

STELARA® (ustekinumab) BILLING GUIDE

INDICATIONS

STELARA® (ustekinumab) is a human interleukin-12 and -23 antagonist indicated for the treatment of:

Adult patients with:

- **moderate to severe plaque psoriasis (Ps)** who are candidates for phototherapy or systemic therapy.
- **active psoriatic arthritis (PsA)**, alone or in combination with methotrexate.
- **moderately to severely active Crohn's disease (CD)** who have
 - failed or were intolerant to treatment with immunomodulators or corticosteroids, but never failed a tumor necrosis factor (TNF) blocker, or
 - failed or were intolerant to treatment with one or more TNF blockers.

Adolescent patients (12 years or older) with:

- **moderate to severe plaque psoriasis**, who are candidates for phototherapy or systemic therapy.

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, one case of Reversible Posterior Leukoencephalopathy Syndrome (RPLS), and noninfectious pneumonia.

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 51 and 52.



INTRODUCTION

Reimbursement Support

Janssen Biotech, Inc., is committed to providing you with detailed information to assist you in obtaining reimbursement for STELARA® (ustekinumab). 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

Third-party reimbursement is affected by many factors. This document and the information and assistance provided by Janssen CarePath are presented for informational purposes only. They do not constitute reimbursement or legal advice. Janssen CarePath does not promise or guarantee coverage, levels of reimbursement, or payment.

Similarly, all CPT* and Healthcare Common Procedure Code System (HCPCS) codes are supplied for informational purposes only and represent no statement, promise, or guarantee, expressed or implied, by Janssen or its third-party service providers that these codes will be appropriate or that reimbursement will be made. The fact that a drug, device, procedure, or service is assigned a HCPCS code and a payment rate does not imply coverage by the Medicare

program, but indicates only how the product, procedure, or service may be paid if covered by the Medicare program.

Laws, regulations, and policies concerning reimbursement are complex and are updated frequently. Accordingly, the information may not be current or comprehensive. Janssen and its third-party service providers strongly recommend you consult your payer for its most current coverage, reimbursement, and coding policies. Janssen and its third-party service providers make no representations or warranties, expressed or implied, as to the accuracy of the information provided. In no event shall the third-party service providers or Janssen, or their employees or agents, be liable for any damages resulting from or relating to any information provided by, or accessed to or through, Janssen CarePath. All HCPs and other users of this information agree that they accept responsibility for the use of this program.

*CPT® – Current Procedural Terminology. CPT® is a registered trademark of the American Medical Association, 2018.



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Please refer to the Dosage and Administration section of the [Prescribing Information](#) and to the [Instructions for Use](#) for complete information on how to prepare and administer STELARA®. Please see Important Safety Information [on pages 51 and 52](#).



AVAILABLE FORMULATIONS OF STELARA®

Single-dose vial for intravenous (IV) infusion*



*IV dose not approved for all indications.

DOSE: 130 mg/26 mL
(5 mg/mL) vial

Coding for single-dose vial for intravenous (IV) infusion is included in this billing guide.

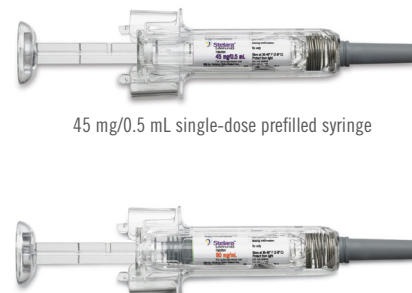
Single-dose vial for subcutaneous injection



DOSE: 45 mg/0.5 mL vial

Coding for single-dose vial for subcutaneous injection is included in this billing guide.

Single-dose prefilled syringe for subcutaneous injection



45 mg/0.5 mL single-dose prefilled syringe

90 mg/mL single-dose prefilled syringe

DOSE: 45 mg/0.5 mL
DOSE: 90 mg/mL

Coding for single-dose prefilled syringe for subcutaneous injection is **not** included in this billing guide.

Please refer to the Dosage and Administration section of the [Prescribing Information](#) and to the [Instructions for Use](#) for complete information on how to prepare and administer STELARA®.

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**FOR CROHN'S DISEASE—STELARA[®]
INTRAVENOUS (IV) USE**

INDUCTION



INDICATION AND USAGE¹

STELARA® is indicated for the treatment of adults with moderately to severely active Crohn's disease who have: 1) failed or were intolerant to treatment with immunomodulators or corticosteroids, but never failed a tumor necrosis factor (TNF) blocker, or 2) failed or were intolerant to treatment with one or more TNF blockers.¹

DOSING AND ADMINISTRATION¹

For the treatment of Crohn's disease STELARA® is administered in two phases: induction and maintenance. Table 1 summarizes the induction doses, provided as a single intravenous infusion.

INDUCTION

Intravenous (IV) Induction: A single IV infusion dose of STELARA® using a weight-based dosage regimen (see Table 1).

Table 1. Initial STELARA® (IV) Dosage¹

Indication	Patient Weight	Dose*	Number of 130 mg/26 mL (5 mg/mL) STELARA® Vials
Crohn's Disease	55 kg or less	260 mg	2 vials
	More than 55 kg to 85 kg	390 mg	3 vials
	More than 85 kg	520 mg	4 vials

Preparation and Administration of STELARA® 130 mg/26 mL (5 mg/mL) Vial for IV Infusion¹



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 of any unused medicinal product in accordance with local requirements.

*Administered over at least 1 hour.

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CODING

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) diagnosis 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 to 7 alpha and numeric digits to achieve this level of detail. Although it is not necessary to use all 7 digits, coding to the highest level of specificity is required. The table below lists possible ICD-10-CM diagnosis codes that you may consider for patients treated with STELARA®.

Table 2. ICD-10-CM Codes² for Consideration*

K50.00	Crohn's disease of small intestine without complications
K50.01	Crohn's disease of small intestine with complications
K50.10	Crohn's disease of large intestine without complications
K50.11	Crohn's disease of large intestine with complications
K50.80	Crohn's disease of both small and large intestine without complications
K50.81	Crohn's disease of both small and large intestine with complications
K50.90	Crohn's disease unspecified without complications
K50.91	Crohn's disease unspecified with complications

*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 exhaustive and additional codes may apply and listed codes may require a higher level of specificity when reporting for individual patients.

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CODING (cont'd)

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)

The National Drug Code 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, 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 in a 5-4-2 sequence. To convert the 10-digit format of STELARA® to the 11-digit format, insert a leading zero into the middle sequence, as illustrated below.

Table 3. NDC for STELARA® (IV)

10-Digit NDC	11-Digit NDC	Description
57894-054-27 ¹	57894-0054-27	130 mg vial Single-use vial containing 130 mg (26 mL) of ustekinumab for IV infusion

NDC Units³

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 liquid form. NDC units dispensed are based on the packaging and numeric quantity administered to the patient. Here is an example for a 390-mg dose of STELARA®:

Table 4. STELARA® (IV) NDC Units

Dose to Be Billed	NDC (11-Digit)	Packaging	NDC Unit of Measure	NDC Units
390 mg	57894-0054-27	130 mg/26 mL vial (liquid)	ML	78

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

EXAMPLE: coding format for 390-mg dose of STELARA® IV from single-dose vials:

N457894005427 ML78

Please refer to the Dosage and Administration section of the [Prescribing Information](#) and to the [Instructions for Use](#) for complete information on how to prepare and administer STELARA®.

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CODING (cont'd)

Healthcare Common Procedure Coding System (HCPCS) Level II Codes

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

Code	Description
J3358	Ustekinumab, for intravenous injection, 1 mg ⁴

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

Each 1-mg dose of STELARA® (IV) equals one billing unit, thus a 130-mg vial of drug represents 130 units of J3358. Inaccurate reporting of drug billing units is a common claims error and can result in denied or delayed payment. When coding for J3358, report the total number of 1-mg increments administered. Table 6 illustrates the correlation between STELARA® (IV) vials, milligrams, and HCPCS billing units.

Number of 130 mg/26 mL vials of ustekinumab	Dose (in milligrams)	HCPCS units J3358 (1 mg ustekinumab per unit)
1	130	130
2	260	260
3	390	390
4	520	520

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CODING FOR DRUG ADMINISTRATION

Codes for Drug Administration Services

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.

Codes for STELARA® Administration⁵

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. The CPT code most commonly required* for the administration of STELARA® (ustekinumab) (IV) is:

- **96365** - Intravenous infusion for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour⁵

This code, often referred to as a “therapeutic” infusion code, typically requires special considerations to prepare, dose, or dispose of the drug/biological and necessitates special training and competency for the administering staff. The services generally require periodic patient assessment during and/or after the procedure.⁵

Rarely payers may permit the use of CPT code:

- **96413** - Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug⁵

This code, often referred to as a “complex” infusion code, applies to the parenteral administration of chemotherapy and also antineoplastic 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.⁵

*Data on file. Six of the 8 Medicare Administrative Contractors (MACs) have published policies specifically requiring the use of CPT 96365 for STELARA® (IV) administration.

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OTHER CODING CONSIDERATIONS

Place of Service Codes⁶

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 "nonfacility" (NF), allowing for the practice expenses to be included in the payment under the PFS. When professional services are performed in a facility (eg, 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 created POS code 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 7 summarizes the potentially applicable POS codes.

Table 7. Place of Service Codes

POS Code	POS Name	POS Descriptor
11	Office	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.
19	Off Campus – Outpatient Hospital	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.
22	On Campus – Outpatient Hospital	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.

Revenue Codes⁷

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
- 0636 Pharmacy, drugs requiring detailed coding

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OTHER CODING CONSIDERATIONS (cont'd)

HCPCS and CPT® Modifiers

Code 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. Code modifiers add more information and help to eliminate the appearance of duplicate billing and unbundling. Appropriately used, modifiers increase coding and reimbursement accuracy. Table 8 summarizes modifiers that may be applicable to coding and billing STELARA® intravenous (IV) use in physician offices and hospital outpatient departments (HOPDs).

