For the treatment of adults with moderately to severely active Crohn’s disease who have failed or were intolerant to conventional therapy (but never failed treatment with a tumor necrosis factor [TNF] blocker) or have failed or were intolerant to treatment with one or more TNF blockers.

Selected Important Safety Information

STELARA® is an immunosuppressant and may increase the risk of infections, reactivation of latent infections, and malignancies. Serious adverse reactions have been reported in STELARA®-treated patients, including bacterial, fungal, and viral infections, malignancies, hypersensitivity reactions and one case of Reversible Posterior Leukoencephalopathy Syndrome (RPLS).

STELARA® should not be given to patients who have had clinically significant hypersensitivity to ustekinumab (or excipients) or patients with any clinically important active infection. Patients should be evaluated for tuberculosis prior to initiating treatment with STELARA®. Live vaccines should not be given to patients receiving STELARA®. If RPLS is suspected, discontinue STELARA®.

Please see related and other Important Safety Information on pages 28 to 30.
Crohn’s Disease Indication

STELARA® (ustekinumab) is indicated for the treatment of adult patients with moderately to severely active Crohn’s disease who have:

- failed or were intolerant to treatment with immunomodulators or corticosteroids, but never failed treatment with a tumor necrosis factor (TNF) blocker, or
- failed or were intolerant to treatment with one or more TNF blockers.

Reimbursement Support

Janssen Biotech, Inc., is committed to providing you and your office staff with detailed information to assist you in obtaining reimbursement for STELARA®. This Billing Guide has been developed to provide you with information regarding:

- Essential Coding Considerations
- Sample Claim Forms
- Important Product Information
- Reimbursement Support Resources

Information about STELARA® access and reimbursement support resources, for both providers and patients, is available through Janssen CarePath. Please call 877-CarePath (877-227-3728) to speak with a Janssen Care Coordinator about any reimbursement-related questions or concerns.

Disclaimer

This document is presented for informational purposes only and is not intended to provide reimbursement or legal advice.

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

* CPT® copyright 2017 American Medical Association. All rights reserved. CPT® is a registered trademark of the American Medical Association.
Intravenous (IV) Induction Dosage Regimen: A single IV infusion dose of STELARA® using a weight-based dosage regimen (see Table 1).

Subcutaneous (subQ) Maintenance Dosage Regimen: The recommended maintenance dosage is a subQ 90 mg dose administered 8 weeks after the initial IV dose, then every 8 weeks thereafter.

Preparation and Administration of STELARA®

130 mg/26 mL (5 mg/mL) Vial for IV Infusion

STELARA® solution for IV infusion must be diluted, prepared, and infused by a healthcare professional using aseptic technique.

1. Calculate the dose and number of STELARA® vials needed based on patient weight (Table 1). Each 26 mL vial of STELARA® contains 130 mg of ustekinumab.

2. Withdraw, and then discard, a volume of the 0.9% Sodium Chloride Injection, USP from the 250 mL infusion bag equal to the volume of STELARA® to be added (discard 26 mL sodium chloride for each vial of STELARA® needed: for 2 vials discard 52 mL, for 3 vials discard 78 mL, for 4 vials discard 104 mL).

3. Withdraw 26 mL of STELARA® from each vial needed and add it to the 250 mL infusion bag. The final volume in the infusion bag should be 250 mL. Gently mix.

4. Visually inspect the diluted solution before infusion. Do not use if visibly opaque particles, discoloration, or foreign particles are observed.

5. Infuse the diluted solution over a period of at least 1 hour. Once diluted, the infusion solution may be stored for up to 4 hours prior to infusion.

6. Use only an infusion set with an in-line, sterile, non-pyrogenic, low-protein-binding filter (pore size 0.2 micrometer).

7. Do not infuse STELARA® concomitantly in the same IV line with other agents.

8. STELARA® does not contain preservatives. Each vial is for single use only. Discard any remaining solution. Dispose any unused medicinal product in accordance with local requirements.

Table 1. Initial IV Dosage of STELARA®

<table>
<thead>
<tr>
<th>Body weight of patient at the time of dosing</th>
<th>Dose</th>
<th>Number of 130 mg/26 mL (5 mg/mL) STELARA® vials</th>
</tr>
</thead>
<tbody>
<tr>
<td>55 kg or less</td>
<td>260 mg</td>
<td>2</td>
</tr>
<tr>
<td>more than 55 kg to 85 kg</td>
<td>390 mg</td>
<td>3</td>
</tr>
<tr>
<td>more than 85 kg</td>
<td>520 mg</td>
<td>4</td>
</tr>
</tbody>
</table>

*Approximately 2.2 pounds per kilogram.
†Administered over at least 1 hour.

Please refer to the Dosage and Administration section of the Prescribing Information for complete information on how to prepare and administer STELARA®.

General Considerations for Administration of SubQ Injection

- STELARA® is intended for use under the guidance and supervision of a physician. STELARA® should only be administered to patients who will be closely monitored and have regular follow-up visits with a physician. The appropriate dose should be determined by a healthcare provider using the patient’s current weight at the time of dosing. If a physician determines that it is appropriate, a patient may self-inject or a caregiver may inject STELARA® after proper training in subcutaneous injection technique. Patients should be instructed to follow the directions provided in the Medication Guide.

- The needle cover on the prefilled syringe contains dry natural rubber (a derivative of latex). The needle cover should not be handled by persons sensitive to latex.

- It is recommended that each injection be administered at a different anatomic location (such as upper arms, gluteal regions, thighs, or any quadrant of abdomen) than the previous injection, and not into areas where the skin is tender, bruised, erythematous, or indurated. When using the single-dose vial, a 1 mL syringe with a 27 gauge, ½ inch needle is recommended.

Please see Important Safety Information on pages 28 to 30.
ICD-10-CM Diagnosis Codes

ICD-10-CM uses 3 to 7 alpha and numeric characters to achieve a high degree of detail when describing patient conditions. Although it is not necessary to use all 7 characters, coding to the highest level of specificity is required. Table 2 below lists possible ICD-10-CM diagnosis codes for Crohn’s disease that you may consider for patients treated with STELARA®.

