

STELARA[®] (ustekinumab) BILLING GUIDE

INDICATIONS

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

- Patients 6 years and older with active psoriatic arthritis
- Patients 6 years or older with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy
- Adult patients with moderately to severely active Crohn's disease
- Adult patients with moderately to severely active ulcerative colitis

SELECTED IMPORTANT SAFETY INFORMATION

STELARA[®] is contraindicated in patients with clinically significant hypersensitivity to ustekinumab or excipients. Serious adverse reactions have been reported in STELARA[®]-treated patients, including bacterial, mycobacterial, fungal, and viral infections, malignancies, hypersensitivity reactions, Posterior Reversible Encephalopathy Syndrome (PRES), and noninfectious pneumonia. STELARA[®] should not be given to 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 PRES is suspected or if noninfectious pneumonia is confirmed, discontinue STELARA[®].

Please see related and other Important Safety Information on [pages 47 and 48](#).



INTRODUCTION

Reimbursement Support

Janssen Biotech, Inc., is committed to providing reimbursement information for STELARA® (ustekinumab) to you. 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 is available through STELARA withMe. For information and assistance, please contact STELARA withMe at **844-4withMe (844-494-8463)** or visit janssencarepath.com/hcp/stelara.

Disclaimer

This document is presented for informational purposes only and is not intended to provide reimbursement or legal advice, nor does it promise or guarantee coverage, levels of reimbursement, payment, or charge. Similarly, all CPT* and HCPCS codes are supplied for informational purposes only and represent no statement, promise, or guarantee by Janssen Biotech, Inc., that these codes will be appropriate or that reimbursement will be made. It is not intended to increase or maximize reimbursement by any payer. Laws, regulations, and policies concerning reimbursement are complex and are updated frequently. While we have made an effort to be current as of the issue date of this document, the information may not be as current or comprehensive when you view it. We strongly recommend you consult the payer organization for its reimbursement policies.

*CPT® – Current Procedural Terminology. CPT® is a registered trademark of the American Medical Association, 2022.



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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 for STELARA® on [pages 47 and 48](#).



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 for those plans continuing to provide coverage under a medical benefit.

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®. Please see Important Safety Information for STELARA® on [pages 47 and 48](#).

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

INDUCTION

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 for STELARA[®] on [pages 47 and 48](#).

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INDICATION AND USAGE¹

STELARA® is indicated for the treatment of adult patients with moderately to severely active Crohn's disease or moderately to severely active ulcerative colitis.

DOSING AND ADMINISTRATION¹

For the treatment of Crohn's disease or ulcerative colitis, 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

Indications	Patient Weight	Dose*	Number of 130 mg/26 mL (5 mg/mL) STELARA® Vials
Crohn's disease or ulcerative colitis	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). Alternatively, a 250 mL infusion bag containing 0.45% Sodium Chloride Injection, USP may be used.
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 one hour. Once diluted, the infusion should be completely administered within eight hours of the dilution in the infusion bag.
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

ICD-10-CM diagnosis codes use 3 to 7 alpha and numeric characters to achieve the greatest level of specificity. Codes with 3 characters are included in ICD-10-CM as the heading of a category of codes that may be further subdivided by use of additional characters to provide greater detail. A 3-character code is to be used only if it is not further subdivided. A code is invalid if it has not been coded to the full number of characters required for that code, including the 7th character, if applicable.² The table below lists possible ICD-10-CM diagnosis codes that you may consider for patients treated with STELARA®.

Table 2. ICD-10-CM Codes³ for Consideration*

<i>Crohn's Disease</i>	
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
<i>Ulcerative Colitis</i>	
K51.00	Ulcerative (chronic) pancolitis without complications
K51.01	Ulcerative (chronic) pancolitis with complications
K51.20	Ulcerative (chronic) proctitis without complications
K51.21	Ulcerative (chronic) proctitis with complications
K51.30	Ulcerative (chronic) rectosigmoiditis without complications
K51.31	Ulcerative (chronic) rectosigmoiditis with complications
K51.50	Left sided colitis without complications
K51.51	Left sided colitis with complications
K51.80	Other ulcerative colitis without complications
K51.81	Other ulcerative colitis with complications
K51.90	Ulcerative colitis, unspecified, without complications
K51.91	Ulcerative colitis, 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.

