with pre- and post-infusion medications.

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**SELECT IMPORTANT SAFETY INFORMATION**

**WARNINGS AND PRECAUTIONS (cont'd)**

**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. Monitor patients with neutropenia for signs of infection. DARZALEX® dose delay may be required to allow recovery of neutrophils. No dose reduction of DARZALEX® is recommended. Consider supportive care with growth factors.

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**Please see Important Safety Information on pages 30-31 and click here to see full Prescribing Information.**
Slower rate of infusion for the first DARZALEX® (daratumumab) dose is recommended, as infusion reactions are more likely to occur with the first 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

The median infusion duration decreased considerably after the first infusion:

- First Infusion: Median duration 7.0 hours
- Second Infusion: Median duration 4.3 hours
- Subsequent Infusion: Median duration 3.4 hours

Dilution volume

<table>
<thead>
<tr>
<th>Per Infusion</th>
<th>Second Infusion</th>
<th>Subsequent Infusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>1000 mL</td>
<td>500 mL</td>
<td>500 mL</td>
</tr>
</tbody>
</table>

Initial rate (first hour)

- First Infusion: 50 mL/hour every hour
- Second Infusion: 50 mL/hour every hour
- Subsequent Infusion: 50 mL/hour every hour

Rate increment*

- First Infusion: 50 mL/hour every hour
- Second Infusion: 50 mL/hour every hour
- Subsequent Infusion: 50 mL/hour every hour

Maximum rate

- Per Infusion: 200 mL/hour
- Second Infusion: 200 mL/hour
- Subsequent Infusion: 200 mL/hour

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

1Use a dilution volume of 1000 mL only if there were no infusion reactions during the first 3 hours of the first infusion. Otherwise, continue to use instructions for the second infusion.

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

**IMPORTANT INFORMATION**

- DARZALEX® should be administered by a healthcare professional, with immediate access to emergency equipment and appropriate medical support to manage infusion reactions if they occur.

- If a planned dose of DARZALEX® is missed, administer the dose as soon as possible and adjust the dosing schedule accordingly, maintaining the treatment interval.

Please see Important Safety Information on pages 30-31 and click here to see full Prescribing Information.
SELECT IMPORTANT SAFETY INFORMATION

DRUG INTERACTIONS

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

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

CODING FOR DARZALEX®

National Drug Code (NDC)

In some cases, you may be required to include the NDC in the appropriate location on a claim form.

<table>
<thead>
<tr>
<th>National Drug Codes for DARZALEX®†</th>
<th>10-digit NDC</th>
<th>11-digit NDC (most commonly used)</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>57894-502-05</td>
<td>57894-0502-05</td>
<td>100 mg/5 mL vial (20 mg/mL) Single-use vial containing 100 mg of daratumumab solution for intravenous infusion</td>
</tr>
<tr>
<td></td>
<td>57894-502-20</td>
<td>57894-0502-20</td>
<td>400 mg/20 mL vial (20 mg/mL) Single-use vial containing 400 mg of daratumumab solution for intravenous infusion</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 see Important Safety Information on pages 30-31 and click here to see full Prescribing Information.
Healthcare Common Procedure Coding System (HCPCS) Codes

The permanent HCPCS code for DARZALEX (daratumumab) replaces all miscellaneous or temporary codes previously used to code DARZALEX.

• J9145 (effective January 1, 2017) is used on both Medicare and commercial claims. It also requires billing in units consistent with the code descriptor:

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Description</th>
<th>Care Setting</th>
</tr>
</thead>
<tbody>
<tr>
<td>J9145</td>
<td>Injection, daratumumab, 10 mg</td>
<td>Physician Practice</td>
</tr>
<tr>
<td>J9145</td>
<td>Injection, daratumumab, 10 mg</td>
<td>HOPD</td>
</tr>
</tbody>
</table>


CPT codes are the most widely accepted medical nomenclature used to report medical procedures and services under public and private health insurance programs. Consider using the following CPT codes for the administration of the DARZALEX infusion:

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>96413</td>
<td>Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug</td>
</tr>
<tr>
<td>96415</td>
<td>Chemotherapy administration, intravenous infusion technique; each additional hour [list separately in addition to code for primary procedure]</td>
</tr>
</tbody>
</table>

Note: 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).