Table 8: Summary of Code Modifiers

Modifier	Description	Indication and Placement	CMS-1500 (Item 24D)	CMS-1450 (Box 44)
25	Significant, separately identifiable evaluation and management (E/M) service by the same physician or other qualified healthcare professional on the same day of the procedure or other service ⁵	<ul style="list-style-type: none"> • Patient requires distinct E/M service in addition to the infusion procedure⁵ • Must be substantiated by documentation that supports the relevant criteria for the reported E/M code⁵ • Append the modifier to the appropriate E/M code⁵ 	✓	✓
PO*	Excepted services provided at an off-campus, outpatient, provider-based department of a hospital ⁴	<ul style="list-style-type: none"> • 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 claim⁸ 	N/A	✓ Required by Medicare
PN*	Non-excepted service provided at an off-campus, outpatient, provider-based department of a hospital ⁴	<ul style="list-style-type: none"> • 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 claim⁸ 	N/A	✓ Required by Medicare
JG	Drug or biological acquired with 340B Drug Pricing Program Discount ⁴	<ul style="list-style-type: none"> • Must be reported by providers that are NOT excepted[†] from the 340B payment policy⁹ • To be reported on the same claim line as the drug HCPCS code for all 340B acquired drugs⁹ 	N/A	✓ Required by Medicare
TB	Drug or biological acquired with 340B Drug Pricing Program Discount, reported for informational purposes ⁴	<ul style="list-style-type: none"> • Must be reported by providers that ARE excepted[†] from the 340B payment policy⁹ • To be reported on the same claim line as the drug HCPCS code for all 340B acquired drugs⁹ 	N/A	✓ Required by Medicare

*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."⁸

[†]The 340B payment 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.⁹

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OTHER CODING CONSIDERATIONS (cont'd)

Same-Day Evaluation and Management (E/M) Services

It may be necessary to provide 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. The policy states:

For services furnished on or after January 1, 2004, do not allow payment for CPT® code 99211, with or without modifier 25, if it is billed with a nonchemotherapy drug infusion code or a chemotherapy administration code.¹⁰

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

Payer policies vary. Please check with your local payer or via Janssen CarePath at www.JanssenCarePath.com or **877-CarePath (877-227-3728)**.

Drugs Supplied at No Cost to the Provider

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.¹¹

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 or any other payers. 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.¹²

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.¹² Payer policies may vary.

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SAMPLE CLAIM FORMS

Physician Office Claims (CMS-1500)

The Form CMS-1500 is the basic form prescribed by CMS for the Medicare and Medicaid programs for claims from suppliers and noninstitutional 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:

<https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c26.pdf>

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. Medicare Administrative Contractors may include a crosswalk between the ASC X12N 837P and the CMS-1500 on their websites.

Hospital Outpatient Claims (CMS-1450)

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:

<https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c25.pdf>

The 837I (Institutional) is the standard format used by institutional providers to transmit healthcare claims electronically. The American National Standards Institute (ANSI) Accredited Standards Committee (ASC) X12N 837I (Institutional) Version 5010A2 is the current electronic claim version. Data elements in the uniform electronic billing specifications are consistent with the hard copy data set to the extent that one processing system can handle both. Medicare Administrative Contractors may include a crosswalk between the ASC X12N 837I and the CMS-1450 on their websites.

For more information on electronic claims, please see the CMS website at:

<https://www.cms.gov/medicare/billing/electronicbillingeditrans/healthcareclaims.html>

Please refer to the Dosage and Administration section of the [Prescribing Information](#) and to the [Instructions for Use](#) for complete information on how to prepare and administer STELARA®.


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SAMPLE CLAIM FORMS (cont'd)

STELARA® for IV Use
2019 Physician Office Sample Claim Form (CMS-1500): 390-mg IV Induction Dose



HEALTH INSURANCE CLAIM FORM

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

CARRIER

<input type="checkbox"/> PICA		<input type="checkbox"/> PICA	
1. MEDICARE <input checked="" type="checkbox"/> (Medicare#) MEDICAID <input type="checkbox"/> (Medicaid#) TRICARE <input type="checkbox"/> (ID#/DoD#) CHAMPVA <input type="checkbox"/> (Member ID#) GROUP HEALTH PLAN <input type="checkbox"/> (ID#) FECA BLK/LING <input type="checkbox"/> (ID#) OTHER <input type="checkbox"/> (ID#)		1a. INSURED'S I.D. NUMBER (For Program in Item 1) 000-00-1234	
2. PATIENT'S NAME (Last Name, First Name, Middle Initial) Doe, John B.		3. PATIENT'S BIRTH DATE SEX MM DD YY M <input checked="" type="checkbox"/> F <input type="checkbox"/> 07 04 50 M <input checked="" type="checkbox"/> F <input type="checkbox"/>	
4. INSURED'S NAME (Last Name, First Name, Middle Initial) Doe, John B.		5. PATIENT'S ADDRESS (No., Street) 3914 Spruce Street	
6. PATIENT RELATIONSHIP TO INSURED Self <input checked="" type="checkbox"/> Spouse <input type="checkbox"/> Child <input type="checkbox"/> Other <input type="checkbox"/>		7. INSURED'S ADDRESS (No., Street) 3914 Spruce Street	
8. RESERVED FOR NUCC USE		9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)	
10. IS PATIENT'S CONDITION RELATED TO: a. EMPLOYMENT? (Current or Previous) YES <input type="checkbox"/> NO <input type="checkbox"/> b. AUTO ACCIDENT? YES <input type="checkbox"/> NO <input type="checkbox"/> PLACE (State) _____ c. OTHER ACCIDENT? YES <input type="checkbox"/> NO <input type="checkbox"/>		11. INSURED'S POLICY GROUP OR FECA NUMBER	
12. PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE. I authorize the release of any medical or other information necessary to process this claim. I also request payment of government benefits either to myself or to the party who accepts assignment below. SIGNED _____ DATE _____		13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE. I authorize payment of medical benefits to the undersigned physician or supplier for services described below. SIGNED _____ DATE _____	
14. DATE OF CURRENT ILLNESS, INJURY, or PREGNANCY (LMP) MM DD YY QUAL. _____		15. OTHER DATE MM DD YY	
16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION FROM MM DD YY TO MM DD YY		17. NAME OF REFERRING PROVIDER OR OTHER SOURCE Dr. Jones	
18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES FROM MM DD YY TO MM DD YY		19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)	
20. OUTSIDE LAB? YES <input type="checkbox"/> NO <input type="checkbox"/> \$ CHARGES _____		21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E) ICD Ind. 0 A. K50.90 B. _____ C. _____ D. _____ E. _____ F. _____ G. _____ H. _____ I. _____ J. _____ K. _____ L. _____	
22. RESUBMISSION CODE ORIGINAL REF. NO.		23. _____ OR _____ NUMBER	
24. A. DATE(S) OF SERVICE From MM DD YY To MM DD YY B. PLACE OF SERVICE C. _____ D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCCPS E. DIAGNOSIS POINTER F. \$ CHARGES G. DAYS OR UNITS H. EFSOT (Family Plan) I. ID. QUAL. J. RENDERING PROVIDER ID.#		25. FEDERAL TAX I.D. NUMBER SSN EIN <input type="checkbox"/> <input type="checkbox"/>	
26. PATIENT'S ACCOUNT NO. 27. ACCEPT ASSIGNMENT? (For 99th claims, see back) YES <input type="checkbox"/> NO <input type="checkbox"/>		28. TOTAL CHARGE \$ _____ 29. AMOUNT PAID \$ _____ 30. Rsvd for NUCC Use	
31. SIGNATURE OF PHYSICIAN OR SUPPLIER INCLUDING DEGREES OR CREDENTIALS (I certify that the statements on the reverse apply to this bill and are made a part thereof). SIGNED _____ DATE _____		32. SERVICE FACILITY LOCATION INFORMATION a. _____ b. _____	
33. BILLING PROVIDER INFO & PH # (203) 555-6543 Dr. Jones 4231 Center Road Anytown, AS 01010		34. BILLING PROVIDER INFO & PH # a. 123 456 7890 b. _____	

NUCC Instruction Manual available at: www.nucc.org

PLEASE PRINT OR TYPE

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

Please refer to the Dosage and Administration section of the [Prescribing Information](#) and to the [Instructions for Use](#) for complete information on how to prepare and administer STELARA®. Please see Important Safety Information on pages 51 and 52.

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SAMPLE CLAIM FORMS (cont'd)

STELARA® for IV Use

2019 Physician Office Sample Claim Form (CMS-1500): 390-mg IV Induction Dose

- 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.
- Item 24A**—If line item NDC information is required, it will be entered in the shaded portion of Item 24A.⁶

24. A.	DATE(S) OF SERVICE						B. PLACE OF SERVICE	C. EMG	D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS MODIFIER	E. DIAGNOSIS POINTER	F. \$ CHARGES	G. DATE OR UNITS	H. ICD-10-CM QUAL.	J. RENDERING PROVIDER ID.#	OR SUPPLIER INFORMATION
	MM	DD	YY	MM	DD	YY									
1	01	01	19	01	01	19		J3358	A		390		NPI	123 456 7890	
2													NPI		
3													NPI		
4													NPI		

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>.

Please refer to the Dosage and Administration section of the [Prescribing Information](#) and to the [Instructions for Use](#) for complete information on how to prepare and administer STELARA®.

Please see Important Safety Information [on pages 51 and 52](#).

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SAMPLE CLAIM FORMS (cont'd)

STELARA® for IV Use
 2019 HOPD Sample Claim Form (CMS-1450/UB-04): 390-mg IV Induction Dose

1 Anytown Hospital 160 Main Street Anytown, Anystate 01010		2 Pay-to-name Pay-to-address Pay-to-city/state		3a PAT. CNTL # b. MED REC.# 5 FED. TAX NO.		XX-XXXX DOE 1234-97 010001010		4 TYPE OF BILL	
8 PATIENT NAME a John B. Doe (ID)		9 PATIENT ADDRESS a 3914 Spruce St.		c AS		d 01010		e US	
10 BIRTHDATE 07-04-50		11 SEX M		ADMISSION 13 HR 14 TYPE 15 SRC 16 DHR 17 STAT		CONDITION CODES 22 23 24 25 26 27 28		29 ACCT STATE 30	
31 OCCURRENCE CODE DATE		32 OCCURRENCE CODE DATE		33 OCCURRENCE CODE DATE		34 OCCURRENCE CODE DATE		35 OCCURRENCE SPAN FROM THROUGH	
36 OCCURRENCE SPAN FROM THROUGH		37 OCCURRENCE SPAN FROM THROUGH		38		39 VALUE CODES AMOUNT		40 VALUE CODES AMOUNT	
41 VALUE CODES AMOUNT		42 REV CD.		43 DESCRIPTION		44 HCPCS / RATE / HIPPS CODE		45 SERV DATE	
46 SERV UNITS		47 TOTAL CHARGES		48 NON-COVERED CHARGES		49			
1		2		3		4		5	
6		7		8		9		10	
11		12		13		14		15	
16		17		18		19		20	
21		22		23		24		25	
26		27		28		29		30	
31		32		33		34		35	
36		37		38		39		40	
41		42		43		44		45	
46		47		48		49		50	
51		52		53		54		55	
56		57		58		59		60	
61		62		63		64		65	
66		67		68		69		70	
71		72		73		74		75	
76		77		78		79		80	
81		82		83		84		85	
86		87		88		89		90	
91		92		93		94		95	
96		97		98		99		100	

6 K50.90

UB-04 CMS-1450 APPROVED OMB NO. 0938-0997 NUBC THE CERTIFICATIONS ON THE REVERSE APPLY TO THIS BILL AND ARE MADE A PART HEREOF.