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>K50</td>
<td>Crohn’s disease (regional enteritis)</td>
</tr>
<tr>
<td>K50.0</td>
<td>Crohn’s disease of small intestine</td>
</tr>
<tr>
<td>K50.00</td>
<td>Crohn’s disease of small intestine without complications</td>
</tr>
<tr>
<td>K50.01</td>
<td>Crohn’s disease of small intestine with complications</td>
</tr>
<tr>
<td>K50.1</td>
<td>Crohn’s disease of large intestine</td>
</tr>
<tr>
<td>K50.10</td>
<td>Crohn’s disease of large intestine without complications</td>
</tr>
<tr>
<td>K50.11</td>
<td>Crohn’s disease of large intestine with complications</td>
</tr>
<tr>
<td>K50.8</td>
<td>Crohn’s disease of both small and large intestine</td>
</tr>
<tr>
<td>K50.80</td>
<td>Crohn’s disease of both small and large intestine without complications</td>
</tr>
<tr>
<td>K50.81</td>
<td>Crohn’s disease of both small and large intestine with complications</td>
</tr>
<tr>
<td>K50.9</td>
<td>Crohn’s disease unspecified</td>
</tr>
<tr>
<td>K50.90</td>
<td>Crohn’s disease unspecified without complications</td>
</tr>
<tr>
<td>K50.91</td>
<td>Crohn’s disease unspecified with complications</td>
</tr>
</tbody>
</table>

*These codes are not intended to be promotional or to encourage or suggest a use of drug that is inconsistent with FDA-approved use. The codes provided are not intended to be exhaustive and may require a higher level of specificity when reporting for individual patients.

Please see Important Safety Information on pages 28 to 30.
CODING FOR STELARA® (IV USE)

The initial dose of STELARA® for Crohn's disease is delivered by IV infusion. This section of the Reimbursement Guide will provide coding and product information related to that service.

**National Drug Code (NDC)**

<table>
<thead>
<tr>
<th>10-digit NDC</th>
<th>11-digit NDC</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>57894-054-27</td>
<td>57894-0054-27</td>
<td>Single-use vial containing 130 mg (26 mL) of ustekinumab for IV infusion</td>
</tr>
</tbody>
</table>

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. In some cases, you may be required to include the NDC number on a claim form, especially when reporting an unclassified drug code. Payer requirements for NDC use and format may vary and should be verified with the payer.

**Healthcare Common Procedure Coding System (HCPCS) Codes**

Drugs are typically reported using permanent, product-specific HCPCS codes (ie, J codes) assigned by the Centers for Medicare & Medicaid Services (CMS). Effective January 1, 2018, the HCPCS code for STELARA® for intravenous use is:

J3358 - ustekinumab, for intravenous injection, 1 mg

This permanent code replaces all HCPCS codes previously used to describe STELARA® for intravenous use, including any miscellaneous or temporary codes. For claims with dates of service January 1, 2018 and beyond, J3358 is the only code that should be reported in both the physician office and hospital outpatient sites of care.

STELARA® for IV use should not be reported with J3357, the HCPCS code assigned to STELARA® for subQ use.

<table>
<thead>
<tr>
<th>Number of 130 mg/26 mL vials of ustekinumab</th>
<th>Dose (in milligrams)</th>
<th>HCPCS units J3358 (1 mg ustekinumab per unit)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>130</td>
<td>130</td>
</tr>
<tr>
<td>2</td>
<td>260</td>
<td>260</td>
</tr>
<tr>
<td>3</td>
<td>390</td>
<td>390</td>
</tr>
<tr>
<td>4</td>
<td>520</td>
<td>520</td>
</tr>
</tbody>
</table>

Each 1 mg dose of STELARA® is equal to one billing unit, thus a 130 mg vial of drug represents 130 units of J3358. When coding for J3358, report the total number of 1 mg increments administered. Table 4 illustrates the correlation between STELARA® vials, milligrams, and billing units.
SAMPLE CLAIM FORMS (IV USE)

Codes for Drug Administration

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 Current Procedural Terminology (CPT®) coding system. Consider using the following CPT® codes for reporting STELARA® infusion services:

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>96365</td>
<td>IV infusion for therapy, prophylaxis, or diagnosis; initial, up to 1 hour*</td>
</tr>
</tbody>
</table>

Please refer to accompanying Core 2018 Immunology Billing Guide for supplementary coding information:

- How to bill with NDCs – p. 6
- Using Place of Service Codes – p. 8
- Using Revenue Codes – p. 10
- Requirements for Therapeutic or Complex Drug Administration Codes – p. 11
- Using Modifiers – p. 12
- Same Day Evaluation and Management Services – p. 14
- Patient-Supplied Drugs – p. 15

Also available at https://www.stelarahcp.com/crohns-disease/resources

The Form CMS-1500 is the basic form prescribed by CMS for the Medicare and Medicaid programs for claims from suppliers and non-institutional providers that qualify for a waiver from the Administrative Simplification Compliance Act (ASCA) requirement for electronic submission of claims. It has also been adopted by the TRICARE Program. For detailed guidance on completing the CMS-1500 items, please see the Medicare Claims Processing Manual, Pub. 100-04, Chapter 26, available at:


The 837P (Professional) is the standard format used by healthcare professionals and suppliers to transmit healthcare claims electronically. The American National Standards Institute (ANSI) Accredited Standards Committee (ASC) X12N 837P (Professional) Version 5010A1 is the current electronic claim version.

Data elements in the CMS uniform electronic billing specifications are consistent with the hard copy data set to the extent that one processing system can handle both. For more information on submitting electronic claims, please see the CMS website at:


To view a crosswalk between the electronic and hard copy claim form, please see:


The Form CMS-1450, also known as the UB-04, is a uniform institutional provider bill suitable for use in billing multiple third-party payers. It is the basic form prescribed by CMS for the Medicare and Medicaid programs for claims from hospitals, including HOPDs. Because it serves many payers, a particular payer may not need some data elements. For detailed guidance on completing the CMS-1450 items, please see the Medicare Claims Processing Manual, Pub. 100-04, Chapter 25, available at:


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 Current Procedural Terminology (CPT®) coding system. Consider using the following CPT® codes for reporting STELARA® infusion services:

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>96365</td>
<td>IV infusion for therapy, prophylaxis, or diagnosis; initial, up to 1 hour*</td>
</tr>
</tbody>
</table>

Please refer to accompanying Core 2018 Immunology Billing Guide for supplementary coding information:

- How to bill with NDCs – p. 6
- Using Place of Service Codes – p. 8
- Using Revenue Codes – p. 10
- Requirements for Therapeutic or Complex Drug Administration Codes – p. 11
- Using Modifiers – p. 12
- Same Day Evaluation and Management Services – p. 14
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The Form CMS-1500 is the basic form prescribed by CMS for the Medicare and Medicaid programs for claims from suppliers and non-institutional providers that qualify for a waiver from the Administrative Simplification Compliance Act (ASCA) requirement for electronic submission of claims. It has also been adopted by the TRICARE Program. For detailed guidance on completing the CMS-1500 items, please see the Medicare Claims Processing Manual, Pub. 100-04, Chapter 26, available at:


The 837P (Professional) is the standard format used by healthcare professionals and suppliers to transmit healthcare claims electronically. The American National Standards Institute (ANSI) Accredited Standards Committee (ASC) X12N 837P (Professional) Version 5010A1 is the current electronic claim version.