ICD-10-CM Diagnosis Codes

All parties covered by the Health Insurance Portability and Accountability Act (HIPAA), not just providers who bill Medicare or Medicaid, are required to use the International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM) codes to document patient diagnoses. ICD-10-CM far exceeds previous coding systems in the number of concepts and codes provided, allowing for greater specificity when describing patient conditions. ICD-10-CM uses 3-7 alpha and numeric digits to achieve this level of detail:

<table>
<thead>
<tr>
<th>ICD-10-CM Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>C90.0</td>
<td>Multiple myeloma</td>
</tr>
<tr>
<td>C90.00</td>
<td>Multiple myeloma not having achieved remission</td>
</tr>
<tr>
<td>C90.01</td>
<td>Multiple myeloma in remission</td>
</tr>
<tr>
<td>C90.02</td>
<td>Multiple myeloma in relapse</td>
</tr>
</tbody>
</table>

SELECT IMPORTANT SAFETY INFORMATION

Adverse Reactions (cont’d) – In patients who received DARZALEX in combination with pomalidomide and dexamethasone, the most frequent adverse reactions (>20%) were fatigue (50%), infusion reactions (50%), upper respiratory tract infection (50%), cough (43%), diarrhea (38%), constipation (33%), dyspepsia (33%), nausea (30%), muscle spasms (26%), back pain (25%), pyrexia (25%), insomnia (23%), arthralgia (22%), dizziness (21%), and vomiting (21%). The overall incidence of serious adverse reactions was 49%. Serious adverse reactions reported in ≥5% patients included pneumonia (7%). Treatment-emergent hematology Grade 3-4 laboratory abnormalities ≥20% were anemia (30%), neutropenia (82%), and lymphopenia (71%).

In patients who received DARZALEX as monotherapy, the most frequently reported adverse reactions (incidence ≥20%) were: infusion reactions (48%), fatigue (39%), nausea (27%), back pain (23%), pyrexia (21%), cough (21%), and upper respiratory tract infection (20%). The overall incidence of serious adverse reactions was 33%. The most frequent serious adverse reactions were pneumonia (6%), general physical health deterioration (3%), and pyrexia (3%). Treatment-emergent Grade 3-4 hematologic laboratory abnormalities ≥20% were lymphopenia (40%) and neutropenia (20%).

Please see Important Safety Information on pages 30-31 and click here to see full Prescribing Information.
**Other Coding Considerations**

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

**Modifiers**

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

<table>
<thead>
<tr>
<th>Modifier</th>
<th>Description</th>
<th>Indication and Placement</th>
<th>CMS-1500 Item 24D</th>
<th>CMS-1450 Locator Box 44</th>
</tr>
</thead>
<tbody>
<tr>
<td>25</td>
<td>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</td>
<td>Patient requires distinct evaluation and management (E/M) service in addition to the infusion procedure; must be substantiated with relevant documentation; append the modifier to the relevant E/M code</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>JW</td>
<td>Drug amount discarded/not administered to any patient</td>
<td>Unused drug remains after applicable dose is administered from single-use vial; CMS has issued a discarded drug policy and requires use of the JW modifier; other payer requirements may vary; 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</td>
<td>Required by Medicare</td>
<td>Required by Medicare</td>
</tr>
<tr>
<td>PN*</td>
<td>Nonexcepted service provided at an off-campus, outpatient, provider-based department of a hospital</td>
<td>To be reported on each claim line for nonexcepted services furnished in an off-campus, provider-based department of a hospital and billed on an institutional claim</td>
<td>N/A</td>
<td>Required by Medicare</td>
</tr>
<tr>
<td>PO*</td>
<td>Excepted services provided at an off-campus, outpatient, provider-based department of a hospital</td>
<td>To be reported on each claim line for excepted services furnished in an off-campus, provider-based department of a hospital and billed on an institutional claim</td>
<td>N/A</td>
<td>Required by Medicare</td>
</tr>
<tr>
<td>JG</td>
<td>Drug or biological acquired with 340B Drug Pricing Program Discount</td>
<td>Beginning January 1, 2018, must be reported by providers that are NOT excepted from the 340B payment policy; to be reported on the same claim line as the drug HCPCS code for all 340B acquired drugs</td>
<td>N/A</td>
<td>Required by Medicare</td>
</tr>
<tr>
<td>TB</td>
<td>Drug or biological acquired with 340B Drug Pricing Program Discount, reported for informational purposes</td>
<td>Beginning January 1, 2018, must be reported by providers that ARE excepted from the 340B payment policy; to be reported on the same claim line as the drug HCPCS code for all 340B acquired drugs</td>
<td>N/A</td>
<td>Required by Medicare</td>
</tr>
</tbody>
</table>