Please refer to the Dosage and Administration section of the [Prescribing Information](#) and to the [Instructions for Use](#) for complete information on how to prepare and administer STELARA®.
 Please see Important Safety Information on [pages 51 and 52](#).

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SAMPLE CLAIM FORMS (cont'd)

STELARA® for IV Use

2019 HOPD Sample Claim Form (CMS-1450/UB-04): 390-mg IV Induction Dose

- 1 **Locator Box 42**—List revenue codes in ascending order.
- 2 **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 43.¹³ Payer requirements for NDC entries may vary.*

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

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)

NOTE: HCPCS modifiers must be reported by all off-campus hospital outpatient departments. The PO modifier is to be reported with every HCPCS code for all items and services furnished in an *excepted*, off-campus, provider-based department of a hospital. The PN modifier is to be reported on each claim line for all items and services furnished in a *nonexcepted*, off-campus, provider-based department of a hospital.⁸

NOTE: HCPCS modifiers must be reported for all 340B-acquired drugs. Providers who are not excepted from the 340B payment policy will report modifier JG. Providers who are excepted from the 340B payment policy will report modifier TB.⁹

- 4 **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

- 5 **Locator Box 47**—Indicate charges.

- 6 **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.

*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>.

Please refer to the Dosage and Administration section of the [Prescribing Information](#) and to the [Instructions for Use](#) for complete information on how to prepare and administer STELARA®.

Please see Important Safety Information [on pages 51 and 52](#).

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FOR CROHN'S DISEASE —
STELARA[®] SUBCUTANEOUS INJECTION
MAINTENANCE



INDICATION AND USAGE¹

STELARA® is indicated for the treatment of adults with moderately to severely active Crohn's disease who have: 1) failed or were intolerant to treatment with immunomodulators or corticosteroids, but never failed a tumor necrosis factor (TNF) blocker, or 2) failed or were intolerant to treatment with one or more TNF blockers.¹

DOSING AND ADMINISTRATION¹

MAINTENANCE

The maintenance doses of STELARA® for Crohn's disease are delivered by subcutaneous injection.

Maintenance Dosage Regimen: The recommended maintenance dosage is a subcutaneous 90-mg dose administered 8 weeks after the initial intravenous dose, then every 8 weeks thereafter.

Table 1. Maintenance STELARA® Dosage¹

Indication	Dose	Frequency
Crohn's Disease	90-mg	<ul style="list-style-type: none"> • 8 weeks after initial IV • Every 8 weeks thereafter

There are two available formulations for the maintenance dosage regimen, NOT to be used for intravenous induction therapy:

- 90-mg single-dose prefilled syringe
- 45-mg/0.5 mL single-use vial

This section of the Billing Guide will provide coding and product information related to the subcutaneous injection of the 45-mg single-dose vial only.



General Considerations for Administration of Subcutaneous Injection

STELARA® is intended for use under the guidance and supervision of a physician and should only be administered to patients who will be closely monitored and have regular follow-up visits with a physician. 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.

Preparation and Administration of STELARA®

Please refer to the Instructions for Use on how to prepare and administer 45 mg/0.5 mL single-dose vial for subcutaneous administration

- Each vial of STELARA® for subcutaneous use contains 45 mg of ustekinumab in 0.5 mL
- Draw required dose using the Instructions for Use

Please refer to the Dosage and Administration section of the [Prescribing Information](#) and to the [Instructions for Use](#) for complete information on how to prepare and administer STELARA®.

Please see Important Safety Information [on pages 51 and 52](#).

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DOSING AND ADMINISTRATION¹ (cont'd)

Preparation and Administration of STELARA® (cont'd)

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, 1/2-inch needle is recommended.

Prior to administration, visually inspect STELARA® for particulate matter and discoloration. STELARA® is a colorless to light yellow solution and may contain a few small translucent or white particles. Do not use STELARA® if it is discolored or cloudy, or if other particulate matter is present. STELARA® does not contain preservatives; therefore, discard any unused product remaining in the vial and/or syringe.

CODING

National Drug Code (NDC)

The National Drug Code 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, 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 in a 5-4-2 sequence. To convert the 10-digit format of STELARA® to the 11-digit format, insert a leading zero into the middle sequence, as illustrated below.

Table 2. STELARA® Single-Dose Vial for Subcutaneous Injection NDC

10-Digit NDC	11-Digit NDC	Description
57894-060-02 ¹	57894-0060-02	45-mg single-dose vial containing 45 mg of ustekinumab per 0.5 mL solution

NDC Units³

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 liquid form. NDC units dispensed are based on the packaging and numeric quantity administered to the patient. Here is an example for the 90-mg dose of STELARA®:

Table 3. STELARA® Single-Dose Vial for Subcutaneous Injection NDC

Dose to Be Billed	NDC (11-Digit)	NDC Unit of Measure	NDC Units
90 mg	57894-0060-02	45 mg/0.5 mL vial	ML
			1

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

EXAMPLE: coding format for 90-mg dose of STELARA® from single-dose vials:

N457894006002 ML1

Please refer to the Dosage and Administration section of the [Prescribing Information](#) and to the [Instructions for Use](#) for complete information on how to prepare and administer STELARA®.

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CODING (cont'd)

Healthcare Common Procedure Code System (HCPCS) Level II Codes

Drugs are typically reported using product-specific HCPCS codes (eg, J codes) assigned by the Centers for Medicare & Medicaid Services (CMS). The HCPCS code for STELARA® (ustekinumab) for subcutaneous use is:

Code	Description
J3357	Ustekinumab, subcutaneous injection, 1 mg⁴

Thus, each 1-mg dose of STELARA® equals one HCPCS billing unit. Inaccurate reporting of drug billing units is a common claims error and can result in denied or delayed payment. When coding for J3357, report the total number of 1-mg increments administered. Table 5 illustrates the correlation between STELARA® vials, milligrams, and HCPCS billing units.

Number of Vials	Total Dose in Milligrams (mg)	Number of HCPCS Billing Units Based on J3357 (1 mg STELARA® per Unit)
Two 45-mg vials	90 mg	90

CODING FOR DRUG ADMINISTRATION

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. The CPT® code most commonly associated with the administration of STELARA® subcutaneous injection is:

Code	Description
96372	Therapeutic, prophylactic, or diagnostic injection; subcutaneous injection or intramuscular⁴

Please refer to the Dosage and Administration section of the [Prescribing Information](#) and to the [Instructions for Use](#) for complete information on how to prepare and administer STELARA®.

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OTHER CODING CONSIDERATIONS

Place of Service Codes⁶

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 "nonfacility" (NF), allowing for the practice expenses to be included in the payment under the PFS. When professional services are performed in a facility (eg, 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 created POS code 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 7 summarizes the potentially applicable POS codes.

Table 7. Place of Service Codes

POS Code	POS Name	POS Descriptor
11	Office	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.
19	Off Campus – Outpatient Hospital	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.
22	On Campus – Outpatient Hospital	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.

Revenue Codes⁷

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:

- 0636 Pharmacy, drugs requiring detailed coding
- 0949 Other therapeutic services

*Data on file. Six of the 8 Medicare Administrative Contractors (MACs) have published policies specifically requiring the use of CPT 96365 for STELARA® (IV) administration.

Please refer to the Dosage and Administration section of the [Prescribing Information](#) and to the [Instructions for Use](#) for complete information on how to prepare and administer STELARA®.

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OTHER CODING CONSIDERATIONS (cont'd)

HCPCS and CPT® Modifiers

Code 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. Code modifiers add more information and help to eliminate the appearance of duplicate billing and unbundling. Appropriately used, modifiers increase coding and reimbursement accuracy. Table 8 summarizes modifiers that may be applicable to coding and billing STELARA® subcutaneous injection in physician offices and hospital outpatient departments (HOPDs).

Table 8. Summary of Code Modifiers

Modifier	Description	Indication and Placement	CMS-1500 (Item 24D)	CMS-1450 (Box 44)
25	Significant, separately identifiable evaluation and management (E/M) service by the same physician or other qualified healthcare professional on the same day of the procedure or other service ⁵	<ul style="list-style-type: none"> • Patient requires distinct E/M service in addition to the infusion procedure⁵ • Must be substantiated by documentation that supports the relevant criteria for the reported E/M code⁵ • Append the modifier to the appropriate E/M code⁵ 	✓	✓
PO*	Excepted services provided at an off-campus, outpatient provider-based department of a hospital ⁴	<ul style="list-style-type: none"> • 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 claim⁸ 	N/A	✓ Required by Medicare
PN*	Non-excepted service provided at an off-campus, outpatient, provider-based department of a hospital ⁴	<ul style="list-style-type: none"> • 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 claim⁸ 	N/A	✓ Required by Medicare
JG	Drug or biological acquired with 340B Drug Pricing Program Discount ⁴	<ul style="list-style-type: none"> • Must be reported by providers that are NOT excepted[†] from the 340B payment policy⁹ • To be reported on the same claim line as the drug HCPCS code for all 340B acquired drugs⁹ 	N/A	✓ Required by Medicare
TB	Drug or biological acquired with 340B Drug Pricing Program Discount, reported for informational purposes ⁴	<ul style="list-style-type: none"> • Must be reported by providers that ARE excepted[†] from the 340B payment policy⁹ • To be reported on the same claim line as the drug HCPCS code for all 340B acquired drugs⁹ 	N/A	✓ Required by Medicare

*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."⁸

[†]The 340B payment 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.⁹

Please refer to the Dosage and Administration section of the [Prescribing Information](#) and to the [Instructions for Use](#) for complete information on how to prepare and administer STELARA®.

