DARZALEX® REIMBURSEMENT & ACCESS GUIDE

IMPORTANT INFORMATION FOR THE REIMBURSEMENT PROCESS

2019

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Janssen Biotech, 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 Biotech, 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.

Please see Important Safety Information on pages 32-34 and click here to see full Prescribing Information.

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**TABLE OF CONTENTS**

- DARZALEX® Dosing and Administration ................................................. 4
- Indication .......................................................................................... 4
- Infusion Rates .................................................................................. 10
- Coding for DARZALEX® ................................................................. 11
- National Drug Codes (NDC) ............................................................. 11
- HCPCS Codes .................................................................................. 13
- CPT® Codes .................................................................................... 14
- ICD-10-CM Diagnosis Codes ............................................................ 15
- Other Coding Considerations .......................................................... 16
- Modifiers ........................................................................................ 16
- CMS Discarded Drug Policies ......................................................... 18
- Same-Day Evaluation and Management Services ......................... 19
- Partial Additional Hours of Infusion Time ....................................... 19
- Donated or Free-of-Charge Drug ..................................................... 20
- Place of Service Codes .................................................................... 21
- Sample Claim Forms for DARZALEX® ............................................. 22
- Physician Office Sample Claim Form: CMS-1500 ......................... 22
- Hospital Outpatient Department Sample Claim Form: CMS-1450 (UB-04) ................. 24
- Using the JW Modifier with Physician Office: CMS-1500 Form .......... 26
- Using the JW Modifier in Hospital Outpatient Department: CMS-1450 (UB-04) Form ...... 27
- NCCN Guidelines® ........................................................................ 28
- Specialty Distributors .................................................................... 29
- Appendix ....................................................................................... 30
- Sample Letter of Medical Necessity ............................................... 30
- Sample Letter of Formulary Exception Request ............................ 31
- Important Safety Information ......................................................... 32
- References ..................................................................................... 35

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Please see Important Safety Information on pages 32-34 and click here to see full Prescribing Information.
DARZALEX® (DARATUMUMAB) IS INDICATED FOR ADULT PATIENTS:

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

DARZALEX® DOSING AND ADMINISTRATION

The recommended dose of DARZALEX® is 16 mg/kg actual body weight administered as an intravenous infusion according to the dosing schedule by indication (please see Tables 1 through 3 on pages 6-8).1 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.1 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.1 Administer pre-infusion and post-infusion medications to reduce the risk of infusion reactions.1

Pre-infusion medications1

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

- Corticosteroid (long-acting or intermediate-acting)
  - for monotherapy, intravenous (IV) methylprednisolone 100 mg, or equivalent. Following the second infusion, the dose of corticosteroid may be reduced (oral or IV methylprednisolone 60 mg)
  - for combination therapy, administer dexamethasone 20 mg (or equivalent) prior to every DARZALEX® infusion.
- When dexamethasone is the background regimen specific corticosteroid, the dexamethasone treatment dose will instead serve as pre-medication on DARZALEX® infusion days. IV dexamethasone 20 mg is given prior to the first infusion and IV or oral dexamethasone 20 mg prior to subsequent infusions
- Oral antihistamines (acetaminophen 650 to 1000 mg), plus
- Oral antipyretics (acetaminophen 650 to 1000 mg), plus
- Oral or IV antihistamine (diphenhydramine 25 mg to 50 mg or equivalent)

Note:

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

Post-infusion medications1

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

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

Note:

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

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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 or within 4 hours of completing DARZALEX®. 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.

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**DARZALEX® (DARATUMUMAB) DOSING FOR MONOTHERAPY AND IN COMBINATION WITH LENALIDOMIDE (Drd) OR POMALIDOMIDE (DPd)**

For the treatment of adults with multiple myeloma:

- as monotherapy, in patients who have received at least three prior lines of therapy, including a proteasome inhibitor (PI) and an immunomodulatory agent or who are double-refractory to a PI and an immunomodulatory agent
- in combination with lenalidomide and dexamethasone in newly diagnosed patients
- DARZALEX® is given as an intravenous (IV) infusion after dilution at 16 mg/kg of actual body weight, with pre- and post-infusion medications
- Split first dose option: the first prescribed 16 mg/kg dose at Week 1 may be split over 2 consecutive days, ie, 8 mg/kg on Day 1 and Day 2, respectively
- For dosing instructions of combination agents administered with DARZALEX®, see the Clinical Studies (14.2) section of the DARZALEX® Prescribing Information, and the respective manufacturers’ Prescribing Information