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 for STELARA® on pages 47 and 48.

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CODING (cont'd)

The initial dose of STELARA® for Crohn's disease or ulcerative colitis 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, Medicare cross-over claims for dual eligible beneficiaries, 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.⁴ Although the FDA uses a 10-digit format when registering NDCs, payers often require an 11-digit NDC format on claim forms for billing purposes. It is important to confirm with your payer if an NDC is needed and the format the payer requires. 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)

FDA-Specified 10-Digit NDC (5-3-2 format)	11-Digit NDC (5-4-2 format)	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 Units

The NDC unit of measure is determined by how the drug is supplied. In the outpatient setting, UN (unit) applies to drugs supplied in a vial in powder form, requiring reconstitution before administration, and ML (milliliters) applies to drugs supplied in liquid form.⁴ 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 components⁴:

- 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

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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 ⁵

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

The fact that a drug, device, procedure, or service is assigned an HCPCS code and a payment rate does not imply coverage by the Medicare and/or Medicaid program, but indicates only how the product, procedure, or service may be paid if covered by the program. Fiscal Intermediaries (FIs)/Medicare Administrative Contractors (MACs) and/or State Medicaid program administration determine whether a drug, device, procedure, or other service meets all program requirements for coverage.

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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® Administration

Drug administration services are reported on claim forms in both the physician office (CMS-1500) and hospital outpatient (CMS-1450) sites of care using the CPT® coding system. 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 hour⁶

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.⁶

Rarely payers may permit the use of CPT® code:

- **96413** - Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug⁶

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.⁶

Payer policies for codes used to describe infusion services may vary. Consult your payers for policies regarding use of 96365 and 96413. For additional support, you may visit Janssen CarePath at [JanssenCarePath.com/hcp/Stelara](https://www.janssen-carepath.com/hcp/Stelara) or contact STELARA withMe at **844-4withMe (844-494-8463)**.

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OTHER CODING CONSIDERATIONS

Place of Service Codes

The Place of Service (POS) code set provides setting information necessary to appropriately pay professional service claims. The place of service is the location of the provider's face-to-face encounter with the beneficiary. POS codes are required on all claims for professional services (billed on CMS-1500). Under the Physician Fee Schedule (PFS), some procedures have separate rates for professional services when provided in facility and non-facility settings; therefore it is important to accurately designate the POS to assure appropriate payment. The physician practice location is considered "nonfacility" (NF), allowing for the practice expenses to be included in the payment under the PFS. When professional services are performed in a facility (e.g., hospital outpatient department), the practice does not incur the same expense (overhead, staff, equipment and supplies, etc.); thus, payment under the PFS is generally lower for facility-based services than for NF.

The physician practice setting is indicated with POS code 11. To differentiate between on-campus and off-campus provider-based departments, CMS 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 Codes⁷

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 Codes

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

- 0260 IV Therapy, General⁸
- 0636 Pharmacy, drugs requiring detailed coding⁸

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OTHER CODING CONSIDERATIONS (cont'd)