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OTHER CODING CONSIDERATIONS (cont'd)

Same-Day Evaluation and Management (E/M) Services

It may be necessary to provide 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. The policy states:

For services furnished on or after January 1, 2005, do not allow payment for CPT® code 99211, with or without modifier 25, if it is billed with a diagnostic or therapeutic injection code.¹⁰

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

Drugs Supplied at No Cost to the Provider

Medicare Part B covers drugs that are furnished incident to a physician's service, provided that 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 according to 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.¹¹

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 or any other payers. 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.¹²

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.¹²

Payer policies vary. Please check with your local payer or via Janssen CarePath at www.JanssenCarePath.com or 877-CarePath (877-227-3728).

Please refer to the Dosage and Administration section of the [Prescribing Information](#) and to the [Instructions for Use](#) for complete information on how to prepare and administer STELARA®.

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SAMPLE CLAIM FORMS

STELARA® for Subcutaneous Injection

2019 Physician Office Sample Claim Form (CMS-1500): 90-mg Subcutaneous Injection Maintenance Dose



HEALTH INSURANCE CLAIM FORM

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

CARRIER

<input type="checkbox"/> PICA		<input type="checkbox"/> PICA	
1. MEDICARE <input checked="" type="checkbox"/> (Medicare#) MEDICAID <input type="checkbox"/> (Medicaid#) TRICARE <input type="checkbox"/> (ID#/DoD#) CHAMPVA <input type="checkbox"/> (Member ID#) GROUP HEALTH PLAN <input type="checkbox"/> (ID#) FECA BLK LUNG <input type="checkbox"/> (ID#) OTHER <input type="checkbox"/> (ID#)		1a. INSURED'S I.D. NUMBER (For Program in Item 1) 000-00-1234	
2. PATIENT'S NAME (Last Name, First Name, Middle Initial) Doe, John B.		3. PATIENT'S BIRTH DATE SEX MM DD YY M <input checked="" type="checkbox"/> F <input type="checkbox"/> 07 01 45 M	
4. INSURED'S NAME (Last Name, First Name, Middle Initial) Doe, John B.		5. PATIENT'S ADDRESS (No., Street) 3914 Spruce Street	
6. PATIENT RELATIONSHIP TO INSURED Self <input checked="" type="checkbox"/> Spouse <input type="checkbox"/> Child <input type="checkbox"/> Other <input type="checkbox"/>		7. INSURED'S ADDRESS (No., Street) 3914 Spruce Street	
8. RESERVED FOR NUCC USE		8. RESERVED FOR NUCC USE	
CITY STATE Anytown AS		CITY STATE Anytown AS	
ZIP CODE TELEPHONE (Include Area Code) 01010 (203) 555-1234		ZIP CODE TELEPHONE (Include Area Code) 01010 (203) 555-1234	
9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)		10. IS PATIENT'S CONDITION RELATED TO:	
a. OTHER INSURED'S POLICY OR GROUP NUMBER		a. EMPLOYMENT? (Current or Previous) <input type="checkbox"/> YES <input type="checkbox"/> NO	
b. RESERVED FOR NUCC USE		b. AUTO ACCIDENT? PLACE (State) <input type="checkbox"/> YES <input type="checkbox"/> NO	
c. RESERVED FOR NUCC USE		c. OTHER ACCIDENT? PLACE (State) <input type="checkbox"/> YES <input type="checkbox"/> NO	
d. INSURANCE PLAN NAME OR PROGRAM NAME Medicare		10d. CLAIM CODES (Designated by NUCC)	
12. PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE. I authorize the release of any medical or other information necessary to process this claim. I also request payment of government benefits either to myself or to the party who accepts assignment below. SIGNED _____ DATE _____		11. INSURED'S POLICY GROUP OR FECA NUMBER	
13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE. I authorize payment of medical benefits to the undersigned physician or supplier for services described below. SIGNED _____ DATE _____		d. IS THERE ANOTHER HEALTH BENEFIT PLAN? <input type="checkbox"/> YES <input type="checkbox"/> NO <i>If yes, complete items 9, 9a, and 9d.</i>	
14. DATE OF CURRENT ILLNESS, INJURY, or PREGNANCY (LMP) MM DD YY QUAL.		15. OTHER DATE MM DD YY QUAL.	
17. NAME OF REFERRING PROVIDER OR OTHER SOURCE Dr. Jones		17a. NPI 17b. NPI 123 456 7890	
19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)		20. OUTSIDE LAB? \$ CHARGES <input type="checkbox"/> YES <input type="checkbox"/> NO	
21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY. Relate A-L to service line below (24E) A. K50.90 B. _____ C. _____ D. _____ E. _____ F. _____ G. _____ H. _____ I. _____ J. _____ K. _____ L. _____		22. RESUBMISSION CODE ORIGINAL REF. NO.	
23. AUTHORIZ. NUMBER		23. AUTHORIZ. NUMBER	
24. A. DATE(S) OF SERVICE B. PLACE OF SERVICE C. EMG D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) E. DIAGNOSIS POINTER F. \$ CHARGES G. DAYS OR UNITS H. EPSDT (Family Plan) I. ID. QUAL. J. RENDERING PROVIDER ID.#		24. A. DATE(S) OF SERVICE B. PLACE OF SERVICE C. EMG D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) E. DIAGNOSIS POINTER F. \$ CHARGES G. DAYS OR UNITS H. EPSDT (Family Plan) I. ID. QUAL. J. RENDERING PROVIDER ID.#	
1 01 01 19 01 01 19 11 J3357 A 90 NPI 123 456 7890		1 01 01 19 01 01 19 11 J3357 A 90 NPI 123 456 7890	
2 01 01 19 01 01 19 11 96372 A 1 NPI 123 456 7890		2 01 01 19 01 01 19 11 96372 A 1 NPI 123 456 7890	
3		3	
4		4	
5		5	
6		6	
25. FEDERAL TAX I.D. NUMBER SSN EIN		26. PATIENT'S ACCOUNT NO.	
27. ACCEPT ASSIGNMENT? (For govt. claims, see back) <input type="checkbox"/> YES <input type="checkbox"/> NO		28. TOTAL CHARGE 29. AMOUNT PAID 30. Rsvd for NUCC Use	
31. SIGNATURE OF PHYSICIAN OR SUPPLIER INCLUDING DEGREES OR CREDENTIALS (If certify that the statements on the reverse apply to this bill and are made a part thereof.) SIGNED _____ DATE _____		32. SERVICE FACILITY LOCATION INFORMATION a. 123 456 7890 b. _____	
33. BILLING PROVIDER INFO & PH # (203) 555-6543 Dr. Jones 4231 Center Road Anytown, AS 01010		33. BILLING PROVIDER INFO & PH # (203) 555-6543 Dr. Jones 4231 Center Road Anytown, AS 01010	

NUCC Instruction Manual available at: www.nucc.org

PLEASE PRINT OR TYPE

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

PATIENT AND INSURED INFORMATION

PHYSICIAN OR SUPPLIER INFORMATION

Please refer to the Dosage and Administration section of the [Prescribing Information](#) and to the [Instructions for Use](#) for complete information on how to prepare and administer STELARA®.

Please see Important Safety Information on [pages 51 and 52](#).

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SAMPLE CLAIM FORMS (cont'd)

STELARA® (Subcutaneous Injection for Maintenance)

2019 Physician Office Sample Claim Form (CMS-1500): 90-mg Subcutaneous Injection Maintenance Dose

- 1 **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.
- 2 **Item 24D**—Indicate appropriate CPT® and HCPCS codes and modifiers, if required.

STELARA® (Subcutaneous Injection)

J3357 - Ustekinumab, subcutaneous injection, 1 mg

If line item NDC information is required, it will be entered in the shaded portion of Item 24A.⁶ For example:

24. A.	DATE(S) OF SERVICE						B. PLACE OF SERVICE	C. EMG	D. PROCEDURES, SERVICES, OR SUPPLIES		E. DIAGNOSIS POINTER	F. \$ CHARGES	G. DAYS OR UNITS	H. EPSONI Family Plan	I. ID. QUAL.	J. RENDERING PROVIDER ID. #	OF SUPPLIER INFORMATION
	From MM DD YY	To MM DD YY	ML1	CPT/HCPCS	MODIFIER												
1	01	01	19	01	01	19			J3357		A		90		NPI	123 456 7890	
2															NPI		
3															NPI		
4															NPI		

Payer requirements for NDC entries may vary.*

Drug Administration

96372 - Therapeutic, prophylactic, or diagnostic injection; subcutaneous or intramuscular

- 3 **Item 24E**—Refer to the diagnosis for this service (see box 21). Enter only one diagnosis pointer per line.
- 4 **Item 24F**—Indicate charges.
- 5 **Item 24G**—Enter the number of HCPCS units: STELARA® 1 mg = 1 unit; STELARA® 90 mg = 90 units.

*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>.

Please refer to the Dosage and Administration section of the [Prescribing Information](#) and to the [Instructions for Use](#) for complete information on how to prepare and administer STELARA®.