Data elements in the CMS uniform electronic billing specifications are consistent with the hard copy data set to the extent that one processing system can handle both. For more information on submitting electronic claims, please see the CMS website at:


To view a crosswalk between the electronic and hard copy claim form, please see:


The Form CMS-1450, also known as the UB-04, is a uniform institutional provider bill suitable for use in billing multiple third-party payers. It is the basic form prescribed by CMS for the Medicare and Medicaid programs for claims from hospitals, including HOPDs. Because it serves many payers, a particular payer may not need some data elements. For detailed guidance on completing the CMS-1450 items, please see the Medicare Claims Processing Manual, Pub. 100-04, Chapter 25, available at:

**STELARA® for IV Use**  
2018 Physician Office Sample Claim Form: CMS-1500

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**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. The “ICD Indicator” identifies the ICD code set being reported. For ICD-10-CM diagnoses, enter 0 (zero) as a single digit between the vertical, dotted lines.

**Item 24A**—If line item NDC information is required, it will be entered in the shaded portion of Item 24A.

For more information on NDC coding, please see the 2018 Core Immunology Billing Guide p. 6. Payer requirements for NDC entries may vary.*

**Item 24D**—Indicate appropriate CPT® and HCPCS codes and modifiers, if required. STELARA® J3358 (Ustekinumab, for intravenous injection, 1 mg)  
NOTE: Do not report STELARA® for IV use with J3357.  
Infusion Services:  
CPT® 96365 (Intravenous infusion, for therapy, prophylaxis, or diagnosis; initial, up to 1 hour)

**Item 24E**—Refer to the diagnosis for this service (see Box 21). Enter only one diagnosis pointer per line.

**Item 24F**—Indicate total charges.

**Item 24G**—Enter the number of units:  
- J3358—Enter the amount of drug in HCPCS units according to dose;  
  - 1 mg = 1 unit, each STELARA 130 mg vial = 130 units  
- 96365—Enter 1 unit for the first hour of infusion

*Contact your local payer or Janssen CarePath at 877-CarePath (877-227-3728) to confirm payer requirements. For additional resources, visit Janssen CarePath online at: https://www.JanssenCarePath.com/hcp/stelara.
**STELARA® for IV Use**  
2018 HOPD Sample Claim Form: CMS-1450 (UB-04)

<table>
<thead>
<tr>
<th><strong>Locator Box 42</strong></th>
<th>List revenue codes in ascending order.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Locator Box 43</strong></td>
<td>Enter narrative description for corresponding revenue code (e.g., IV therapy, drug). If line item NDC information is required it will be entered in the unshaded portions of Locator Box 43. Payer requirements for NDC entries may vary.*</td>
</tr>
<tr>
<td><strong>Locator Box 44</strong></td>
<td>Indicate appropriate CPT®, HCPCS codes, and modifiers as required by the payer.</td>
</tr>
</tbody>
</table>
| **Locator Box 46** | Enter the number of units:  
• 96365—Enter 1 unit for the first hour of infusion  
• J3358—Enter the amount of drug in HCPCS units according to dose;  
  1 mg = 1 unit, each STELARA 130 mg vial = 130 units |
| **Locator Box 47** | Indicate charges. |
| **Locator Box 49** | Diagnoses may vary.* |

*Contact your local payer or Janssen CarePath at 877-CarePath (877-227-3728) to confirm payer requirements. For additional resources, visit Janssen CarePath online at: [https://www.JanssenCarePath.com/hcp/stelara](https://www.JanssenCarePath.com/hcp/stelara). For more information on relevant modifiers and their appropriate use, please refer to the Core 2018 Immunology Billing Guide, pp. 12-13.
CODING FOR STELARA® (SubQ USE)

The maintenance doses of STELARA® for Crohn’s disease are delivered by subQ injection. This section of the Reimbursement Guide will provide coding and product information related to that service.

NDC

<p>| Table 6. NDC: STELARA® for SubQ Use |</p>
<table>
<thead>
<tr>
<th>10-digit NDC</th>
<th>11-digit NDC</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>57894-061-03</td>
<td>57894-0061-03</td>
<td>90 mg prefilled syringe</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Single-use syringe containing 90 mg of ustekinumab for subQ injection</td>
</tr>
</tbody>
</table>

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. In some cases, you may be required to include the NDC number on a claim form, especially when reporting an unclassified drug code. Payer requirements for NDC use and format may vary and should be verified with the payer.

HCPCS Codes

The following HCPCS code may be used to describe STELARA® on claim forms submitted from either the physician office or hospital outpatient sites of care:

J3357 - ustekinumab, for subcutaneous injection, 1 mg

The HCPCS code for STELARA® (J3357) is described as: “Ustekinumab, for subcutaneous injection, 1 mg.” Thus each 1 mg dose is equal to one HCPCS billing unit. Table 9 illustrates the correlation between syringes, milligrams, and billing units.

Codes for Drug Administration

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. Consider using the following CPT® code for reporting STELARA® injection services:

Table 8. Potential CPT® Code for SubQ STELARA® Administration

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>96372</td>
<td>Therapeutic, prophylactic, or diagnostic injection; subQ or intramuscular</td>
</tr>
</tbody>
</table>
**CODING FOR STELARA® (SubQ USE) (cont’d)**

**Coding for Patient Self-injection Training**

After proper training in subQ injection technique, a patient may self-inject if a physician determines that it is appropriate. Patients should be instructed to follow the directions provided in the accompanying Medication Guide.