HCPCS and CPT® Modifiers

Modifiers are used to report or indicate that a service or procedure has been altered by some specific circumstance, but not changed in its definition or code. They provide additional information about a service or procedure and help to eliminate the appearance of duplicate billing and unbundling. This could include using modifiers to designate a specific site of service, or to document an interrupted procedure, wasted product, same-day procedure, etc. Appropriately used, modifiers improve coding and reimbursement accuracy. Table 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 code⁶ • Append the modifier to the appropriate E/M code⁶ 	<p>✓</p> <p>Required by Medicare</p>	<p>✓</p> <p>Required by Medicare</p>
PO*	Excepted services provided at an off-campus, outpatient, provider-based department of a hospital ⁵	<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 claim⁹ 	N/A	<p>✓</p> <p>Required by Medicare</p>
PN*	Non-excepted service provided at an off-campus, outpatient, provider-based department of a hospital ⁵	<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 claim⁹ 	N/A	<p>✓</p> <p>Required by Medicare</p>
JW	Drug amount discarded/not administered to any patient ⁵	<ul style="list-style-type: none"> • Applies only to the unused drug that is discarded after applicable dose has been administered from a single-use vial¹⁰ • Append the modifier to the drug code on a line separate from that reporting the administered dose¹⁰ 	<p>✓</p> <p>Required by Medicare</p>	<p>✓</p> <p>Required by Medicare</p>
JZ	Zero drug amount discarded/not administered to any patient ⁵	<ul style="list-style-type: none"> • To be used for single-dose containers or single-use packages when the entire amount has been administered to the patient (no wastage)¹¹ 	<p>✓</p> <p>Required by Medicare</p>	<p>✓</p> <p>Required by Medicare</p>
JG	Drug or biological acquired with 340B Drug Pricing Program discount, reported for informational purposes ⁵	<ul style="list-style-type: none"> • Must be reported by hospitals (except for rural sole community hospitals, children's hospitals, and PPS-exempt cancer hospitals) to identify 340B drugs for informational purposes only⁹ • To be reported on the same claim line as the drug HCPCS code for all 340B acquired drugs⁹ 	N/A	<p>✓</p> <p>Required by Medicare</p>
TB	Drug or biological acquired with 340B Drug Pricing Program discount, reported for informational purposes for select entities ⁵	<ul style="list-style-type: none"> • Must be reported by hospitals designated as "select entities" (rural sole community hospitals, children's hospitals, and PPS-exempt cancer hospitals) to identify 340B drugs for informational purposes⁹ • To be reported on the same claim line as the drug HCPCS code for all 340B acquired drugs⁹ 	N/A	<p>✓</p> <p>Required by Medicare</p>

*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."⁹

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OTHER CODING CONSIDERATIONS (cont'd)

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

It may be necessary to provide evaluation and management (E/M) services on the same day as a drug administration procedure. Depending on the payer, E/M services that are medically necessary, separate and distinct from the drug administration procedure, 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: **CPT® code 99211 cannot be paid if it is billed, with or without modifier 25, with a chemotherapy or non-chemotherapy drug administration code.**¹²

Thus, CPT® code 99211 cannot be paid on the same day as an office-based infusion of STELARA®. If a therapeutic or complex drug administration service and a significantly identifiable, separate and distinct evaluation and management service are provided on the same day, a different diagnosis is not required.¹²

Payer policies vary. For information and assistance, please contact STELARA withMe at **844-4withMe (844-494-8463)** or visit Janssen CarePath at JanssenCarePath.com/hcp/Stelara.

CMS Discarded Drug Policy¹⁰

When a physician, hospital, or other provider or supplier must discard the remainder of a single-use vial or other single-use package after administering a dose/quantity of the drug or biological to a Medicare patient, the program provides payment for the amount of drug or biological discarded as well as the dose administered, up to the amount of the drug or biological as indicated on the vial or package label.

Medicare contractors require the modifier JW to identify unused drugs or biologicals from single-use vials or single-use packages that are appropriately discarded. This modifier, billed on a separate claim line, supports payment for the amount of discarded drug or biological.

For example, a single-use vial that is labeled to contain 100 units of a drug has 95 units administered to the patient and 5 units discarded. The 95-unit dose is billed on one line, while the discarded 5 units is billed on another line accompanied by the JW modifier. Both line items will be processed for payment. Providers must record the discarded amounts of drugs and biologicals in the patient's medical record.

JW Modifier Summary:

- Payment for discarded amounts of drug/biological applies only to single-use vials or packages
- Multi-use vials are not subject to payment for discarded amounts
- Discarded amounts of drugs/biologicals must be recorded in the patient's medical record
- Medicare contractors require the JW modifier; other payer policies may vary

CMS Policy for Reporting of No Drug Wastage

Effective July 1, 2023, Medicare will require the JZ modifier on all claims that bill for drugs from single-dose containers that are separately payable under Medicare Part B when there are no discarded amounts. This policy applies to all providers and suppliers who buy and bill separately payable drugs under Medicare Part B. The provider or supplier must file a claim with one line for the drug.