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

†This policy does not apply to critical access hospitals (CAHs) or Maryland hospitals; for 2018, the following provider types are excepted from the 340B payment policy: rural sole community hospitals, children’s hospitals, PPS-exempt cancer hospitals, and nonexcepted, off-campus, provider-based departments.

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**Select Important Safety Information**

**Contraindications**

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

Please see Important Safety Information on pages 30-31 and click here to see full Prescribing Information.
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 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 require the JW modifier on claims for unused drug or biological.

Check with other payers for specific requirements

Please see examples of using the JW modifier on pages 24 and 25.

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:

- CPT code 99211 cannot be paid if it is billed with a drug administration service (e.g., chemotherapy or non-chemotherapy drug infusion code) or a therapeutic or diagnostic injection code.

Thus, CPT code 99211 cannot be paid 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 (i.e., when drug is not flowing, IV saline to keep a line open with no drug flowing) does not count toward billable infusion time.
Item 21 - Indicate diagnosis using appropriate ICD-10-CM code(s).

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

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 22 for an example).

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.

Billing Unit Conversion

<table>
<thead>
<tr>
<th>HCPCS J9145® (Injection, daratumumab, 10 mg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>10 mg</td>
</tr>
<tr>
<td>100 mg vial</td>
</tr>
<tr>
<td>400 mg vial</td>
</tr>
</tbody>
</table>

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.

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

*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)

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

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

B  Locator Box 42 - List revenue codes in ascending order.
 Locator Box 43 - Enter narrative description for corresponding revenue code (e.g., IV therapy; clinic visit).

Revenue Codes:
• 0260 (IV therapy)
• 0636 (Drugs requiring detailed coding)

C  Locator Box 44 - 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 23 for an example).

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

Billing Unit Conversion

HCPCS J9145² (Injection, daratumumab, 10 mg)

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

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

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

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

Note: The PO modifier is required on institutional claims submitted by excepted, off-campus, provider-based departments; the PN modifier is required on institutional claims submitted by nonexcepted, off-campus, provider-based departments. Neither the PO nor the PN modifier’s is to be reported for a provider-based department that is “on campus.”³⁶

Note: HCPCS modifiers must be reported for all 340B acquired drugs. Providers that are not excepted from the 340B payment policy will report modifier JG. Providers that are excepted from the 340B payment policy will report modifier TB.⁷

³ Insert appropriate number of units based on dose administered. This claim illustrates a 1200-mg dose.

Please see Important Safety Information on pages 30-31 and click here to see full Prescribing Information.
Using the JW Modifier with Physician Office: CMS-1500 Form

Example of DARZALEX® (daratumumab) 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: 110 units administered and 10 units discarded; append the JW modifier to the amount discarded.

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: 110 units administered and 10 units discarded; append the JW modifier to the amount discarded.
DARATUMUMAB IN NCCN GUIDELINES® FOR MULTIPLE MYELOMA

Therapy for Multiple Myeloma

Preferred Regimens for Non-Transplant Candidates:
- Daratumumab | bortezomib | melphalan | prednisone (category 1†)

Preferred Regimens for Previously Treated Multiple Myeloma:
- Daratumumab | bortezomib | dexamethasone (category 1†)
- Daratumumab | lenalidomide | dexamethasone (category 1†)

Other Recommended Regimens for Previously Treated Multiple Myeloma:
- Daratumumab | pomalidomide | dexamethasone (category 2A‡)
- Daratumumab (category 2A‡)

†Regimens that contain daratumumab

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®.

SELECT 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®.

Please see Important Safety Information on pages 30-31 and click here to see full Prescribing Information.