Under Medicare, self-injection training is not assigned a specific CPT® code but rather is considered part of Evaluation and Management (E/M) services. If the training is provided by a nurse, and not as part of a physician service, consider using CPT® code 99211 (office or other outpatient visit for the E/M of an established patient who may not require the presence of a physician). If other services are provided on the same day, certain restrictions may apply:

- MACs may not pay 2 E/M office visits billed by a physician (or physician of the same specialty from the same group practice) for the same beneficiary on the same day unless the physician documents that the visits were for unrelated problems that could not be provided during the same encounter (eg, an office visit for Crohn’s disease evaluation, followed 5 hours later by a visit for evaluation of leg pain following an accident).
- Medicare policy prohibits payment for CPT® code 99211, with or without modifier 25, if it is billed with a drug administration code. This means that 99211 cannot be billed on the same day as an injection of STELARA® (96372).

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**SAMPLE CLAIM FORMS (SubQ USE)**

The Form CMS-1500 is the basic form prescribed by CMS for the Medicare and Medicaid programs for claims from suppliers and non-institutional providers that qualify for a waiver from the Administrative Simplification Compliance Act (ASCA) requirement for electronic submission of claims. It has also been adopted by the TRICARE Program. For detailed guidance on completing the CMS-1500 items, please see the Medicare Claims Processing Manual, Pub. 100-04, Chapter 26, available at:


The 837P (Professional) is the standard format used by healthcare professionals and suppliers to transmit healthcare claims electronically. The American National Standards Institute (ANSI) Accredited Standards Committee (ASC) X12N 837P (Professional) Version 5010A1 is the current electronic claim version.

Data elements in the CMS uniform electronic billing specifications are consistent with the hard copy data set to the extent that one processing system can handle both. For more information on submitting electronic claims, please see the CMS website at:


To view a crosswalk between the electronic and hard copy claim form, please see:


The Form CMS-1450, also known as the UB-04, is a uniform institutional provider bill suitable for use in billing multiple third-party payers. It is the basic form prescribed by CMS for the Medicare and Medicaid programs for claims from hospitals, including HOPDs. Because it serves many payers, a particular payer may not need some data elements. For detailed guidance on completing the CMS-1450 items, please see the Medicare Claims Processing Manual, Pub. 100-04, Chapter 25, available at:


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Stelara (ustekinumab)
Item 19—Additional information is generally not required when reporting J3357 (Ustekinumab, for subcutaneous injection, 1 mg). Payer requirements for information and codes may vary.*

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. The “ICD Indicator” identifies the ICD code set being reported. For ICD-10-CM diagnoses, enter 0 (zero) as a single digit between the vertical, dotted lines.

Item 24A—If line item NDC information is required, it will be entered in the shaded portion of Item 24A. For more information on NDC coding, please see the 2018 Core Immunology Billing Guide p. 6. Payer requirements for NDC entries may vary.*

Item 24D—Indicate appropriate CPT® and HCPCS codes and modifiers, if required.

STELARA®
HCPCS code J3357 (Ustekinumab, for subcutaneous injection, 1 mg)
Injection
CPT® 96372 (Therapeutic, prophylactic, or diagnostic injection; subQ or intramuscular)

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

Item 24F—Indicate total charges.

Item 24G—Enter the number of units:
- 96372—Enter 1 unit for the injection
- J3357—Enter the amount of drug in HCPCS units; STELARA® 90 mg is equal to 90 units (1 mg = 1 unit)

*Contact your local payer or Janssen CarePath at 877-CarePath (877-227-3728) to confirm payer requirements.
For additional resources, visit Janssen CarePath online at: https://www.JanssenCarePath.com/hcp/stelara.
STELARA® for SubQ Use
2018 HOPD Sample Claim Form: CMS-1450 (UB-04)

Locator Box 42—List revenue codes in ascending order.

Locator Box 43—Enter narrative description for corresponding revenue code (eg, IV therapy, drug). If line item NDC information is required, it will be entered in the unshaded portions of Locator Box 43. Payer requirements for NDC entries may vary.*

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

STELARA®
HCPCS code J3357 (Ustekinumab, for subcutaneous injection, 1 mg)
Injection
CPT® 96372 (Therapeutic, prophylactic, or diagnostic injection; subQ or intramuscular)
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.*

Locator Box 46—Enter the number of units:
• 96372—Enter 1 unit for the injection
• J3357—Enter the amount of drug in HCPCS units; STELARA® 90 mg is equal to 90 units (1 mg=1 unit)

Locator Box 47—Indicate charges.

Locator Box 67—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. For ICD-10-CM diagnoses enter “0” in Locator Box 66.

Locator Box 80—Additional information is generally not required when reporting J3357 (Ustekinumab, for subcutaneous injection, 1 mg). Payer requirements for information and codes may vary.*

*Contact your local payer or Janssen CarePath at 877-CarePath (877-227-3728) to confirm payer requirements. For additional resources, visit Janssen CarePath online at: https://www.JanssenCarePath.com/hcp/stelara.
Janssen CarePath is your one source for resources focused on access, affordability, and treatment support for your patients. We’re committed to helping you get your patients started on STELARA® (ustekinumab), finding financial assistance options, and providing ongoing support to help them stay on STELARA® as prescribed.

Access Support to Help You Navigate Payer Processes
- Janssen CarePath helps verify insurance coverage for your patients and provides reimbursement information. Our offerings include:
  - Benefits investigations and insurance coverage information
  - Prior authorization support and status monitoring
  - Information on the exceptions and appeals process
  - Coding and billing information
  - Convenient, electronic Provider Portal for online benefits investigation and prior authorization support

Janssen CarePath Savings Program Can Help Patients Using Commercial Insurance With Their Out-of-Pocket Medication Costs for STELARA®
- Eligible patients pay just $5 for each dose with a $20,000 maximum program benefit per calendar year
- Program does not cover cost to give patients their treatment
- Patients using Medicare, Medicaid, or other government-funded programs to pay for their medications are not eligible to participate. See full eligibility requirements at Stelara.JanssenCarePathSavings.com

Janssen CarePath Can Help Your Patients With Information About Independent Resources for Affordability Support
- State-sponsored programs
- Medicare Savings Program
- Medicare Part D Extra Help—Low-Income Subsidy
- Independent foundations
Visit JanssenPrescriptionAssistance.com or call a Janssen CarePath Care Coordinator at 877-CarePath (877-227-3728).