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- who are ineligible for autologous stem cell transplant and in patients with relapsed or refractory multiple myeloma who have received at least one prior therapy
- in combination with pomalidomide and dexamethasone in patients who have received at least two prior therapies including lenalidomide and a proteasome inhibitor

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**Table 1: DARZALEX® Dosing in Drd, DPd, and Monotherapy Regimens**

<table>
<thead>
<tr>
<th>Doses Per Cycle</th>
<th>Cycle 1</th>
<th>Cycle 2</th>
<th>Cycle 3</th>
<th>Cycle 4</th>
<th>Cycle 5-6</th>
<th>Cycle 7+</th>
<th>Week 25+ until disease progression</th>
</tr>
</thead>
<tbody>
<tr>
<td>4</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>estimated year 1 infusion visits</td>
</tr>
<tr>
<td>2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

| The dosing schedules for Drd, DPd, and DARZALEX® monotherapy are based on a 28-day (4-week) cycle throughout therapy. Note: For DARZALEX® infusion rates, please see Table 5 on page 10.

<table>
<thead>
<tr>
<th>Dose Per Cycle</th>
<th>Cycle</th>
<th>Infusion Schedule</th>
<th>Days</th>
<th>Estimated Year 1 Infusion Visits</th>
</tr>
</thead>
<tbody>
<tr>
<td>3 Doses Per Cycle</td>
<td>Cycles 1 to 3, Weeks 1 to 9</td>
<td>as a weekly infusion</td>
<td>every 4 Weeks</td>
<td>21 visits</td>
</tr>
<tr>
<td>1 Dose Per Cycle</td>
<td>Cycles 4 to 8, Weeks 10 to 24</td>
<td>as 1 infusion every 3 weeks</td>
<td>Bio-weekly</td>
<td>21 visits</td>
</tr>
<tr>
<td>1 Dose Per Cycle</td>
<td>Cycles 9+, Weeks 25+ until disease progression</td>
<td>as 1 infusion every 4 weeks</td>
<td>Weekly</td>
<td>21 visits</td>
</tr>
</tbody>
</table>

**Table 2: DARZALEX® Dosing in DVd Regimen**

- Starting at Week 25, administration frequency for DARZALEX® regimens is every 4 weeks and median duration averages 3.4 hours.
- Starting at Week 25, administration frequency for DARZALEX® regimens is every 4 weeks and median duration averages 3.4 hours.
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- Starting at Week 25, administration frequency for DARZALEX® regimens is every 4 weeks and median duration averages 3.4 hours.

**SELECT IMPORTANT SAFETY INFORMATION**

**WARNINGS AND PRECAUTIONS (cont’d)**

**Infusion Reactions (cont’d)**

- 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 who are double-refractory to a PI and an immunomodulatory agent or who are ineligible for autologous stem cell transplant and in patients with relapsed or refractory multiple myeloma who have received at least one prior therapy.

To reduce the risk of delayed infusion reactions, administer oral corticosteroids to all patients who are double-refractory to a PI and an immunomodulatory agent or who are ineligible for autologous stem cell transplant and in patients with relapsed or refractory multiple myeloma who have received at least one prior therapy.

Consider prescribing short- and long-acting bronchodilators and inhaled corticosteroids for patients with chronic obstructive pulmonary disease.

**Please see Important Safety Information on pages 32-34 and click here to see full Prescribing Information.**
DARZALEX® (DARATUMUMAB) DOSING IN COMBINATION WITH BORTEZOMIB, THALIDOMIDE, AND DEXAMETHASONE

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

- DARZALEX® is given as an intravenous (IV) infusion after dilution at 16 mg/kg of actual body weight, with pre- and post-infusion medications
- Split first dose option: the first prescribed 16 mg/kg dose at Week 1 may be split over 2 consecutive days, ie, 8 mg/kg on Day 1 and Day 2, respectively
- For dosing instruction of combination agents administered with DARZALEX®, see the Clinical Studies (14.2) section of the DARZALEX® Prescribing Information, and the respective manufacturers’ Prescribing Information

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

### Table 3: DARZALEX® Dosing in DVTd Regimen

<table>
<thead>
<tr>
<th>Cycle</th>
<th>Per Dose</th>
<th>Given as 1 Infusion (Cycles 1 to 2)</th>
<th>Every 2 Weeks (Cycles 3 to 6)</th>
</tr>
</thead>
<tbody>
<tr>
<td>4</td>
<td>4</td>
<td>1 weekly infusion (Cycles 1 to 2)</td>
<td>2 weeks (Cycles 3 to 6)</td>
</tr>
<tr>
<td>2</td>
<td>2</td>
<td>1 infusion every 2 weeks</td>
<td></td>
</tr>
</tbody>
</table>