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SAMPLE CLAIM FORMS (cont'd)

STELARA® (Subcutaneous Injection for Maintenance) 2019 HOPD Sample Claim Form (CMS-1450/UB-04): 90-mg Subcutaneous Injection Maintenance Dose

1 Anytown Hospital 160 Main Street Anytown, Anystate 01010		2 Pay-to-name Pay-to-address Pay-to-city/state		3a PAT. CNTL. # b. MED. REC. # c. STATEMENT COVERS PERIOD FROM THROUGH		4 TYPE OF BILL	
8 PATIENT NAME a. John B. Doe (ID)		9 PATIENT ADDRESS a. 3914 Spruce St.		5 FED. TAX NO. 010001010		7	
10 BIRTHDATE 07-01-45		11 SEX M		12 DATE		13 HR	
14 TYPE		15 SRC		16 DHR		17 STAT	
18		19		20		21	
22		23		24		25	
26		27		28		29 ACDT STATE	
30		31		32		33	
34		35		36		37	
38		39		40		41	
42 REV. CD.		43 DESCRIPTION		44 HCPCS / RATE / HIPPS CODE		45 SERV. DATE	
46 SERV. UNITS		47 TOTAL CHARGES		48 NON-COVERED CHARGES		49	
0636		STELARA®		J3357		01-01-19 90	
0949		Other therapeutic services		96372		01-01-19 1	
PAGE		OF		CREATION DATE		TOTALS	
50 PAYER NAME Medicare		51 HEALTH PLAN ID		52 REL. INFO.		53 ARR. BEN.	
54 PRIOR PAYMENTS		55 EST. AMOUNT DUE		56 NPI		246 890 1234	
57 OTHER PRV ID		58 INSURED'S NAME		59 P. REL.		60 INSURED'S UNIQUE ID	
61 GROUP NAME		62 INSURANCE GROUP NO.		63 TREATMENT AUTHORIZATION CODES		64 DOCUMENT CONTROL NUMBER	
65 EMPLOYER NAME		66		67		68	
69 ADMIT DX K0.90		70 PATIENT REASON DX		71 PPS CODE		72 ECI	
73		74		75		76 ATTENDING NPI	
77 OPERATING NPI		78 OTHER NPI		79 OTHER NPI		80 REMARKS	
81		82		83		84	
85		86		87		88	

Please refer to the Dosage and Administration section of the [Prescribing Information](#) and to the [Instructions for Use](#) for complete information on how to prepare and administer STELARA®. Please see Important Safety Information on [pages 51 and 52](#).

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SAMPLE CLAIM FORMS (cont'd)

STELARA® Subcutaneous Injection

2019 HOPD Sample Claim Form (CMS-1450/UB-04): 90-mg Subcutaneous Injection Maintenance Dose

- 1 **Locator Box 42**—List revenue codes in ascending order.
- 2 **Locator Box 43**—Enter narrative description for corresponding revenue code. If line item NDC information is required it will be entered in the unshaded portions of Locator Box 43.¹³ Payer requirements for NDC entries may vary.
- 3 **Locator Box 44**—Indicate appropriate CPT® and HCPCS codes and modifiers as required by the payer.

STELARA® (Subcutaneous Injection)

J3357 - Ustekinumab, subcutaneous injection, 1 mg

Drug Administration

96372 - Therapeutic, prophylactic, or diagnostic injection; subcutaneous or intramuscular

NOTE: HCPCS modifiers must be reported by all off-campus hospital outpatient departments. The PO modifier is to be reported with every HCPCS code for all items and services furnished in an *excepted*, off-campus, provider-based department of a hospital. The PN modifier is to be reported on each claim line for all items and services furnished in a *nonexcepted*, off-campus, provider-based department of a hospital.⁸

NOTE: HCPCS modifiers must be reported for all 340B-acquired drugs. Providers who are not excepted from the 340B payment policy will report modifier JG. Providers who are excepted from the 340B payment policy will report modifier TB.⁹

- 4 **Locator Box 46**—Enter the number of HCPCS units: STELARA® 1 mg = 1 unit; STELARA® 90 mg = 90 units.
- 5 **Locator Box 47**—Indicate total charges.
- 6 **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.

Please refer to the Dosage and Administration section of the [Prescribing Information](#) and to the [Instructions for Use](#) for complete information on how to prepare and administer STELARA®.

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FOR PLAQUE PSORIASIS AND
PSORIATIC ARTHRITIS —
STELARA[®] 45-MG VIAL FOR
SUBCUTANEOUS INJECTION

 **Stelara**[®]
(ustekinumab)

INDICATIONS AND USAGE¹

STELARA® is indicated for the treatment of patients 12 years and older with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy. Additionally it is indicated for the treatment of adult patients with active psoriatic arthritis, alone or in combination with methotrexate.

DOSING AND ADMINISTRATION¹

STELARA® dosing is weight based. Induction and maintenance doses are administered by subcutaneous injection.

Table 1. STELARA® Subcutaneous Injection Dosage

Indication	Patient Weight	Induction	Maintenance	STELARA® Vials 45 mg/0.5 mL
Plaque Psoriasis <i>Adult</i>	100 kg or less	45 mg	45 mg at 4 weeks after initial dose then 45 mg every 12 weeks	1 vial
	More than 100 kg	90 mg	90 mg at 4 weeks after initial dose then 90 mg every 12 weeks	2 vials
Plaque Psoriasis <i>Adolescent</i>	Less than 60 kg	0.75 mg/kg	0.75 mg/kg at 4 weeks after initial dose then 0.75 mg/kg every 12 weeks	<1 vial*
	60 kg – 100 kg	45 mg	45 mg at 4 weeks after initial dose then 45 mg every 12 weeks	1 vial
	More than 100 kg	90 mg	90 mg at 4 weeks after initial dose then 90 mg every 12 weeks	2 vials
Psoriatic Arthritis	All adult patients (see exception below)	45 mg	45 mg at 4 weeks after initial dose then 45 mg every 12 weeks	1 vial
	Patients with co-existent moderate-to-severe plaque psoriasis weighing more than 100 kg	90 mg	90 mg at 4 weeks after initial dose then 90 mg every 12 weeks	2 vials

*Please refer to complete Prescribing Information, Table 2, "Injection volumes of STELARA® 45 mg/0.5 mL single-dose vials for adolescent psoriasis patients less than 60 kg" for correlation between weight, dose, and injection volume.

There are two available dosage forms for subcutaneous injection:

- 45-mg or 90-mg single-dose prefilled syringe
- 45-mg/0.5 mL single-use vial

This section of the Billing Guide will provide coding and product information related to the subcutaneous injection of the 45-mg single-dose vial only.



Preparation and Administration of STELARA® for Subcutaneous Injection

STELARA® is intended for use under the guidance and supervision of a physician and 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. Patients should be instructed to follow the directions provided in the Medication Guide. In adolescent patients, it is recommended that STELARA® be administered by a healthcare provider.

Please refer to the Dosage and Administration section of the [Prescribing Information](#) and to the [Instructions for Use](#) for complete information on how to prepare and administer STELARA®.

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DOSING AND ADMINISTRATION¹ (cont'd)

General Considerations for Healthcare Provider Administration of STELARA®

45 mg/0.5 mL single-dose vial for subcutaneous administration

- Each vial of STELARA® for subcutaneous use contains 45 mg of ustekinumab in 0.5 mL. Determine the dose and number of STELARA® vials needed based on the indication and patient weight
- Prior to administration, visually inspect STELARA® for particulate matter and discoloration. STELARA® is a colorless to light yellow solution and may contain a few small translucent or white particles. Do not use STELARA® if it is discolored or cloudy, or if other particulate matter is present. STELARA® does not contain preservatives; therefore, discard any unused product remaining in the vial
- Draw required dose using the Instructions for Use

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, 1/2-inch needle is recommended.

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. In adolescent patients, it is recommended that STELARA® be administered by a healthcare provider.

CODING

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) diagnosis 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 to 7 alpha and numeric digits to achieve this level of detail. Although it is not necessary to use all 7 digits, coding to the highest level of specificity is required. Table 2 below lists possible ICD-10-CM diagnosis codes that you may consider for patients treated with STELARA®.

Table 2. ICD-10-CM Codes² for Consideration*

Psoriatic Arthritis	
L40.50	Arthropathic psoriasis, unspecified
L40.59	Other psoriatic arthropathy
Psoriasis	
L40.0	Psoriasis vulgaris
L40.9	Psoriasis, unspecified

*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 exhaustive and additional codes may apply, and listed codes may require a higher level of specificity when reporting for individual patients.

Please refer to the Dosage and Administration section of the [Prescribing Information](#) and to the [Instructions for Use](#) for complete information on how to prepare and administer STELARA®.

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CODING (cont'd)

National Drug Code (NDC)

The National Drug Code 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, 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 in a 5-4-2 sequence. To convert the 10-digit format of STELARA® to the 11-digit format, insert a leading zero into the middle sequence, as illustrated below.

Table 3. STELARA® Single-Dose Vial for Subcutaneous Injection NDC

10-Digit NDC ¹	11-Digit NDC	Description
57894-060-02	57894-0060-02	45-mg vial Single-dose vial containing 45 mg of ustekinumab per 0.5 mL solution

NDC Units³

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 liquid form. NDC units dispensed are based on the packaging and numeric quantity administered to the patient. Here are examples for 45-mg and 90-mg doses of STELARA®:

Table 4. STELARA® Subcutaneous Injection NDC

Dose to Be Billed	NDC (11-Digit)	Packaging	NDC Unit of Measure	NDC Units
45 mg	57894-0060-02	45 mg/0.5 mL vial	ML	0.5
90 mg	57894-0060-02	45 mg/0.5 mL vial	ML	1

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

EXAMPLE: coding format for 45-mg dose of STELARA® from single-dose vials:

N457894006002 ML0.5

Payer requirements for NDC use and format may vary. Please contact your payers for specific coding policies and more information on correct billing and claims submission. For additional support, you may contact Janssen CarePath at <https://www.janssencarepath.com/hcp/stelara> or 877-CarePath (877-227-3728).

Please refer to the Dosage and Administration section of the [Prescribing Information](#) and to the [Instructions for Use](#) for complete information on how to prepare and administer STELARA®.

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CODING (cont'd)

Healthcare Common Procedure Code System (HCPCS) Level II Codes

Drugs are typically reported using product-specific HCPCS codes (eg, J codes) assigned by the Centers for Medicare & Medicaid Services (CMS). The HCPCS code for STELARA® (ustekinumab) for subcutaneous use is:

Table 5. HCPCS Code for STELARA®	
Code	Description
J3357	Ustekinumab, subcutaneous injection, 1 mg ⁴

Thus, each 1-mg dose of STELARA® equals one HCPCS billing unit. Inaccurate reporting of drug billing units is a common claims error and can result in denied or delayed payment. When coding for J3357, report the total number of 1-mg increments administered. Table 6 illustrates the correlation between STELARA® vials, milligrams, and HCPCS billing units.