For the administered amount, the claim line should include the billing and payment code (such as HCPCS code) describing the given drug, the JZ modifier (attesting that there were no discarded amounts), and the number of units administered in the Units field.¹¹

Drugs Supplied at No Cost to the Provider

Under certain circumstances, qualified patients may acquire donated or no-cost drugs, or drugs may be covered under a pharmacy benefit and delivered to the administering provider. When the drug is supplied by a third party, at no cost to the provider, it should NOT be billed to Medicare or any other payer. However, the administration of the drug, regardless of the source, is a service that represents an expense to the physician. Therefore, administration of the drug is payable if the drug would have been covered if the physician purchased it. When reporting drug administration services for free-of-charge drugs, it may be necessary to include drug information on the claim and enter "0.01" charges.¹³ 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>

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SAMPLE CLAIM FORMS (cont'd)

STELARA® for IV Use 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

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 MM DD YY 07 04 50 SEX 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:		11. INSURED'S POLICY GROUP OR FECA NUMBER	
a. EMPLOYMENT? (Current or Previous) <input type="checkbox"/> YES <input type="checkbox"/> NO		a. INSURED'S DATE OF BIRTH MM DD YY M <input type="checkbox"/> F <input type="checkbox"/>	
b. AUTO ACCIDENT? PLACE (State) <input type="checkbox"/> YES <input type="checkbox"/> NO		b. OTHER CLAIM ID (Designated by NUCC)	
c. OTHER ACCIDENT? <input type="checkbox"/> YES <input type="checkbox"/> NO		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 If yes, complete items 9, 9a, and 9d.	
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		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 A-L to service line below (24E) ICD Ind. 0	
22. RESUBMISSION CODE ORIGINAL REF. NO.		23. ORDER NUMBER	
24. A. DATE(S) OF SERVICE From MM DD YY To MM DD YY B. PLACE OF SERVICE C. CPT/HPCS D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) E. DIAGNOSIS POINTER F. \$ CHARGES G. DAYS Off UNITS H. EPSON Family Plan I. ID. QUAL. J. RENDERING PROVIDER ID. #		25. FEDERAL TAX I.D. NUMBER SSN EIN	
26. PATIENT'S ACCOUNT NO.		27. ACCEPT ASSIGNMENT? (For gov. 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.)	
32. SERVICE FACILITY LOCATION INFORMATION		33. BILLING PROVIDER INFO & PH # (203) 555-6543 Dr. Jones 4231 Center Road Anytown, AS 01010	
SIGNED _____ DATE _____		a. 123 456 7890 b.	

NUCC Instruction Manual available at: www.nucc.org

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

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6

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 for STELARA® on pages 47 and 48.

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SAMPLE CLAIM FORMS (cont'd)

STELARA® for IV Use

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.⁷

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. #	REF INFORMATION
	From MM DD YY	To MM DD YY	(Explain Unusual Circumstances)		CPT/HCPCS	MODIFIER											
1	N457894005427 ML78								J3358	JZ	A		390		NPI	123 456 7890	
2															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)

When it is necessary to discard the remainder of a single-use vial after administering a dose of drug/biological to a Medicare patient, the program provides payment for the amount discarded as well as the dose administered. Medicare requires the modifier JW be appended to the discarded amount, billed on a separate line from the administered dose.¹⁰ Other payer policies may vary.*

If there is no discarded drug or wastage, use the JZ modifier to attest that no amount of drug was discarded and eligible for payment. The modifier should only be used for claims that bill for drugs from single-dose containers. The modifier would be placed on the same line as the drug code.¹¹

- Item 24E**—Refer to the diagnosis for this service (see Item 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

The fact that a drug, device, procedure, or service is assigned an HCPCS code and a payment rate does not imply coverage by the Medicare and/or Medicaid program, but indicates only how the product, procedure, or service may be paid if covered by the program. Fiscal Intermediaries (FIs)/Medicare Administrative Contractors (MACs) and/or State Medicaid program administration determine whether a drug, device, procedure, or other service meets all program requirements for coverage.