**STOP FOR HIGH-DOSE CHEMOTHERAPY AND ASCt**

<table>
<thead>
<tr>
<th>Cycle</th>
<th>Per Dose</th>
<th>Given as 1 infusion every 2 weeks (Cycles 5 to 6)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>2</td>
<td>(Weeks 1 to 8 of consolidation phase)</td>
</tr>
<tr>
<td>1</td>
<td></td>
<td>(Weeks 1 to 8 of consolidation phase)</td>
</tr>
</tbody>
</table>

**Note:** For DARZALEX® infusion rates, please see Table 5 on page 10.

**SELECT IMPORTANT SAFETY INFORMATION**

**WARNINGS AND PRECAUTIONS (cont’d)**

**Interference With Serological Testing** – Daratumumab binds to CD38 on red blood cells (RBCs) and results in a positive indirect antiglobulin test (Indirect Coombs test). Daratumumab-mediated positive indirect antiglobulin test may persist for up to 6 months after the last daratumumab 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®.

### Table 4: DARZALEX® Dosing in DVMP Regimen

<table>
<thead>
<tr>
<th>Cycle</th>
<th>Per Dose</th>
<th>Given as 1 weekly infusion (Cycles 1, Weeks 1 to 6)</th>
</tr>
</thead>
<tbody>
<tr>
<td>6</td>
<td></td>
<td>(Cycles 1, Weeks 1 to 6)</td>
</tr>
<tr>
<td>2</td>
<td></td>
<td>(Cycles 2, Weeks 1 to 6)</td>
</tr>
<tr>
<td>1</td>
<td></td>
<td>(Cycles 3, Weeks 1 to 6)</td>
</tr>
</tbody>
</table>

**Note:** For DARZALEX® infusion rates, please see Table 5 on page 10.

### SELECT IMPORTANT SAFETY INFORMATION

**WARNINGS AND PRECAUTIONS (cont’d)**

**Neutropenia and Thrombocytopenia** – DARZALEX® may increase neutropenia and/or thrombocytopenia induced by background therapy. Monitor complete blood cell counts periodically during treatment according to the 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 and/or platelets. No dose reduction of DARZALEX® is recommended. Consider supportive care with growth factors for neutropenia or transfusions for thrombocytopenia.

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INFUSION RATES

Administer DARZALEX® (daratumumab) infusions intravenously at the rates described in the table below. Consider incremental escalation of the infusion rate only in the absence of infusion reactions.1

<table>
<thead>
<tr>
<th>Table 5: Infusion rates for DARZALEX® administration1</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Dilution volume</strong></td>
</tr>
<tr>
<td><strong>Option 1 (single dose infusion)</strong></td>
</tr>
<tr>
<td>Week 1</td>
</tr>
<tr>
<td>Day 1 (16 mg/kg)</td>
</tr>
<tr>
<td><strong>Option 2 (split dose infusion)</strong></td>
</tr>
<tr>
<td>Week 1</td>
</tr>
<tr>
<td>Day 1 (8 mg/kg)</td>
</tr>
<tr>
<td>Week 1</td>
</tr>
<tr>
<td>Day 2 (8 mg/kg)</td>
</tr>
<tr>
<td><strong>Subsequent Infusions</strong></td>
</tr>
<tr>
<td>Week 2 (16 mg/kg) infusion†</td>
</tr>
<tr>
<td><strong>(Week 3 onwards, 16 mg/kg)‡</strong></td>
</tr>
</tbody>
</table>

*Consider incremental escalation of the infusion rate only in the absence of infusion reactions.
†Use a dilution volume of 500 mL for the 16 mg/kg dose only if there were no infusion reactions the previous week. Otherwise, use a dilution volume of 1000 mL.
‡Use a modified initial rate (100 mL/hour) for subsequent infusions (ie, week 3 onwards) only if there were no infusion reactions during the previous infusion. Otherwise, continue to use instructions in the table for the Week 2 infusion rate.