Table 6. STELARA® for Subcutaneous Injection HCPCS Billing Units		
Number of Vials	Total Dose in Milligrams (mg)	Number of HCPCS Billing Units Based on J3357 (1 mg STELARA® per Unit)
One 45-mg vial	45 mg	45
Two 45-mg vials	90 mg	90

Coding for Drug Administration

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. The CPT® code most commonly associated with the administration of STELARA® subcutaneous injection is:

Table 7. Potential CPT® Code for STELARA® for Subcutaneous Injection	
Code	Description
96372	Therapeutic, prophylactic, or diagnostic injection; subcutaneous injection or intramuscular ⁵

Please refer to the Dosage and Administration section of the [Prescribing Information](#) and to the [Instructions for Use](#) for complete information on how to prepare and administer STELARA®.

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OTHER CODING CONSIDERATIONS

Place of Service Codes⁶

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 "nonfacility" (NF), allowing for the practice expenses to be included in the payment under the PFS. When professional services are performed in a facility (eg, 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 created POS code 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 8 summarizes the potentially applicable POS codes.

Table 8. Place of Service Codes

POS Code	POS Name	POS Descriptor
11	Office	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.
19	Off Campus – Outpatient Hospital	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.
22	On Campus – Outpatient Hospital	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.

Revenue Codes⁷

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:

- 0636 Pharmacy, drugs requiring detailed coding
- 0949 Other therapeutic services

Please refer to the Dosage and Administration section of the [Prescribing Information](#) and to the [Instructions for Use](#) for complete information on how to prepare and administer STELARA®.

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OTHER CODING CONSIDERATIONS (cont'd)

HCPCS and CPT® Modifiers

Code 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. Code modifiers add more information and help to eliminate the appearance of duplicate billing and unbundling. Appropriately used, modifiers increase coding and reimbursement accuracy. Table 9 summarizes modifiers that may be applicable to coding and billing STELARA® subcutaneous injection in physician offices and hospital outpatient departments (HOPDs).

Modifier	Description	Indication and Placement	CMS-1500 (Item 24D)	CMS-1450 (Box 44)
25	Significant, separately identifiable evaluation and management (E/M) service by the same physician or other qualified healthcare professional on the same day of the procedure or other service ⁵	<ul style="list-style-type: none"> • Patient requires distinct E/M service in addition to the infusion procedure⁵ • Must be substantiated by documentation that supports the relevant criteria for the reported E/M code⁵ • Append the modifier to the appropriate E/M code⁵ 	✓	✓
PO*	Excepted services provided at an off-campus, outpatient provider-based department of a hospital ⁴	<ul style="list-style-type: none"> • 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 claim⁸ 	N/A	✓ Required by Medicare
PN*	Non-excepted service provided at an off-campus, outpatient, provider-based department of a hospital ⁴	<ul style="list-style-type: none"> • 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 claim⁸ 	N/A	✓ Required by Medicare
JG	Drug or biological acquired with 340B Drug Pricing Program Discount ⁴	<ul style="list-style-type: none"> • Must be reported by providers that are NOT excepted[†] from the 340B payment policy⁹ • To be reported on the same claim line as the drug HCPCS code for all 340B acquired drugs⁹ 	N/A	✓ Required by Medicare
TB	Drug or biological acquired with 340B Drug Pricing Program Discount, reported for informational purposes ⁴	<ul style="list-style-type: none"> • Must be reported by providers that ARE excepted[†] from the 340B payment policy⁹ • To be reported on the same claim line as the drug HCPCS code for all 340B acquired drugs⁹ 	N/A	✓ Required by Medicare

*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."⁸

[†]The 340B payment 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.⁹

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OTHER CODING CONSIDERATIONS (cont'd)

Same-Day Evaluation and Management (E/M) Services

It may be necessary to provide 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. The policy states:

For services furnished on or after January 1, 2005, do not allow payment for CPT® code 99211, with or without modifier 25, if it is billed with a diagnostic or therapeutic injection code.¹⁰

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

Drugs Supplied at No Cost to the Provider

Medicare Part B covers drugs that are furnished incident to a physician's service, provided that 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 according to 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.¹¹

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 or any other payers. 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.¹²

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.¹²

Payer policies vary. Please check with your local payer or via Janssen CarePath at www.JanssenCarePath.com or 877-CarePath (877-227-3728).

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SAMPLE CLAIM FORMS

Physician Office Claims (CMS-1500)

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 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:

<https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c26.pdf>

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. Medicare Administrative Contractors may include a crosswalk between the ASC X12N 837P and the CMS-1500 on their websites.

Hospital Outpatient Claims (CMS-1450)

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:

<https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c25.pdf>

The 837I (Institutional) is the standard format used by institutional providers to transmit healthcare claims electronically. The American National Standards Institute (ANSI) Accredited Standards Committee (ASC) X12N 837I (Institutional) Version 5010A2 is the current electronic claim version. Data elements in the uniform electronic billing specifications are consistent with the hard copy data set to the extent that one processing system can handle both. Medicare Administrative Contractors may include a crosswalk between the ASC X12N 837I and the CMS-1450 on their websites.

For more information on electronic claims, please see the CMS website at:

<https://www.cms.gov/medicare/billing/electronicbillingeditrans/healthcareclaims.html>

Please refer to the Dosage and Administration section of the [Prescribing Information](#) and to the [Instructions for Use](#) for complete information on how to prepare and administer STELARA®.


Please see Important Safety Information [on pages 51 and 52](#).

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SAMPLE CLAIM FORMS (cont'd)

STELARA® for Subcutaneous Injection 2019 Physician Office Sample Claim Form: CMS-1500



HEALTH INSURANCE CLAIM FORM

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

CARRIER

<input type="checkbox"/> PICA		<input type="checkbox"/> PICA	
1. MEDICARE <input checked="" type="checkbox"/> (Medicare#) MEDICAID <input type="checkbox"/> (Medicaid#) TRICARE <input type="checkbox"/> (ID#/DoD#) CHAMPVA <input type="checkbox"/> (Member ID#) GROUP HEALTH PLAN <input type="checkbox"/> (ID#) FECA BLK LUNG <input type="checkbox"/> (ID#) OTHER <input type="checkbox"/> (ID#)		1a. INSURED'S I.D. NUMBER (For Program in Item 1) 000-00-1234	
2. PATIENT'S NAME (Last Name, First Name, Middle Initial) Doe, John B.		4. INSURED'S NAME (Last Name, First Name, Middle Initial) Doe, John B.	
5. PATIENT'S ADDRESS (No., Street) 3914 Spruce Street		7. INSURED'S ADDRESS (No., Street) 3914 Spruce Street	
CITY Anytown STATE AS		CITY Anytown STATE AS	
ZIP CODE 01010 TELEPHONE (Include Area Code) (203) 555-1234		ZIP CODE 01010 TELEPHONE (Include Area Code) (203) 555-1234	
9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)		11. INSURED'S POLICY GROUP OR FECA NUMBER	
a. OTHER INSURED'S POLICY OR GROUP NUMBER		a. INSURED'S DATE OF BIRTH MM DD YY SEX M <input type="checkbox"/> F <input type="checkbox"/>	
b. RESERVED FOR NUCC USE		b. OTHER CLAIM ID (Designated by NUCC)	
c. RESERVED FOR NUCC USE		c. INSURANCE PLAN NAME OR PROGRAM NAME	
d. INSURANCE PLAN NAME OR PROGRAM NAME Medicare		d. IS THERE ANOTHER HEALTH BENEFIT PLAN? <input type="checkbox"/> YES <input type="checkbox"/> NO <i>If yes, complete items 9, 9a, and 9d.</i>	
READ BACK OF FORM BEFORE COMPLETING & SIGNING THIS FORM.			
12. PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE I authorize the release of any medical or other information necessary to process this claim. I also request payment of government benefits either to myself or to the party who accepts assignment below. SIGNED _____ DATE _____		13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE I authorize payment of medical benefits to the undersigned physician or supplier for services described below. SIGNED _____	
14. DATE OF CURRENT ILLNESS, INJURY, or PREGNANCY (LMP) MM DD YY QUAL _____		15. OTHER DATE MM DD YY QUAL _____	
16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION FROM MM DD YY TO MM DD YY		17. NAME OF REFERRING PROVIDER OR OTHER SOURCE Dr. Jones	
18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES FROM MM DD YY TO MM DD YY		17a. NPI 123 456 7890	
19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)		20. OUTSIDE LAB? <input type="checkbox"/> YES <input type="checkbox"/> NO \$ CHARGES _____	
21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate ALE to service line below (24E) ICD Ind. 0		22. RESUBMISSION CODE ORIGINAL REF. NO.	
A. L40.50 B. _____ C. _____ D. _____ E. _____ F. _____ G. _____ H. _____ I. _____ J. _____ K. _____		23. PRIOR AUTHORIZATION NUMBER	
24. DATE(S) OF SERVICE From MM DD YY To MM DD YY PLACE OF SERVICE EMG		24. DATE(S) OF SERVICE OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS MODIFIER	
25. FEDERAL TAX I.D. NUMBER SSN EIN		26. PATIENT'S ACCOUNT NO.	
27. ACCEPT ASSIGNMENT? (For govt. claims, see back) <input type="checkbox"/> YES <input type="checkbox"/> NO		28. TOTAL CHARGE \$	
29. AMOUNT PAID \$		30. Rsvd for NUCC Use	
31. SIGNATURE OF PHYSICIAN OR SUPPLIER INCLUDING DEGREES OR CREDENTIALS (It certifies that the statements on the reverse apply to this bill and are made a part thereof.) SIGNED _____ DATE _____		32. SERVICE FACILITY LOCATION INFORMATION 33. BILLING PROVIDER INFO & PH # (203) 555-6543 Dr. Jones 4231 Center Road Anytown, AS 01010	
a. 123 456 7890 b. _____		a. 123 456 7890 b. _____	

NUCC Instruction Manual available at: www.nucc.org

PLEASE PRINT OR TYPE

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

Please refer to the Dosage and Administration section of the [Prescribing Information](#) and to the [Instructions for Use](#) for complete information on how to prepare and administer STELARA®.

Please see Important Safety Information on pages 51 and 52.

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SAMPLE CLAIM FORMS (cont'd)

STELARA® for Subcutaneous Injection 2019 Physician Office Sample Claim Form: CMS-1500

- 1 **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.
- 2 **Item 24D**—Indicate appropriate CPT® and HCPCS codes and modifiers, if required.