CPT®—Current Procedural Terminology. CPT® is a registered trademark of the American Medical Association, 2022.

*For information and assistance, please contact STELARA withMe at 844-4withMe (844-494-8463) or visit Janssen CarePath at [JanssenCarePath.com/hcp/stelara](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 for STELARA® on pages 47 and 48.

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SAMPLE CLAIM FORMS (cont'd)

STELARA® for IV Use

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 (e.g., IV therapy, drug). If line item NDC information is required, it will be entered in the unshaded portions of Locator Box 43.¹⁴ 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)

Modifiers

- When it is necessary to discard the remainder of a single-use vial after administering a dose of drug/biological to a Medicare patient, the program provides payment for the amount discarded as well as the dose administered. Medicare requires the modifier JW be appended to the discarded amount, billed on a separate line from the administered dose.¹⁰ Other payer policies may vary.*
- If there is no discarded drug or wastage, use the JZ modifier to attest that no amount of drug was discarded and eligible for payment. The modifier should only be used for claims that bill for drugs from single-dose containers. The modifier would be placed on the same line as the drug code.¹¹
- PO or PN modifiers must be reported by all off-campus HOPDs. The PO modifier is to be reported with every HCPCS code for all items and services furnished in an *excepted*, off-campus, PBD 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, PBD of a hospital.⁹
- For informational purposes, JG and TB modifiers must be reported for all 340B-acquired drugs. Hospitals designated as "select entities" (rural sole community hospitals, children's hospitals, and PPS-exempt cancer hospitals) report TB. All others report JG.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.

The fact that a drug, device, procedure, or service is assigned an HCPCS code and a payment rate does not imply coverage by the Medicare and/or Medicaid program, but indicates only how the product, procedure, or service may be paid if covered by the program. Fiscal Intermediaries (FIs)/Medicare Administrative Contractors (MACs) and/or State Medicaid program administration determine whether a drug, device, procedure, or other service meets all program requirements for coverage.

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*For information and assistance, please contact STELARA withMe at **844-4withMe (844-494-8463)** or visit Janssen CarePath at [JanssenCarePath.com/hcp/stelara](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 for STELARA®** on [pages 47 and 48](#).

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FOR CROHN'S DISEASE OR
ULCERATIVE COLITIS—STELARA®
SUBCUTANEOUS INJECTION

MAINTENANCE

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 for STELARA® on [pages 47 and 48](#).

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INDICATION AND USAGE¹

STELARA® is indicated for the treatment of adult patients with moderately to severely active Crohn's disease or moderately to severely active ulcerative colitis.

DOSING AND ADMINISTRATION¹

MAINTENANCE

The maintenance doses of STELARA® for Crohn's disease or ulcerative colitis 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

Indications	Dose	Frequency
Crohn's disease or ulcerative colitis	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.



Preparation and Administration of STELARA® for Subcutaneous Injection

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

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.

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
- 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, ½-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.

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 for STELARA® on [pages 47 and 48](#).

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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, some 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.⁴ Although the FDA uses a 10-digit format when registering NDCs, payers often require an 11-digit NDC format on claim forms for billing purposes. It is important to confirm with your payer if an NDC is needed and the format the payer requires. 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

FDA-Specified 10-Digit NDC (5-3-2 format)	11-Digit NDC (5-4-2 format)	Description
57894-060-02 ¹	57894-0060-02	45-mg single-dose vial containing 45 mg of ustekinumab per 0.5 mL solution

NDC Units

The NDC unit of measure is determined by how the drug is supplied. In the outpatient setting, UN (unit) applies to drugs supplied in a vial in powder form, requiring reconstitution before administration, and ML (milliliters) applies to drugs supplied in liquid form.⁴ 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 components⁴:

- 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®.

Please see Important Safety Information for STELARA® on pages 47 and 48.