For infusion reactions of any grade/severity, immediately interrupt the DARZALEX® infusion and manage symptoms. Depending on the infusion reaction severity, management may require further reduction in the infusion rate or discontinuation of the DARZALEX® treatment.1

**Table 6: Median Length of Infusion1,2**

<table>
<thead>
<tr>
<th><strong>Option 1: Single dose Week 1 infusion</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Week 1, Day 1</td>
</tr>
<tr>
<td>Week 2, Day 1</td>
</tr>
<tr>
<td>Subsequent Infusions</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Option 2: Split dose Week 1 infusion</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Week 1, Day 1</td>
</tr>
<tr>
<td>Week 1, Day 2</td>
</tr>
<tr>
<td>Week 2, Day 1</td>
</tr>
<tr>
<td>Subsequent Infusions</td>
</tr>
</tbody>
</table>

CODING FOR DARZALEX® (daratumumab)

National Drug Codes (NDC)

The National Drug Code (NDC) is a unique number that identifies a drug’s labeler, product, and trade package size. The NDC is most often used on pharmacy claims, including drugs provided for home infusion. However, the NDC is also required on Medicare claims for dual-eligible beneficiaries (Medicaid cross-over claims),3 Medicaid fee-for-service claims,3 and by some private payers.4 Although the FDA uses a 10-digit format when registering NDCs, 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 below:

<table>
<thead>
<tr>
<th>Table 7: National Drug Codes for DARZALEX®4</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>10-digit NDC</strong></td>
</tr>
<tr>
<td>57894-502-05</td>
</tr>
<tr>
<td>57894-502-20</td>
</tr>
</tbody>
</table>

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WARNINGS AND PRECAUTIONS (cont’d)

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.

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National Drug Codes (NDC) (cont’d)

Reporting the NDC on professional or institutional claims requires similar information and formats. The NDC unit of measure is determined by how a drug is supplied. In the outpatient setting, ML (milliliters) applies to drugs supplied in vials in liquid form. The NDC quantity reported is based on the NDC quantity dispensed. If the NDC unit of measure is ML, then the NDC quantity reported will equal the amount of mL given to the patient. Here is an example for a 1200 mg dose of DARZALEX®

<table>
<thead>
<tr>
<th>Dose to be Billed</th>
<th>NDC (11-digit)</th>
<th>Packaging</th>
<th>NDC Unit of Measure</th>
<th>NDC Units</th>
</tr>
</thead>
<tbody>
<tr>
<td>1200 mg</td>
<td>57894-0502-20</td>
<td>400 mg/20 mL vial (liquid)</td>
<td>ML</td>
<td>60</td>
</tr>
</tbody>
</table>

In this example the drug is supplied as a liquid in 400 mg/20 mL vials. One 400 mg/20 mL vial = 20 NDC units. The total dose to be billed is 1200 mg (3 vials, each containing 400 mg/20 mL = 60 mL) or 60 NDC units. The drug is packaged in liquid form so the NDC unit of measure is “ML.”

Accurate NDC coding* typically requires the following components:

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

Using the same 1200 mg DARZALEX® example, here is how this format would appear on a claim:

N4578940-502-20 ML 60

For professional claims (CMS-1500), report the NDC information in the shaded portion of Item 24.5 For institutional claims (CMS-1450), report the NDC information in Locator Box 43.6

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HCPCS Codes

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

- J9145 - Injection, daratumumab, 10 mg

Each 100 mg vial of drug represents 10 units of J9145, and each 400 mg vial represents 40 units. Inaccurate reporting of drug HCPCS units is a common claims error and can result in denied or delayed payment. When coding for J9145, report the total number of 10 mg increments administered. Table 9 illustrates the correlation between DARZALEX® vials, milligrams, and HCPCS units used for billing.

<table>
<thead>
<tr>
<th>Number of 100 mg vials of DARZALEX®</th>
<th>Total milligrams (mg)</th>
<th>Number of billing units based on J9145 (10 mg DARZALEX® per unit)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>100</td>
<td>10</td>
</tr>
<tr>
<td>2</td>
<td>200</td>
<td>20</td>
</tr>
<tr>
<td>3</td>
<td>300</td>
<td>30</td>
</tr>
</tbody>
</table>

Table 9: DARZALEX® HCPCS Billing Units

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WARNINGS AND PRECAUTIONS (cont’d)

Adverse Reactions – The most frequently reported adverse reactions (incidence ≥20%) were:

- infusion reactions
- neutropenia
- thrombocytopenia
- fatigue
- asthenia
- nausea
- diarrhea
- constipation
- decreased appetite
- vomiting
- muscle spasm
- arthralgia
- back pain
- pyrexia
- chills
- dizziness
- insomnia
- cough
- dyspnea
- peripheral edema
- peripheral sensory neuropathy
- bronchitis
- pneumonia
- and upper respiratory tract infection.