STELARA® Subcutaneous Injection

J3357 - Ustekinumab, subcutaneous injection, 1 mg

If line item NDC information is required, it will be entered in the shaded portion of Item 24A.⁶ For example:

24. A.	DATE(S) OF SERVICE						B. PLACE OF SERVICE	C. EMG	D. PROCEDURES, SERVICES, OR SUPPLIES		E. DIAGNOSIS POINTER	F. \$ CHARGES	G. DAYS OR UNITS	H. EPSDT (Family Plan)	I. ID. QUAL.	J. RENDERING PROVIDER ID. #	OR SUPPLIER INFORMATION	
	MM	DD	YY	MM	DD	YY			CPT/HCPCS	MODIFIER								
1	N457894006002 ML0.5								J3357		A		45			NPI	123 456 7890	
2															NPI			
3															NPI			
4															NPI			

Payer requirements for NDC entries may vary.*

Drug Administration

96372 - Therapeutic, prophylactic, or diagnostic injection; subcutaneous or intramuscular

- 3 **Item 24E**—Refer to the diagnosis for this service (see box 21). Enter only one diagnosis pointer per line.
- 4 **Item 24F**—Indicate charges.
- 5 **Item 24G**—Enter the number of HCPCS units: STELARA® 1 mg = 1 unit
STELARA® 45 mg = 45 units
STELARA® 90 mg = 90 units

*Contact your local payer or Janssen CarePath at 877-CarePath (877-227-3728) to confirm payer requirements. For additional resources, visit Janssen CarePath at <https://www.janssencarepath.com/hcp/stelara>.

Please refer to the Dosage and Administration section of the [Prescribing Information](#) and to the [Instructions for Use](#) for complete information on how to prepare and administer STELARA®.

Please see Important Safety Information [on pages 51 and 52](#).

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SAMPLE CLAIM FORMS (cont'd)

STELARA® for Subcutaneous Injection 2019 HOPD Sample Claim Form: CMS-1450 (UB-04)

1 Anytown Hospital 160 Main Street Anytown, Anystate 01010		2 Pay-to-name Pay-to-address Pay-to-city/state		3a PAT CNTL # b. MED REC # XX-XXXX DOE 1234-97		4 TYPE OF BILL	
5 FED TAX NO. 010001010		6 STATEMENT COVERS PERIOD FROM		7 THROUGH			
8 PATIENT NAME a. John B. Doe (ID)		9 PATIENT ADDRESS a. 3914 Spruce St.					
b. John B. Doe		b. Anytown,		c. AS		d. 01010	
e. US							
10 BIRTHDATE 07-01-45		11 SEX M		ADMISSION DATE 13 HR 14 TYPE 15 SRC 16 DHR		17 STAT	
18		19		20		21	
22		23		24		25	
26		27		28		29 ACCT STATE	
30		31 OCCURRENCE DATE		32 OCCURRENCE DATE		33 OCCURRENCE DATE	
34		35		36		37	
38		39 VALUE CODES AMOUNT		40 VALUE CODES AMOUNT		41 VALUE CODES AMOUNT	
42 REV. CD.		43 DESCRIPTION		44 HCPCS / RATE / HIPPS CODE		45 SERV. DATE	
46 SERV. UNITS		47 TOTAL CHARGES		48 NON-COVERED CHARGES		49	
0636		STELARA®		J3357		01-01-19 45	
0949		Other therapeutic services		96372		01-01-19 1	
PAGE		OF		CREATION DATE		TOTALS	
50 PAYER NAME Medicare		51 HEALTH PLAN ID		52 REL INFO		53 PRIOR PAYMENTS	
54 EST. AMOUNT DUE		55 NPI		56 NPI		246 890 1234	
57 OTHER PRV ID		58 INSURED'S NAME		59 P.REL		60 INSURED'S UNIQUE ID	
61 GROUP NAME		62 INSURANCE GROUP NO.		63 TREATMENT AUTHORIZATION CODES		64 DOCUMENT CONTROL NUMBER	
65 EMPLOYER NAME		66		67		68	
69 ADMIT DX		70 PATIENT REASON DX		71 PPS CODE		72 ECI	
73		74 PRINCIPAL PROCEDURE CODE		75		76 ATTENDING NPI	
77 OPERATING NPI		78 OTHER NPI		79 OTHER NPI		80 REMARKS	
81		82		83		84	
85		86		87		88	
89		90		91		92	
93		94		95		96	
97		98		99		00	

Please refer to the Dosage and Administration section of the [Prescribing Information](#) and to the [Instructions for Use](#) for complete information on how to prepare and administer STELARA®. Please see Important Safety Information on [pages 51 and 52](#).

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SAMPLE CLAIM FORMS (cont'd)

STELARA® Subcutaneous Injection 2019 HOPD Sample Claim Form: CMS-1450 (UB-04)

- 1 Locator Box 42**—List revenue codes in ascending order.
- 2 Locator Box 43**—Enter narrative description for corresponding revenue code. If line item NDC information is required it will be entered in the unshaded portions of Locator Box 43.¹³ Payer requirements for NDC entries may vary.
- 3 Locator Box 44**—Indicate appropriate CPT® and HCPCS codes and modifiers as required by the payer.

STELARA®**J3357** - Ustekinumab, subcutaneous injection, 1 mg**Drug Administration****96372** - Therapeutic, prophylactic, or diagnostic injection; subcutaneous or intramuscular

NOTE: HCPCS modifiers must be reported by all off-campus hospital outpatient departments. The PO modifier is to be reported with every HCPCS code for all items and services furnished in an *excepted*, off-campus, provider-based department of a hospital. The PN modifier is to be reported on each claim line for all items and services furnished in a *nonexcepted*, off-campus, provider-based department of a hospital.⁸

NOTE: HCPCS modifiers must be reported for all 340B-acquired drugs. Providers who are not excepted from the 340B payment policy will report modifier JG. Providers who are excepted from the 340B payment policy will report modifier TB.⁹

- 4 Locator Box 46**—Enter the number of HCPCS units: STELARA® 1 mg = 1 unit; STELARA® 45 mg = 45 units.
- 5 Locator Box 47**—Indicate total charges.
- 6 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.

Please refer to the Dosage and Administration section of the [Prescribing Information](#) and to the [Instructions for Use](#) for complete information on how to prepare and administer STELARA®.

Please see Important Safety Information [on pages 51 and 52](#).

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COVERAGE CONSIDERATIONS

Factors That Influence Coverage

Third-party payers (eg, commercial insurers, Medicare, Medicaid) will generally cover parenteral drugs for their approved U.S. Food and Drug Administration (FDA) indications and the associated professional administration services. 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 policies. Next, payers will look for evidence supporting the medical necessity of the 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 (eg, peer-reviewed studies and compendia monographs)
- Full 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 services that they define or determine to be medically necessary.

Medicare National Coverage Determinations (NCD) and Medicare Administrative Contractors (MACs) Local Coverage Determinations (LCDs) define medical necessity requirements for Medicare coverage. These documents contain guidance on covered diagnoses, required documentation, and limitations of coverage for specific services in accordance with 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 indicate the sites of care that may bill 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. 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” or within that plan’s network, requiring them to abide by the contract charge structure when providing care for that plan’s members.
- If required by the plan, has the appropriate referral or prior authorization been obtained? 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.

Please refer to the Dosage and Administration section of the [Prescribing Information](#) and to the [Instructions for Use](#) for complete information on how to prepare and administer STELARA®.

Please see Important Safety Information [on pages 51 and 52](#).

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COVERAGE CONSIDERATIONS (cont'd)

SUPPORTING APPROPRIATE PAYER COVERAGE DECISIONS

An essential component of successfully providing drug therapies is working with payers. Most payers will cover medically necessary drug therapies but may require clinical justification beyond a diagnosis to establish the patient's need and appropriateness for the therapy. Such requirements may be detailed in drug-specific policies, such as a Medicare Administrative Contractor's (MAC) Local Coverage Determination (LCD) or a commercial payer's medical benefit policy or addressed through a general prior authorization process.

Prior Authorization

Prior authorization (PA) is a payer-required approval process used to assure that certain drugs, services, procedures or sites of care are medically necessary and used appropriately. Although not applicable to Original Medicare, PA may be required by Medicare Advantage and non-Medicare payers. During the PA process providers are required to submit evidence of medical necessity which may include:

- the expected outcome of a prescribed therapy,
- potential consequences of not using that therapy, and
- why alternatives are not clinically appropriate.

An adequately supported and appropriately submitted PA will generally result in a favorable coverage decision. If for some reason a patient cannot meet a payer's requirements for the drug they need, they have the right to request a coverage determination, also known as requesting an exception.

Exception Request

An exception request is a specific type of coverage determination that asks a payer to reconsider a coverage denial or to deviate from standard process. It provides the payer an opportunity to influence, or make more patient-specific, a coverage decision-making process when the payer's coverage policies do not meet a patient's unique needs. An exception request again requires the prescriber to submit evidence of medical necessity. It is helpful to specifically respond to the reason(s) coverage was denied (e.g., drug not on formulary, dose restrictions, step therapy, etc.). An exception request that is appropriately submitted and adequately supported will often result in a favorable payer decision. If the request is not granted, the payer will provide the patient with a written explanation and include information about how to request an appeal.

Appeals

Appeals are a response to a payers' denial of benefits the enrollee believes they are entitled to receive. The appeals process typically includes a series of progressive steps and specific timelines. If supporting an appeal, contact the payer for guidance as individual policies may vary. Steps patients or providers can take to support an appeal include:

- submitting supporting evidence to counter the specific reason for the denial
- presenting the patient's story in a manner that leads to the therapeutic request (e.g., events leading to current condition, results of previous therapies, expected clinical progression, etc.)
- expressing willingness to collaborate (e.g., offer contact information, invite discussion with medical director or specialist, etc.)

Following a positive coverage decision at any stage, it is important to provide feedback to the payer and reinforce that their decision resulted in a positive patient outcome.

Please refer to the Dosage and Administration section of the [Prescribing Information](#) and to the [Instructions for Use](#) for complete information on how to prepare and administer STELARA®.

Please see Important Safety Information [on pages 51 and 52](#).

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Janssen CarePath is your one source for access, affordability, and treatment support for your patients



Access support to help navigate payer processes

Janssen CarePath helps verify insurance coverage for your patients taking STELARA® and provides reimbursement information.