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></td>
<td></td>
<td></td>
<td></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://curascriptsd.com">https://curascriptsd.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>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.
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.*

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

Sample Letter of Formulary Exception Request

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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9/16 035901-160915

Please see Important Safety Information on pages 30-31 and click here to see full Prescribing Information.
IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

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

WARNINGS AND PRECAUTIONS

Infusion Reactions – DARZALEX® can cause severe and/or serious infusion reactions, including anaphylactic reactions. In clinical trials, approximately half of all patients experienced an infusion reaction. Most infusion reactions occurred during the first infusion and were grade 1-2. 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, tachycardia, 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, antipyrretics, and corticosteroids. Frequently monitor patients during the entire infusion. Interrupt infusion for any severity and institute medical management as needed. Permanently discontinue therapy if an anaphylactic reaction or life-threatening (Grade 4) reaction occurs and institute appropriate emergency care. For patients with Grade 1, 2, or 3 reactions, reduce the infusion rate when re-starting the infusion.

To reduce the risk of delayed infusion 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 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. The determination of a patient’s ABO and Rh blood type are not impacted. Notify blood transfusion centers of this interference.

Antibody formation with daratumumab may occur. Antibodies 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.

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

Effect of Daratumumab on Other Drugs: The coadministration of DARZALEX® in combination with bortezomib, melphalan, and prednisone (DVPMP), the most frequently reported adverse reactions (incidence ≥ 20%) were: upper respiratory tract infection (68%), infusion reactions (28%), and peripheral edema (21%). Serious adverse reactions (≥ 2% compared to the VMP arm) were pneumonia (11%), upper respiratory tract infection (5%), and pulmonary edema (2%). Treatment-emergent Grade 3-4 hematological laboratory abnormalities ≥ 20% were lymphopenia (38%), neutropenia (44%), and thrombocytopenia (38%).

In patients who received DARZALEX® in combination with lenalidomide and dexamethasone, the most frequently reported adverse reactions (incidence ≥ 20%) were: upper respiratory tract infection (65%), infusion reactions (48%), dyspnea (43%), fatigue (33%), cough (30%), muscle spasms (26%), nausea (24%), dyspnea (21%), and pyrexia (20%). The overall incidence of serious adverse reactions was 49%.

Serious adverse reactions (≥ 2% compared to Rd) were pneumonia (12%), upper respiratory tract infection (7%), influenza (3%), and pyrexia (3%). Treatment-emergent Grade 3-4 hematological laboratory abnormalities ≥ 20% were neutropenia (53%) and lymphopenia (52%).

In patients who received DARZALEX® in combination with bortezomib and dexamethasone, the most frequently reported adverse reactions (incidence ≥ 20%) were: 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 (≥ 2% compared to Vd) were upper respiratory tract infection (5%), diarrhea (2%) and atrial fibrillation (2%). Treatment-emergent Grade 3-4 hematological laboratory abnormalities ≥ 20% were lymphopenia (48%) and thrombocytopenia (47%).

In patients who received DARZALEX® in combination with pomalidomide and dexamethasone, the most frequent adverse reactions (≥ 20%) were: fatigue (50%), infusion reactions (50%), upper respiratory tract infection (50%), cough (49%), diarrhea (39%), constipation (32%), myelosuppression (31%), nausea (30%), muscle spasms (26%), back pain (25%), pyrexia (25%), insomnia (23%), arthralgia (22%), dizziness (21%), and vomiting (21%). The overall incidence of serious adverse reactions was 49%. Serious adverse reactions reported in ≥ 5% patients included pneumonia (7%). Treatment-emergent hematologic Grade 3-4 laboratory abnormalities ≥ 20% were anemia (30%), neutropenia (82%), and lymphopenia (71%).

In patients who received DARZALEX® as monotherapy, the most frequently reported adverse reactions (incidence ≥ 20%) were: infusion reactions (48%), fatigue (39%), nausea (27%), back pain (23%), pyrexia (21%), cough (21%), and upper respiratory tract infection (20%). The overall incidence of serious adverse reactions was 33%. The most frequent serious adverse reactions were pneumonia (6%), general physical health deterioration (3%), and pyrexia (3%). Treatment-emergent Grade 3-4 hematological laboratory abnormalities ≥ 20% were lymphopenia (40%) and neutropenia (20%).

DRUG INTERACTIONS

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

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

cp-60862v1

Please click here to see full Prescribing Information.