Coverage For Your Patients
- STELARA® is available for more than 125 million commercial patients as a first-line biologic with open access through several national plans and PBMs*10

Support to Help Your Patients Start and Stay on Track
Nurse Navigators from Janssen CarePath help keep your patients on the path of Crohn’s disease treatment with a single point of contact by providing:
- Education on how STELARA® is administered for Crohn’s disease
- IV infusion center details and appointment reminders when they are getting started on STELARA®
- Partnering with Janssen CarePath Care Coordinators to help patients understand their insurance coverage
- Live self-injection training at no cost to continue maintenance therapy with confidence
- Consistent communication via phone, e-mail, and text message so patients know exactly what to expect

Janssen CarePath provides additional support to your patients, including:
- Treatment reminders
- Patient education and tools, including Internet resources
- Infusion site locator at 2infuse.com
- Safe Returns®—simple and safe used injection device disposal service at no cost for your patients

For more information or to reach a Janssen CarePath Care Coordinator, call 877-CarePath (877-227-3728) Monday to Friday, 8 am to 8 pm ET, or visit www.JanssenCarePath.com/hcp/Stelara.

*Including Cigna®, UnitedHealthcare®, UHC West®, OptumRx®, Aetna®, Anthem®, Express Scripts®, and Humana® (medical benefit only); as of November 22, 2017.

Please see Important Safety Information on pages 28 to 30.
Some payers and other formulary decision makers may require that treating physicians complete a Letter of Medical Necessity or Letter of Formulary Exception Request before patients can receive a specific therapy. We have provided a sample Letter of Medical Necessity and a sample Letter of Formulary Exception Request for your convenience.
Indication

STELARA® (ustekinumab) is indicated for the treatment of adult patients with moderately to severely active Crohn’s disease who have:

• failed or were intolerant to treatment with immunomodulators or corticosteroids, but never failed treatment with a tumor necrosis factor (TNF) blocker, or
• failed or were intolerant to treatment with one or more TNF blockers.

Important Safety Information

Infections

STELARA® (ustekinumab) may increase the risk of infections and reactivation of latent infections. Serious bacterial, fungal, and viral infections, some requiring hospitalization, were reported. In patients with psoriasis, serious infections included diverticulitis, cellulitis, pneumonia, appendicitis, cholecystitis, sepsis, osteomyelitis, viral infections, gastroenteritis and urinary tract infections. In patients with psoriatic arthritis, serious infections included cholecystitis. In patients with Crohn’s disease, serious or other clinically significant infections included anal abscess, gastroenteritis, ophthalmic herpes, pneumonia, and Listeria meningitis.

Treatment with STELARA® should not be initiated in patients with a clinically important active infection until the infection resolves or is adequately treated. Consider the risks and benefits of treatment prior to initiating use of STELARA® in patients with a chronic infection or a history of recurrent infection.

Instruct patients to seek medical advice if signs or symptoms suggestive of an infection occur while on treatment with STELARA® and consider discontinuing STELARA® for serious or clinically significant infections until the infection resolves or is adequately treated.

Theoretical Risk for Vulnerability to Particular Infections

Individuals genetically deficient in IL-12/IL-23 are particularly vulnerable to disseminated infections from mycobacteria, Salmonella, and Bacillus Calmette-Guerin (BCG) vaccinations. Serious infections and fatal outcomes have been reported in such patients. It is not known whether patients with pharmacologic blockade of IL-12/IL-23 from treatment with STELARA® may be susceptible to these types of infections. Appropriate diagnostic testing should be considered, e.g., tissue culture, stool culture, as dictated by clinical circumstances.

Pre-Treatment Evaluation of Tuberculosis (TB)

Evaluate patients for TB prior to initiating treatment with STELARA®. Do not administer STELARA® to patients with active tuberculosis infection. Initiate treatment of latent TB before administering STELARA®. Closely monitor patients receiving STELARA® for signs and symptoms of active TB during and after treatment.

Malignancies

STELARA® is an immunosuppressant and may increase the risk of malignancy. Malignancies were reported among patients who received STELARA® in clinical studies. The safety of STELARA® has not been evaluated in patients who have a history of malignancy or who have a known malignancy.

There have been reports of the rapid appearance of multiple cutaneous squamous cell carcinomas in patients receiving STELARA® who had risk factors for developing non-melanoma skin cancer (NMSC). All patients receiving STELARA®, especially those >60 years or those with a history of PUVA or prolonged immunosuppressant treatment, should be monitored for the appearance of NMSC.

Hypersensitivity Reactions

STELARA® is contraindicated in patients with clinically significant hypersensitivity to ustekinumab or excipients. Hypersensitivity reactions, including anaphylaxis and angioedema, have been reported with STELARA®. If an anaphylactic or other clinically significant hypersensitivity reaction occurs, institute appropriate therapy and discontinue STELARA®.

Reversible Posterior Leukoencephalopathy Syndrome (RPLS)

One case of reversible posterior leukoencephalopathy syndrome (RPLS) was observed in clinical studies of psoriasis and psoriatic arthritis. No cases of RPLS were observed in clinical studies of Crohn’s disease. If RPLS is suspected, administer appropriate treatment and discontinue STELARA®. RPLS is a neurological disorder, which is not caused by an infection or demyelination. RPLS can present with headache, seizures, confusion, and visual disturbances. RPLS has been associated with fatal outcomes.

Immunizations

Prior to initiating therapy with STELARA®, patients should receive all age-appropriate immunizations recommended by current guidelines. Patients being treated with STELARA® should not receive live vaccines. BCG vaccines should not be given during treatment or within one year of initiating or discontinuing STELARA®. Exercise caution when administering live vaccines to household contacts of STELARA® patients, as shedding and subsequent transmission to STELARA® patients may occur. Non-live vaccinations received during a course of STELARA® may not elicit an immune response sufficient to prevent disease.
**IMPORTANT SAFETY INFORMATION (cont’d)**

**Concomitant Therapies**

The safety of STELARA® in combination with other immunosuppressive agents or phototherapy was not evaluated in clinical studies of psoriasis. Ultraviolet-induced skin cancers developed earlier and more frequently in mice. In psoriasis studies, the relevance of findings in mouse models for malignancy risk in humans is unknown. In psoriatic arthritis studies, concomitant MTX use did not appear to influence the safety or efficacy of STELARA®. In Crohn's disease studies, concomitant use of 6-mercaptopurine, azathioprine, methotrexate and corticosteroids did not appear to influence the overall safety or efficacy of STELARA®.