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CPT® Codes

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

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

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

These codes, often referred to as “complex” infusion codes, apply to the parenteral administration of chemotherapy and also anti-neoplastic agents provided for treatment of non-cancer diagnoses, or to substances such as certain monoclonal antibodies and other biologic response modifiers. Complex drug administration services require special considerations to prepare, dose, or dispose and typically entail professional skill and patient monitoring significantly beyond that required for therapeutic infusions.8

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

ICD-10-CM Diagnosis Codes

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

ICD-10-CM diagnosis codes use 3 to 7 alpha and numeric characters to achieve this level of detail. Codes with 3 characters are included in ICD-10-CM as the heading of a category of codes that may be further subdivided by use of additional characters to provide greater detail. A 3-character code is to be used only if it is not further subdivided. A code is invalid if it has not been coded to the full number of characters required for that code, including the 7th character, if applicable.9

<table>
<thead>
<tr>
<th>Table 10: Multiple Myeloma Diagnosis Codes* for Consideration</th>
</tr>
</thead>
<tbody>
<tr>
<td>ICD-10-CM Codes and Descriptors10</td>
</tr>
<tr>
<td>C90.00 Multiple myeloma not having achieved remission</td>
</tr>
<tr>
<td>C90.01 Multiple myeloma in remission</td>
</tr>
<tr>
<td>C90.02 Multiple myeloma in relapse</td>
</tr>
</tbody>
</table>

8These codes are not intended to be promotional or to encourage or suggest a use of drug that is inconsistent with FDA-approved use. The codes provided are not intended to be exhaustive and depending on the patient, additional codes may apply.

SELECT IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (cont’d)

Adverse Reactions (cont’d) – DARZALEX® in combination with lenalidomide and dexamethasone (DRd): The most frequent (≥20%) adverse reactions for newly diagnosed or relapsed/refractory patients were, respectively, infusion reactions (41%, 48%), diarrhea (57%, 43%), nausea (32%, 24%), fatigue (40%, 35%), pyrexia (23%, 20%), upper respiratory tract infection (52%, 65%), muscle spasms (29%, 26%), dyspnea (32%, 21%), and cough (30%, 30%). In newly diagnosed patients, constipation (41%), peripheral edema (41%), back pain (34%), anemia (32%), bronchitis (29%), pneumonia (26%), peripheral sensory neuropathy (24%), and decreased appetite (22%) were also reported. In newly diagnosed patients, serious adverse reactions (≥2% compared to Rd) were pneumonia (15%), bronchitis (4%), and dehydration (2%), and treatment-emergent Grade 3-4 hematology/laboratory abnormalities (≥20%) were neutropenia (56%), lymphopenia (52%), and leukopenia (35%). In relapsed/refractory patients, serious adverse reactions (≥2% compared to Rd) were pneumonia (12%), upper respiratory tract infection (7%), influenza (3%), and pyrexia (3%), and treatment-emergent Grade 3-4 hematology/laboratory abnormalities (≥20%) were neutropenia (53%) and lymphopenia (52%).

Please see Important Safety Information on pages 32-34 and click here to see full Prescribing Information.
OTHER CODING CONSIDERATIONS

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

Modifiers

Modifiers are used to report or indicate that a service or procedure has been altered by some specific circumstance, but not changed in its definition or code. They provide additional information about a service or procedure and help to eliminate the appearance of duplicate billing and unbundling. This could include using modifiers to designate a specific site of service, or to document an interrupted procedure, wasted product, same-day procedure, etc. Appropriately used, modifiers improve coding and reimbursement accuracy. Table 11 summarizes modifiers that may be applicable to the provision of DARZALEX® in physician offices and hospital outpatient departments.

SELECT IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (cont’d)

Adverse Reactions (cont’d) – DARZALEX® in combination with bortezomib, melphalan, and prednisone (DVMP): The most frequently reported adverse reactions (≥20%) were upper respiratory tract infection (48%), 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 hematology laboratory abnormalities (≥20%) were lymphopenia (58%), neutropenia (44%), and thrombocytopenia (38%). DARZALEX® in combination with bortezomib and dexamethasone (DVd): The most frequently reported adverse reactions (≥2%) 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 hematology laboratory abnormalities (≥20%) were lymphopenia (48%) and thrombocytopenia (47%).