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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 (e.g., 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 mg⁵

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

The fact that a drug, device, procedure, or service is assigned an HCPCS code and a payment rate does not imply coverage by the Medicare and/or Medicaid program, but indicates only how the product, procedure, or service may be paid if covered by the program. Fiscal Intermediaries (FIs)/Medicare Administrative Contractors (MACs) and/or State Medicaid program administration determine whether a drug, device, procedure, or other service meets all program requirements for coverage.

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 intramuscular⁶

Please refer to the summary of code modifiers on page 12 for details.

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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 for STELARA® on [pages 47 and 48](#).

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SAMPLE CLAIM FORMS

THE FOLLOWING CLAIM SAMPLES ILLUSTRATE
CODING FOR THE SUBCUTANEOUS
INJECTION OF STELARA[®] (J3357)

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 for STELARA[®] on [pages 47 and 48](#).

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SAMPLE CLAIM FORMS

STELARA® for Subcutaneous Injection 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#) <input type="checkbox"/> MEDICAID <input type="checkbox"/> (Medicaid#) <input type="checkbox"/> TRICARE <input type="checkbox"/> (ID#/DoD#) <input type="checkbox"/> CHAMPVA <input type="checkbox"/> (Member ID#) <input type="checkbox"/> GROUP HEALTH PLAN <input type="checkbox"/> (ID#) <input type="checkbox"/> FECA BLK/LUNG <input type="checkbox"/> (ID#) <input type="checkbox"/> 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.	
3. PATIENT'S BIRTH DATE MM DD YY 07 01 50		6. PATIENT RELATIONSHIP TO INSURED Self <input checked="" type="checkbox"/> Spouse <input type="checkbox"/> Child <input type="checkbox"/> Other <input type="checkbox"/>	
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)		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? <input type="checkbox"/> YES <input type="checkbox"/> NO PLACE (State)	
c. RESERVED FOR NUCC USE		c. OTHER ACCIDENT? <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.		11. INSURED'S POLICY GROUP OR FECA NUMBER	
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 _____		SIGNED _____	
14. DATE OF CURRENT ILLNESS, INJURY, or PREGNANCY (LIMP) MM DD YY QUAL.		15. OTHER DATE QUAL. MM DD YY	
17. NAME OF REFERRING PROVIDER OR OTHER SOURCE Dr. Jones		16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION FROM MM DD YY TO MM DD YY	
19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)		18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES. FROM MM DD YY TO MM DD YY	
21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E) ICD Ind. 0		20. OUTSIDE LAB? \$ CHARGES <input type="checkbox"/> YES <input type="checkbox"/> NO	
A. K50.90 B. C. D. E. F. G. H. I. J. K. L.		22. RESUBMISSION CODE ORIGINAL REF. NO.	
24. A. DATE(S) OF SERVICE From MM DD YY To MM DD YY B. PLACE OF SERVICE C. EMG D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS MODIFIER E. DIAGNOSIS POINTER F. \$ CHARGES G. DAYS OR UNITS H. EPSDT (Family Plan) I. ID. QUAL. J. RENDERING PROVIDER ID.#		23. AUTHORIZED NUMBER	
1 MM DD YY MM DD YY 11		1 A 90 NPI 123 456 7890	
2 MM DD YY MM DD YY 11		2 A 1 NPI 123 456 7890	
3		NPI	
4		NPI	
5		NPI	
6		NPI	
25. FEDERAL TAX I.D. NUMBER SSN EIN		26. PATIENT'S ACCOUNT NO.	
27. ACCEPT ASSIGNMENT? (By gov. claims, see back) <input type="checkbox"/> YES <input type="checkbox"/> NO		28. TOTAL CHARGE \$	
29. AMOUNT PAID \$		30. Rsvld 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.)		32. SERVICE FACILITY LOCATION INFORMATION	
SIGNED _____ DATE _____		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)

CARRIER

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 for STELARA® on pages 47 and 48.

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SAMPLE CLAIM FORMS (cont'd)

STELARA® (Subcutaneous Injection for Maintenance)

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.