**Allergen Immunotherapy**

STELARA® may decrease the protective effect of allergen immunotherapy (decrease tolerance) which may increase the risk of an allergic reaction to a dose of allergen immunotherapy. Therefore, caution should be exercised in patients receiving or who have received allergen immunotherapy, particularly for anaphylaxis.

**Most Common Adverse Reactions**

The most common adverse reactions (≥3% and higher than that with placebo) in adults from psoriasis clinical studies for STELARA® 45 mg, STELARA® 90 mg, or placebo were: nasopharyngitis (8%, 7%, 8%), upper respiratory tract infection (5%, 4%, 5%), headache (5%, 5%, 3%), and fatigue (3%, 3%, 2%), respectively. The safety profile in adolescents with plaque psoriasis through Week 60 was similar to that of adults with plaque psoriasis. In psoriatic psoriatic arthritis (PsA) studies, a higher incidence of arthralgia and nausea was observed in patients treated with STELARA® when compared with placebo (3% vs 1% for both). In Crohn's disease induction studies, common adverse reactions (3% or more of patients treated with STELARA® and higher than placebo) reported through Week 8 for STELARA® 6 mg/kg intravenous single infusion or placebo included: vomiting (4% vs 3%). In the Crohn's disease maintenance study, common adverse reactions (3% or more of patients treated with STELARA® and higher than placebo) reported through Week 44 were: nasopharyngitis (11% vs 8%), injection site erythema (5% vs 0%), vulvovaginal candidiasis/mycotic infection (5% vs 1%), bronchitis (5% vs 3%), pruritus (4% vs 2%), urinary tract infection (4% vs 2%) and sinusitis (3% vs 2%).

Please see accompanying full [Prescribing Information](#) and [Medication Guide](#) for STELARA®. Provide the [Medication Guide](#) to your patients and encourage discussion.
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Factors That Influence Coverage

Third-party payers (e.g., commercial insurers, Medicare, Medicaid) will generally cover parenteral drugs for their approved U.S. Food and Drug Administration indications, and the associated professional administration services (infusion or injection). However, benefits may vary depending upon the payer and the specific plan (“insurance product”) in which a patient is enrolled.

Medical Necessity

When third-party payers review infusible drug claims, they will first determine if the type of service provided is covered under their coverage policies. Next, payers will look for evidence supporting the medical necessity of therapy. This evidence may include:

- Information about the patient’s medical condition and history
- A physician’s statement or letter of medical necessity
- Supporting literature (e.g., peer-reviewed studies and compendia monographs)
- Prescribing information
- Availability of other treatment alternatives

Medical necessity refers to a decision by a health plan that a treatment, test, or procedure is necessary for health or to treat a diagnosed medical problem. Health insurance companies provide coverage only for health-related serves that they define or determine to be medically necessary. Medicare National Coverage Determinations (NCD) and Medicare Administrative Contractors (MAC) Local Coverage Determinations (LCD) define medical necessity requirements. These documents contain guidance on covered diagnoses, documentation requirements, and limitations of coverage for specific services in order to establish medical necessity.

Administrative Considerations

Other considerations may be involved in a payer’s decision to cover a product or service:

Does the payer's contract specifically preclude physician offices from billing for infusion services or infused drugs?
A small portion of payers have exclusive contracts with designated preferred providers for infusion services. This may include certain clinics or specialty pharmacies that deliver drugs to healthcare providers or other infusion centers.

Does the payer cover the therapy only when provided through a specific treatment site?
Payers may have site-specific coverage rules that restrict provision of infused therapies. For example, currently Medicare does not cover infusions when they are billed by Medicare-certified ambulatory surgery centers. Medicare and other payers also may restrict coverage for certain infused drugs in the home or hospital outpatient setting.

Is the billing provider a “participating” member of, or “in-network” provider for, that particular plan?
Payers contract with providers to deliver services to the plan’s members. Providers are thus “participating” within that plan’s network, requiring them to abide by the contract charge structure when providing care for that plan’s members.

Did the patient obtain the appropriate referral or prior authorization if required by their plan?
Many plans require that non-emergency services be pre-approved or that a primary care physician make the referral for specialty care. Failing to obtain appropriate referrals or pre-authorization can result in non-payment by the plan.
Coding for Drugs Provided in Physician Office and Hospital Outpatient Settings

This section reviews general coding guidelines for drugs billed by physician offices using the CMS-1500 claim form and hospital outpatient departments using the CMS-1450 (UB-04) claim form. Please note that 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. It is advisable to contact your local payer with regard to local payment policies.

ICD-10-CM Diagnosis Codes

All parties covered by 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 characters to achieve this level of detail. Although it is not necessary to use all 7 characters, coding to the highest level of specificity is required.

Healthcare Common Procedure Code System (HCPCS) Level II Codes

Medicare Administrative Contractors (MACs), many private payers, and most Medicaid agencies require healthcare providers to use HCPCS codes to identify drugs on claim forms in both the physician office setting and hospital outpatient departments. HCPCS codes have a five-character alphanumeric format. Established drugs are typically reported using product specific HCPCS codes beginning with the letter “J” followed by a 4-digit unique identifier. For new drugs, until a drug-specific code is assigned, a miscellaneous or “unclassified” code may be used (Table 1).

When billing HCPCS codes on the CMS-1500, enter the appropriate code in Item 24D. If billing with unclassified drug codes, report additional information in item 19. When billing HCPCS codes on the CMS-1450, enter the appropriate code in Locator Box 44. If reporting unclassified drug codes, include additional information in “remarks,” Locator Box 80.

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Descriptor</th>
<th>Site of Care</th>
<th>Payer</th>
</tr>
</thead>
<tbody>
<tr>
<td>J3490</td>
<td>Unclassified drug</td>
<td>Physician office</td>
<td>Medicare</td>
</tr>
<tr>
<td>J3590</td>
<td>Unclassified biologics</td>
<td>Physician office</td>
<td>Medicare</td>
</tr>
<tr>
<td>C9399*</td>
<td>Unclassified drugs or biologicals</td>
<td>Hospital outpatient department</td>
<td>Medicare</td>
</tr>
</tbody>
</table>

*Beginning on or after the date of FDA approval, hospitals may bill for the drug or biological using HCPCS code C9399. Non-Medicare payer coding requirements may vary.

When using unclassified codes, you will usually be required to submit additional information:
- drug name
- strength
- dose administered
- route of administration
- National Drug Code (NDC)

Some payers may require that you include the drug purchase invoice, prescribing information, documentation of medical necessity or other support for the claim. Because requirements may vary by payer, it is advisable to check local requirements before submitting claims using unclassified codes.