Our electronic resources available at www.JanssenCarePathPortal.com include:

- eBenefits investigations
- ePrior authorization support and status monitoring
 - Payer-specific Prior Authorization (PA) forms delivered in Portal
- eCreation of medical necessity and exceptions letters
- eRequest for exceptions and appeals information
- Online coding and billing information
- Online Live Chat feature to answer questions
- Triage to specialty pharmacy providers, if needed

[Learn more](#)



Affordability support to help your patients start and stay on the Janssen treatment you prescribe

Janssen CarePath can help you find out what affordability assistance may be available for your patients taking STELARA®.

Support for patients using commercial or private insurance:

- **Janssen CarePath Savings Program** allows eligible patients to save on their out-of-pocket medication costs. Depending on the health insurance plan, savings may apply toward co-pay, co-insurance, or deductible.
 - Eligible patients **pay \$5 for each injection**, with a \$20,000 maximum program benefit per calendar year. For medication costs only; program does not cover cost to give patients their injection.
 - Not valid for patients using Medicare, Medicaid, or other government-funded programs to pay for their medications. Terms expire at the end of each calendar year and may change. There is no income requirement. The Savings Program for STELARA® provides a rebate when used with medical/primary insurance and provides instant savings when used with pharmacy/prescription insurance. See full eligibility requirements at Stelara.JanssenCarePathSavings.com.
- Online enrollment and tracking of patient Savings Program benefits by you, the pharmacy, or the patient.
 - Comprehensive Provider Portal at www.JanssenCarePathPortal.com allows you to enroll eligible patients in Savings Programs, view patients' available benefit and transactions as requested by the patient, and receive timely alerts and program updates.
 - Patients can manage Savings Program benefits and more on their Janssen CarePath Account at MyJanssenCarePath.com

Support for patients using government-funded healthcare programs or patients without insurance coverage:

- Janssen CarePath can provide information about other resources that may be able to help your patients with their out-of-pocket medication costs, including:
 - State Pharmaceutical Assistance Programs (SPAPs)
 - State Health Insurance Programs (SHIPs)
 - Medicare Savings Program
 - Medicare Part D Extra Help—Low-Income Subsidy
 - Independent Foundations*
- Call a Janssen CarePath Care Coordinator at 877-CarePath (877-227-3728) or visit JanssenPrescriptionAssistance.com for more information on affordability programs that may be available.

[Learn more](#)

*Independent co-pay assistance foundations have their own rules for eligibility. We have no control over these independent foundations and can only refer your patients to a foundation that supports their disease state. We do not endorse any particular foundation.

Please refer to the Dosage and Administration section of the [Prescribing Information](#) and to the [Instructions for Use](#) for complete information on how to prepare and administer STELARA®.

Please see Important Safety Information [on pages 51 and 52](#).

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Treatment support to help your patients get informed and stay on prescribed treatment

Janssen CarePath provides additional support to your patients taking STELARA®, including:

- Care coordination with treatment provider or pharmacy
- Treatment demonstration videos
- Nurse Support to answer patients' questions*
- Personalized treatment reminders
- Access to Care4Today® Connect mobile app
- Patient education and tools
- Infusion site locator at www.2infuse.com
- Safe Returns® – used injection device disposal service at no cost for your patients

[Learn more](#)

Patients can manage Savings Program benefits and more on their Janssen CarePath Account at MyJanssenCarePath.com

- Enroll in the Janssen CarePath Savings Program
- Manage Savings Program benefits
- Learn about their insurance coverage
- Sign up for treatment reminders



**Call a Janssen CarePath Care Coordinator at
877-CarePath (877-227-3728),
Monday-Friday, 8:00 AM to 8:00 PM ET
Multilingual phone support available.**



**Sign Up or Log In to the Provider Portal at
www.JanssenCarePathPortal.com**



Visit www.JanssenCarePath.com/hcp/Stelara

*Nurse Support is limited to education for patients about their Janssen therapy, its administration, and/or their disease. It is intended to supplement a patient's understanding of their therapy, and is not intended to provide medical advice, replace a treatment plan from the patient's doctor or nurse, provide case management services, or serve as a reason to prescribe.

Please refer to the Dosage and Administration section of the [Prescribing Information](#) and to the [Instructions for Use](#) for complete information on how to prepare and administer STELARA®.

Please see Important Safety Information [on pages 51 and 52](#).

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APPENDIX

Sample Letter of Medical Necessity

Some payers and other formulary decision makers may require that treating physicians complete a Letter of Medical Necessity before patients can receive a specific therapy. We have provided a sample Letter of Medical Necessity for your convenience.

[Insert Physician Letterhead]

[Insert Name of Medical Director] RE: Member Name: [Insert Member Name]
 [Insert Payer Name] Member Number: [Insert Member Number]
 [Insert Address] Group Number: [Insert Group Number]
 [Insert City, State Zip]

REQUEST: Authorization for treatment with STELARA® (ustekinumab)

DIAGNOSIS: [Insert Diagnosis] [Insert ICD]

DOSE AND FREQUENCY: [Insert Dose & Frequency]

REQUEST TYPE: Standard EXPEDITED

Dear [Insert Name of Medical Director]:

I am writing to support my request for an **authorization** for the above-mentioned patient to receive treatment with STELARA® for [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 those interventions, description of patient's recent symptoms/condition, summary of your professional opinion of the patient's likely prognosis or disease progression without treatment with STELARA®. Note: Exercise your medical judgement 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 uses of STELARA®, I believe treatment with STELARA® at this time is warranted, appropriate, and medically necessary, and should be a covered and reimbursed service. Include the full Prescribing Information for STELARA® and any peer reviewed journal articles or supporting clinical guidelines that provide additional clinical information to support the recommendation for STELARA® for this patient.]

[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]

If this request is denied, I am requesting an expedited Exception review by a professional in my specialty.

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

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Please refer to the Dosage and Administration section of the [Prescribing Information](#) and to the [Instructions for Use](#) for complete information on how to prepare and administer STELARA®.

Please see Important Safety Information [on pages 51 and 52](#).

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APPENDIX (cont'd)

Crohn's Disease Sample Format Exception Letter

[Insert Physician Letterhead]

[Insert Name of Medical Director] RE: Member Name: [Insert Member Name]
 [Insert Payer Name] Member Number: [Insert Member Number]
 [Insert Address] Group Number: [Insert Group Number]
 [Insert City, State Zip]

REQUEST: Authorization for treatment with STELARA® (ustekinumab)

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 STELARA® for Crohn's disease. The patient requires [an initial induction of] [insert appropriate dose 260 mg/390 mg/520 mg by infusion] [and] [90 mg injections for maintenance therapy.] 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 those interventions, description of patient's recent symptoms/condition, summary of your professional opinion of the patient's likely prognosis or disease progression without treatment with STELARA®. Note: Exercise your medical judgement 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 uses of STELARA®, I believe treatment with STELARA® at this time is medically necessary, and should be a covered and reimbursed service. You may consider including documents that provide additional clinical information to support the recommendation for STELARA® for this 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]

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Please refer to the Dosage and Administration section of the [Prescribing Information](#) and to the [Instructions for Use](#) for complete information on how to prepare and administer STELARA®.

Please see Important Safety Information [on pages 51 and 52](#).

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APPENDIX (cont'd)

PsA Sample Exception Format Letter

[Insert Physician Letterhead]

[Insert Name of Medical Director] RE: Member Name: [Insert Member Name]
 [Insert Payer Name] Member Number: [Insert Member Number]
 [Insert Address] Group Number: [Insert Group Number]
 [Insert City, State Zip]

REQUEST: Authorization for treatment with STELARA® (ustekinumab)

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 STELARA® [45 mg or 90 mg] for active psoriatic arthritis. 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 those interventions, description of patient's recent symptoms/condition, summary of your professional opinion of the patient's likely prognosis or disease progression without treatment with STELARA®. Note: Exercise your medical judgement 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 uses of STELARA®, I believe treatment with STELARA® at this time is warranted, appropriate, and medically necessary, and should be a covered and reimbursed service. Include the full Prescribing Information for STELARA® and any peer reviewed journal articles or supporting clinical guidelines that provide additional clinical information to support the recommendation for STELARA® for this patient.]

[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]

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Please refer to the Dosage and Administration section of the [Prescribing Information](#) and to the [Instructions for Use](#) for complete information on how to prepare and administer STELARA®.

Please see Important Safety Information [on pages 51 and 52](#).

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APPENDIX (cont'd)

Psoriasis Sample Format Exception Letter

[Insert Physician Letterhead]

[Insert Name of Medical Director] RE: Member Name: [Insert Member Name]
 [Insert Payer Name] Member Number: [Insert Member Number]
 [Insert Address] Group Number: [Insert Group Number]
 [Insert City, State Zip]

REQUEST: Authorization for treatment with STELARA® (ustekinumab)

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 STELARA® [0.75 mg/kg, 45 mg, or 90 mg] for moderate to severe plaque psoriasis. 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 those interventions, description of patient's recent symptoms/condition, summary of your professional opinion of the patient's likely prognosis or disease progression without treatment with STELARA®. Note: Exercise your medical judgement 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 uses of STELARA®, I believe treatment with STELARA® at this time is warranted, appropriate, and medically necessary, and should be a covered and reimbursed service. Include the full Prescribing Information for STELARA® and any peer reviewed journal articles or supporting clinical guidelines that provide additional clinical information to support the recommendation for STELARA® for this patient.]

[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]

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IMPORTANT SAFETY INFORMATION

Indications

STELARA® (ustekinumab) is indicated for the treatment of adult patients with active psoriatic arthritis. STELARA® can be used alone or in combination with methotrexate (MTX).

STELARA® (ustekinumab) is indicated for the treatment of patients 12 years or older with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy.

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.



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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®.

Noninfectious Pneumonia

Cases of interstitial pneumonia, eosinophilic pneumonia, and cryptogenic organizing pneumonia have been reported during post-approval use of STELARA®. Clinical presentations included cough, dyspnea, and interstitial infiltrates following one to three doses. Serious outcomes have included respiratory failure and prolonged hospitalization. Patients improved with discontinuation of therapy and, in certain cases, administration of corticosteroids. If diagnosis is confirmed, discontinue STELARA® and institute appropriate treatment.

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 ($\geq 3\%$ 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 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 full [Prescribing Information](#) and [Medication Guide](#) for STELARA®. Provide the [Medication Guide](#) to your patients and encourage discussion.

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