DARZALEX® in combination with bortezomib, thalidomide, and dexamethasone (DVTd): The most frequent adverse reactions (≥20%) were infusion reactions (35%), nausea (30%), upper respiratory tract infection (27%), pyrexia (26%), and bronchitis (20%). Serious adverse reactions (≥2% compared to the VTd arm) were bronchitis (DVTd 2% vs VTd <1%) and pneumonia (DVTd 6% vs VTd 4%). Treatment-emergent Grade 3-4 hematology laboratory abnormalities (≥20%) were lymphopenia (59%), neutropenia (33%), and leukopenia (24%).

Table 11: Summary of Code Modifiers

<table>
<thead>
<tr>
<th>Modifier</th>
<th>Description</th>
<th>Indication and Placement</th>
<th>CMS-1500 Item 240</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*&lt;sup&gt;2&lt;/sup&gt; • Must be substantiated with relevant documentation*&lt;sup&gt;2&lt;/sup&gt; • Append the modifier to the relevant E/M code*&lt;sup&gt;2&lt;/sup&gt;</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*&lt;sup&gt;1&lt;/sup&gt; • 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*&lt;sup&gt;1&lt;/sup&gt;</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PN*</td>
<td>Nonexcepted service provided at an off-campus, outpatient, provider-based department of a hospital&lt;sup&gt;11&lt;/sup&gt;</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&lt;sup&gt;12&lt;/sup&gt;</td>
<td>N/A</td>
<td>Required by Medicare</td>
</tr>
<tr>
<td>PO&lt;sup&gt;‡&lt;/sup&gt;</td>
<td>Excepted services provided at an off-campus, outpatient provider-based department of a hospital&lt;sup&gt;11&lt;/sup&gt;</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&lt;sup&gt;12&lt;/sup&gt;</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&lt;sup&gt;13&lt;/sup&gt;</td>
<td>• Must be reported by providers that are NOT excepted&lt;sup&gt;13&lt;/sup&gt; from the 340B payment policy&lt;sup&gt;13&lt;/sup&gt; • To be reported on the same claim line as the drug HCPCS code for all 340B acquired drugs&lt;sup&gt;13&lt;/sup&gt;</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&lt;sup&gt;13&lt;/sup&gt;</td>
<td>• Must be reported by providers that ARE excepted&lt;sup&gt;13&lt;/sup&gt; from the 340B payment policy&lt;sup&gt;13&lt;/sup&gt; • To be reported on the same claim line as the drug HCPCS code for all 340B acquired drugs&lt;sup&gt;13&lt;/sup&gt;</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.”††<sup>11</sup>

†This policy does not apply to critical access hospitals (CAHs) or Maryland hospitals for 2019. The following provider types are excepted from the 340B payment policy: rural sole community hospitals, children’s hospitals, and PPS-exempt cancer hospitals.”<sup>13</sup>

Please see Important Safety Information on pages 32-34 and click here to see full Prescribing Information.
When a physician, hospital, or other provider or supplier must discard the remainder of a single-use vial or other single-use package after administering a dose/quantity of the drug or biological to a Medicare patient, the program provides payment for the amount of drug or biological discarded as well as the dose administered, up to the amount of the drug or biological as indicated on the vial or package label. Medicare contractors require the modifier JW to identify unused drugs or biologicals from single-use vials or single-use packages that are appropriately discarded. This modifier, billed on a separate claim line, supports payment for the amount of discarded drug or biological. For example, a single-use vial that is labeled to contain 100 units of a drug has 95 units administered to the patient and 5 units discarded. The 95 unit dose is billed on one line, while the discarded 5 units are billed on another line, accompanied by the JW modifier. Both line items will be processed for payment.

Providers must record the discarded amounts of drugs and biologicals in the patient’s medical record.

Summary
- Both the administered and discarded drug amounts should be clearly documented in the medical record
- Payment for discarded amounts of drug or 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

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 the 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 (eg, chemotherapy or non-chemotherapy drug infusion code) or a therapeutic or diagnostic injection code.¹⁴

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.”¹³ If the incremental amount of infusion time is 30 minutes or less, the time is not to be billed separately. Document infusion start and stop times in the medical record. Some payers may require reporting the actual number of minutes on claims. Time associated with interruptions in the infusion process (ie, when drug is not flowing, IV saline to keep a line open with no drug flowing) does not count toward billable infusion time.