When billing HCPCS codes on the CMS-1500, enter the appropriate code in Item 24D. If billing with unclassified drug codes, report additional information in item 19. When billing HCPCS codes on the CMS-1450, enter the appropriate code in Locator Box 44. If reporting unclassified drug codes, include additional information in “remarks,” Locator Box 80.
HCPCS Units

HCPCS units are determined by the specific HCPCS descriptor for the J code assigned to the drug that is being coded. The descriptor is not necessarily the same as the package or therapeutic dose so the dose must be converted to billable HCPCS units to accurately complete a claim. Here is an example:

<table>
<thead>
<tr>
<th>Dose to Be Billed</th>
<th>Jxxxx HCPCS Descriptor</th>
<th>Packaging</th>
<th>HCPCS Units</th>
</tr>
</thead>
<tbody>
<tr>
<td>400 mg ABC drug</td>
<td>Injection, ABC drug, 10 mg</td>
<td>100-mg vial</td>
<td>40</td>
</tr>
</tbody>
</table>

In this example, the descriptor is 10 mg therefore one 100-mg vial equals 10 HCPCS units (10 x 10 mg). The total dose to be billed is 400 mg (40 x 10 mg), or 40 units. Unclassified codes are not drug-specific thus their descriptors do not include HCPCS units. Unclassified codes are always reported as 1 unit. Here is an example:

<table>
<thead>
<tr>
<th>Dose to Be Billed</th>
<th>J3590 HCPCS Descriptor</th>
<th>Packaging</th>
<th>HCPCS Units</th>
</tr>
</thead>
<tbody>
<tr>
<td>400 mg ABC drug</td>
<td>Unclassified biologics</td>
<td>100-mg vial</td>
<td>1</td>
</tr>
</tbody>
</table>

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 has typically been reserved for pharmacy billing, including drugs provided for home infusion. However, Medicaid fee-for-service programs and some private payers now also require the NDC for billing instead of, or in addition to, the HCPCS code, for physician claims and those of other service providers. Although the FDA uses a 10-digit format when registering NDCs, payers often require an 11-digit NDC format on claim forms. It is important to confirm with your payer which NDC format they require. To convert an NDC from the 5-3-2 format, add a leading zero in the middle sequence. Here is how the 10-digit NDC and 11-digit alternative NDC formats look:

- 10-Digit NDC format: XXXXX-XXX-XX (5-3-2)
- 11-Digit NDC format (used by most payers): XXXXX-0XXX-XX (5-4-2)

NDC Units°

The NDC unit of measure is determined by how the drug is supplied. In the outpatient setting, UN (unit) applies to drugs supplied in a vial in powder form, requiring reconstitution before administration, and ML (milliliters) applies to drugs supplied in vials in liquid form. NDC units dispensed are based on the packaging and numeric quantity administered to the patient. Here is an example:

<table>
<thead>
<tr>
<th>Dose to Be Billed</th>
<th>NDC (11-digit)</th>
<th>Packaging</th>
<th>Unit of Measure</th>
<th>NDC Units</th>
</tr>
</thead>
<tbody>
<tr>
<td>400 mg ABC drug</td>
<td>11111-0111-01</td>
<td>100-mg vial</td>
<td>UN (powder)</td>
<td>4</td>
</tr>
</tbody>
</table>

In this example the drug is supplied in 100-mg vials, in powder form for reconstitution. The NDC is specific to that packaging, thus one 100-mg vial equals 1 NDC unit. The total dose to be billed is 400 mg (400 divided by 100), or 4 NDC units. The drug is packaged in powder form so the unit of measure is “UN.” 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 (i.e., UN, ML)
- Reporting the number of NDC units dispensed
- Reporting the qualifier, N4, in front of the NDC

Using the same 400 mg example, here is how this format would appear:

N4111111-0111-01 UN4

Guidelines for reporting the NDC in the appropriate format, quantity, and unit of measure vary by state and by payer, and should be reviewed prior to submitting a claim.
Place of Service Codes

The Place of Service (POS) code set provides setting information necessary to appropriately pay professional service claims. The place of service 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 non-facility settings, therefore it is important to accurately designate the POS to assure appropriate payment. The physician practice location is considered “non-facility” (NF), allowing for the practice expenses to be included in the payment under the Physician Fee Schedule (PFS). When professional services are performed in a facility (e.g., hospital outpatient department) the practice does not incur the same expense (overhead, staff, equipment and supplies, etc.), thus, payment under the PFS is generally lower for facility-based services than for NF.

The physician practice setting is indicated with POS code 11. To differentiate between on-campus and off-campus provider-based departments, CMS recently 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>
<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. (Effective January 1, 2016)</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. (Description change effective January 1, 2016)</td>
</tr>
</tbody>
</table>
Revenue Codes

Many payers require use of American Hospital Association (AHA) revenue codes to bill for services provided in hospital outpatient departments. Revenue codes consist of a leading zero followed by three other digits and are used on claim forms to assign costs to broad categories of hospital revenue centers. Codes used for Medicare claims are available from Medicare contractors. The following revenue codes may be applicable to CMS-1450 claims for drugs and their administration:

- 0260  IV Therapy, General
- 0510  Clinic, General
- 0636  Pharmacy, drugs requiring detailed coding

Coding for Drug Administration Services in Physician Office and Hospital Outpatient Settings

This section reviews general coding guidelines for drug administration services coded by physician offices using the CMS-1500 claim form and by hospital outpatient departments using the CMS-1450 (UB-04) claim form. Please note that 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. It is advisable to contact your local payer with regard to local payment policies.


Current Procedural Terminology (CPT®) is a set of codes, descriptions, and guidelines intended to describe procedures and services performed by physicians and other healthcare professionals. CPT® is also used by other entities to report outpatient services.

Drug Administration Codes

Drug administration services are reported on claim forms in both the physician office and hospital outpatient settings using the CPT® code set. Services for the parenteral administration of drugs are classified as either Therapeutic, Prophylactic, and Diagnostic (“Therapeutic”) or Chemotherapy and Other Highly Complex Drug or Highly Complex Biologic Agent Administration (“Complex”) and include both intravenous infusions and injections.

Therapeutic Infusions and Injections

Therapeutic drug administration services typically require special considerations to prepare, dose or dispose of the drug/biological and necessitate special training and competency for the staff who administer them. These services generally require periodic patient assessment during and/or after the procedure. Therapeutic infusion and injection codes include, but are not limited to:

- 96365 - Intravenous infusion for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour
- 96366 - Intravenous infusion for therapy, prophylaxis, or diagnosis, each additional hour (list separately in addition to code for primary procedure)
- 96372 - Therapeutic, prophylactic or diagnostic injection (specify substance or drug); subcutaneous or intramuscular

Complex Infusions and Injections

Complex infusion and injection 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 also require special considerations to prepare, dose or dispose and typically entail professional skill and patient monitoring significantly beyond that required for therapeutic infusions. Complex infusion and injection codes include, but are not limited to:

- 96413 - Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug
- 96415 - Chemotherapy administration, intravenous technique, each additional hour (list separately in addition to code for primary procedure)
- 96401 - Chemotherapy administration, subcutaneous or intramuscular; non-hormonal, anti-neoplastic
- 96402 - Chemotherapy administration, subcutaneous or intramuscular; hormonal anti-neoplastic

Payer policies regarding the use of the therapeutic or complex codes may vary.
Partial Additional Hours of Infusion Time

CMS has a policy for reporting the add-on infusion codes when less than a full hour of service is provided. Providers may report the add-on infusion code for “each additional hour” only if the infusion interval is greater than 30 minutes beyond the 1 hour increment. For example, if the patient receives an infusion of a single drug that lasts 1 hour and 45 minutes, the provider would report the “initial” code up to 1 hour and the add-on code for the additional 45 minutes. If the incremental amount of infusion time is 30 minutes or less the time is not to be billed separately. Note that some payers may require reporting the actual number of minutes on the claim.

Other Coding Considerations for Drugs and Drug Administration Services in Physician Office and Hospital Outpatient Settings

HCPCS and CPT® Modifiers

Modifiers provide a means 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 add more information and help to eliminate the appearance of duplicate billing and unbundling. Appropriately used, modifiers increase coding and reimbursement accuracy. The following table summarizes modifiers that may be applicable to drug and drug administration coding in physician offices and hospital outpatient departments.

---

Table 3: Summary of Code Modifiers

<table>
<thead>
<tr>
<th>Modifier</th>
<th>Description</th>
<th>Indication and Placement</th>
<th>CMS-1500 (Item 24D)</th>
<th>CMS-1450 (Box 44)</th>
</tr>
</thead>
</table>
| 25       | Significant, separately identifiable evaluation and management (E/M) service by the same physician or other qualified health care professional on the same day of the procedure or other service | • Patient requires distinct E/M service in addition to the infusion procedure\(^6\)  
• Must be substantiated by documentation that supports the relevant criteria for the reported E/M code\(^6\)  
• Append the modifier to the appropriate E/M code\(^6\) | ✓ ✓ | ✓ ✓ |
| JW       | Drug amount discarded/not administered to any patient\(^1\)                  | • Required by Medicare beginning January 1, 2017\(^7\)  
• Applies only to the unused drug that is discarded after applicable dose has been administered from a single-use vial\(^8\)  
• Append the modifier to the drug code on a line separate from that reporting the administered dose\(^9\) | ✓ Required by Medicare | ✓ Required by Medicare |
| PO*      | Excepted services provided at an off-campus, outpatient provider-based department of a hospital\(^3\) | • 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\(^2\) | N/A | ✓ Required by Medicare |
| PN*      | Non-excepted service provided at an off-campus, outpatient, provider-based department of a hospital\(^3\) | • To be reported on each claim line for non-excepted services furnished in an off-campus provider-based department of a hospital and billed on an institutional claim\(^2\) | N/A | ✓ Required by Medicare |
| JG       | Drug or biological acquired with 340B Drug Pricing Program Discount\(^2\)   | • Beginning January 1, 2018, must be reported by providers that are NOT excepted\(^7\) from the 340B payment policy\(^7\)  
• To be reported on the same claim line as the drug HCPCS code for all 340B acquired drugs\(^7\) | N/A | ✓ Required by Medicare |
| TB       | Drug or biological acquired with 340B Drug Pricing Program Discount, reported for informational purposes\(^3\) | • Beginning January 1, 2018, must be reported by providers that ARE excepted\(^7\) from the 340B payment policy\(^7\)  
• To be reported on the same claim line as the drug HCPCS code for all 340B acquired drugs\(^7\) | N/A | ✓ Required by Medicare |

\(^{\text{*}}\) 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”\(^1\).

\(^{\text{†}}\) 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.\(^7\)
Same Day Evaluation and Management Services

It may be necessary to provide evaluation and management (E/M) services on the same
day as a drug administration procedure. Depending on the payer, E/M services that are
medically necessary, separate, and distinct from the drug administration procedure
(CPT® codes 99201-99205 and 99211-99215 in the physician office and HCPCS code G0463
in the hospital outpatient setting), and documented appropriately are generally covered.

CMS has a specific policy regarding use of CPT® code 99211 (level 1 medical visit for an
established patient) in the physician office:

For services furnished on or after January 1, 2004, do not allow payment for CPT® code
99211, with or without modifier 25, if it is billed with a non-chemotherapy drug infusion
code or a chemotherapy administration code. Apply this policy to code 99211 when it is
billed with a diagnostic or therapeutic injection code on or after January 1, 2005.14

This means that a level 1 medical visit for an established patient (99211) cannot be billed
on the same day as an office-based therapeutic or complex infusion or injection.

CMS Discarded Drug Policy11

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, local
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 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 is billed on another line by using 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.

JW Modifier Summary

• Payment for discarded amounts of drug/biological applies only to single-use vials
  or packages
• Multi-use vials are not subject to payment for discarded amounts
• Discarded amounts of drugs/biologicals must be recorded in the patient’s
  medical record
• Effective January 1, 2017, Medicare contractors require the JW modifier
• Other payer policies may vary

Patient-Supplied Drugs

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.15

Alternatively, payers, including Medicare Part D, may cover the drug under the patient’s
pharmacy benefit. Under this model, the drug may be directly obtained by the patient
and brought to the site of care for administration (“brown bagging”) or may be delivered
to the administering site via a specialty pharmacy channel (“white bagging”). Under
certain circumstances, qualified patients may acquire donated or no-cost drug. When
the drug is purchased by the beneficiary, or 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.16

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.17 Payer
policies may vary.