Please see Important Safety Information on pages 32-34 and click here to see full Prescribing Information.
**Donated or Free-of-Charge Drug**

Medicare Part B covers drugs that are furnished incident to a physician’s service, provided the drugs are not usually self-administered by the patients who take them, and are reasonable and necessary for the diagnosis or treatment of the illness or injury per accepted standards of medical practice. To meet all the general requirements for coverage under the incident to provision, an FDA-approved drug or biological must be furnished by a physician and administered by the physician or by auxiliary personnel employed by the physician and under the physician’s personal supervision. The charge for the drug or biological must be included in the physician’s bill, and the cost of the drug or biological must represent an expense to the physician. Under certain circumstances, qualified patients may acquire donated or no-cost drug. When the drug was supplied without charge by a third party, it should NOT be billed to Medicare. However, the administration of the drug, regardless of the source, is a service that represents an expense to the physician. Therefore, administration of the drug is payable if the drug would have been covered if the physician purchased it.

When reporting drug administration services for patient-supplied drugs, it may be necessary to include drug information on the claim and enter “0.01” charges.

**Place of Service Codes**

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

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

Table 12 summarizes the potentially applicable place of service codes:

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

**SELECT IMPORTANT SAFETY INFORMATION**

**WARNINGS AND PRECAUTIONS (cont’d)**

**Adverse Reactions (cont’d) – DARZALEX® in combination with pomalidomide and dexamethasone (DPd):** The most frequent adverse reactions (>20%) were fatigue (50%), infusion reactions (50%), upper respiratory tract infection (50%), cough (43%), diarrhea (38%), constipation (33%), dyspnea (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% of patients included pneumonia (7%), treatment-emergent Grade 3-4 hematologic laboratory abnormalities (≥20%) were neutropenia (82%), lymphopenia (71%), and anemia (30%).
Physician Office Sample Claim Form: CMS-1500

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

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

C Item 24D - Indicate appropriate CPT®, HCPCS codes, and modifiers (if applicable). DARZALEX® J9145 – Injection, daratumumab, 10 mg

Infusion Services
96413 – Chemotherapy administration, intravenous infusion technique; up to 1 hour
96415 – Each additional hour

Payer requirements for drug administration coding may vary*

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

E Item 24G - Enter the units for items/services provided.
DARZALEX® - Enter number of HCPCS units based on dose administered (10 mg = 1 unit)

Infusion services
96413 – Enter 1 unit for the first hour of infusion
96415 – Enter number of units for additional hours based on the duration of the infusion

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

Infusion services
96413 – Enter 1 unit for the first hour of infusion
96415 – Enter the number of units for additional hours based on the duration

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

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

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

Please see Important Safety Information on pages 32-34 and click here to see full Prescribing Information.
Locator Box 42 - List revenue codes in ascending order.

Locator Box 43 - Enter narrative description for corresponding revenue code (e.g., IV therapy).

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

- DARZALEX®
  J9145 – Injection, daratumumab, 10 mg

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

Payer requirements for drug administration coding may vary.*

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

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

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

Split Dose Regimen

- DARZALEX® - The initial dose (16 mg/kg) is divided evenly over 2 consecutive days: Day 1 (8 mg/kg); Day 2 (8 mg/kg); enter the number of units based on the dose administered each day (10 mg = 1 unit).
  96413 – Enter 1 unit for the first hour of infusion
  96415 – Enter the number of units for additional hours based on the duration of the infusion. Although the DARZALEX® dose is the same on both days, the length of the infusion may vary.

Locator Box 47 - Indicate diagnosis using appropriate ICD-10-CM codes. Code to the highest level of specificity for the date of service and enter diagnoses in priority order.

Locator Box 50 - When submitting claims for the initial infusion as a split dose regimen, indicate that the initial dose is being delivered on 2 consecutive days. For example: Day 1 of 2, first dose of split dose regimen; Day 2 of 2, final dose of split dose regimen. Payer requirements may vary* and can include requests for additional documentation (e.g., Prescribing Information) to accompany the claim.

*Contact your local payer or Janssen CarePath at 877-CarePath (877-227-3728).
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® (daratumumab) 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.

Please see Important Safety Information on pages 32-34 and click here to see full Prescribing Information.
Therapy for Multiple Myeloma

Preferred Regimen for Primary Therapy for Non-Transplant Candidates*:
- Daratumumab | lenalidomide | dexamethasone (category 1†)

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

Other Recommended Regimens for Primary Therapy for Non-Transplant Candidates:
- Daratumumab | bortezomib | melphalan | prednisone (category 1†)

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

Useful in Certain Circumstances Regimen for Primary Therapy for Transplant Candidates§:
- Daratumumab | bortezomib | thalidomide | dexamethasone (category 2A‡)

*Regimens that contain daratumumab.
†See nccn.org for definitions of NCCN Categories of Preference.
‡Category 2A: Based upon lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate.
§When no other alternative is feasible.

Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Multiple Myeloma V2.2020. © National Comprehensive Cancer Network, Inc. 2019. All rights reserved. Accessed October 9, 2019. To view the most recent and complete version of the guideline, go online to www.nccn.org.

1Category 1: Based upon high-level evidence, there is uniform NCCN consensus that the intervention is appropriate.

SELECT IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (cont’d)

Adverse Reactions (cont’d) – DARZALEX® as monotherapy: The most frequently reported adverse reactions (≥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%).

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>Hospitals/All Other: 1-866-677-4844</td>
<td>1-614-652-7043</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://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>Multispecialty: 1-800-482-6700</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.

Please see Important Safety Information on pages 32-34 and click here to see full Prescribing Information.
APPENDIX

Sample Letter of Medical Necessity

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

REQUEST: Authorization for treatment with DARZALEX® (daratumumab)

Dear [Insert Name of Medical Director]:

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

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

Summary of Patient’s History
[Insert previous therapies/procedures, response to these interventions, description of patient’s recent symptoms/condition, summary of your professional opinion of the patient’s likelihood of disease progression without treatment with DARZALEX®. Note: Exercise your medical judgment and discretion when providing a diagnosis and characterization of the patient’s medical condition]

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

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

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

Sincerely,
[Insert Physician Name and Participating Provider Number]

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

Please see Important Safety Information on pages 32-34 and click here to see full Prescribing Information.

Sample Letter of Formulary Exception Request

[Insert Physician Letterhead]

[Insert Name of Medical Director] RE: [Member Name] [Member Number]

[Insert Payer Name] Member Number [Insert Member Number]

[Insert Address] Group Number [Insert Group Number]

[Insert City, State Zip]

REQUEST: Authorization for treatment with DARZALEX® (daratumumab)

DIAGNOSIS: [Insert Diagnosis][Insert ICD]

DOSE AND FREQUENCY: [Insert Dose & Frequency]

REQUEST TYPE: [Standard || Expedited]

Dear [Insert Name of Medical Director]:

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

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

Summary of Patient’s History
[Insert previous therapies/procedures, response to these interventions, description of patient’s recent symptoms/condition, summary of your professional opinion of the patient’s likelihood of disease progression without treatment with DARZALEX®. Note: Exercise your medical judgment and discretion when providing a diagnosis and characterization of the patient’s medical condition]

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

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

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

Sincerely,
[Insert Physician Name and Participating Provider Number]

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

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

**CONTRAINDICATIONS**

DARZALEX® (daratumumab) is contraindicated in patients with a history of severe hypersensitivity (e.g., 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 DARZALEX®. 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, antipyretics, and corticosteroids. Frequently monitor patients during the entire infusion. Interrupt infusion for reactions of any severity 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.

**Intolerance 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®.

**Neutropenia and Thrombocytopenia** – DARZALEX® may increase neutropenia and/or thrombocytopenia induced by background therapy. Monitor complete blood cell counts periodically during treatment according to the 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 and/or platelets. No dose reduction of DARZALEX® is recommended. Consider supportive care with growth factors for neutropenia or transfusions for thrombocytopenia.

**Intolerance 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.
IMPORTANT SAFETY INFORMATION (cont’d)

WARNINGS AND PRECAUTIONS (cont’d)

Adverse Reactions (cont’d)

DARZALEX® in combination with pomalidomide and dexamethasone (DPd): The most frequent adverse reactions (>20%) were fatigue (50%), infusion reactions (50%), upper respiratory tract infection (50%), cough (43%), diarrhea (38%), constipation (33%), dyspnea (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% of patients included pneumonia (7%), treatment-emergent Grade 3-4 hematology laboratory abnormalities (≥20%) were neutropenia (82%), lymphopenia (71%), and anemia (30%).

DARZALEX® as monotherapy: The most frequently reported adverse reactions (≥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%).

cp-60862v3

REFERENCES:


Please see Important Safety Information on pages 32-34 and click here to see full Prescribing Information.
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Janssen CarePath is your one source for access, affordability, and treatment support for your patients.

Janssen CarePath helps verify insurance coverage for your patients, provides reimbursement information, helps find financial assistance options for eligible patients, and provides ongoing support to help patients start and stay on DARZALEX®, which you prescribed.

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