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.⁷ 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. EPST Family Plan	I. ID. QUAL.	J. RENDERING PROVIDER ID. #	OR SUPPLIER INFORMATION	
	From MM DD YY	To MM DD YY	(Explain Unusual Circumstances)		CPT/HCPCS	MODIFIER												
1	N457894006002 ML1								J3357	JZ	A		90				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

Modifiers

When it is necessary to discard the remainder of a single-use package/container after administering a dose of drug/biological to a Medicare patient, the program provides payment for the amount discarded as well as the dose administered. Medicare requires the modifier JW be appended to the discarded amount, billed on a separate line from the administered dose.¹⁰ Other payer policies may vary.*

If there is no discarded drug or wastage, use the JZ modifier to attest that no amount of drug was discarded and eligible for payment. The modifier should only be used for claims that bill for drugs from single-dose containers. The modifier would be placed on the same line as the drug code.¹¹

Please refer to page 12 of this guide for a list of modifiers that may apply.

- 3 **Item 24E**—Refer to the diagnosis for this service (see Item 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.

The fact that a drug, device, procedure, or service is assigned an HCPCS code and a payment rate does not imply coverage by the Medicare and/or Medicaid program, but indicates only how the product, procedure, or service may be paid if covered by the program. Fiscal Intermediaries (FIs)/Medicare Administrative Contractors (MACs) and/or State Medicaid program administration determine whether a drug, device, procedure, or other service meets all program requirements for coverage.

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*For information and assistance, please contact STELARA withMe at **844-4withMe (844-494-8463)** or visit Janssen CarePath at [JanssenCarePath.com/hcp/Stelara](https://www.janssen-carepath.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 for STELARA® on pages 47 and 48.**

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SAMPLE CLAIM FORMS (cont'd)

STELARA® (Subcutaneous Injection for Maintenance)

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. # XX-XXXX b. MED. REC. # 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 07-01-50		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 / HPPS CODE		45 SERV. DATE	
46 SERV. UNITS		47 TOTAL CHARGES		48 NON-COVERED CHARGES		49	
0636		STELARA®		J3357JZ		MM-DD-YY 90	
0940		Other therapeutic services		96372		MM-DD-YY 1	
PAGE		OF		CREATION DATE		TOTALS	
50 PAYER NAME Medicare		51 HEALTH PLAN ID		52 PPS INFO		53 ACDT	
54 PRIOR PAYMENTS		55 EST. AMOUNT DUE		56 NPI		57 OTHER PRV ID	
58 INSURED'S NAME		59 FREL		60 INSURED'S UNIQUE ID		61 GROUP NAME	
62 INSURANCE GROUP NO.		63 TREATMENT AUTHORIZATION CODES		64 DOCUMENT CONTROL NUMBER		65 EMPLOYER NAME	
66 EX 0		67		68		69	
70 PATIENT REASON DX		71 PPS CODE		72 ECI		73	
74 PRINCIPAL PROCEDURE CODE		75 OTHER PROCEDURE CODE		76 ATTENDING NPI		77 OPERATING NPI	
78 OTHER NPI		79 OTHER NPI		LAST		FIRST	
80 REMARKS		b1 CCG a		b		c	
		b		c		d	
		b		c		d	
		b		c		d	
		b		c		d	

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 for STELARA® on pages 47 and 48.

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SAMPLE CLAIM FORMS (cont'd)

STELARA® Subcutaneous Injection

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 Locator Box 43.¹⁴ Payer requirements for NDC entries may vary.
- 3 **Locator Box 44**—Indicate appropriate CPT® and HCPCS codes.

STELARA® (Subcutaneous Injection)

J3357 - Ustekinumab, subcutaneous injection, 1 mg

Drug Administration

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

Modifiers

When it is necessary to discard the remainder of a single-use package/container after administering a dose of drug/biological to a Medicare patient, the program provides payment for the amount discarded as well as the dose administered. Medicare requires the modifier JW be appended to the discarded amount, billed on a separate line from the administered dose.¹⁰ Other payer policies may vary.*

If there is no discarded drug or wastage, use the JZ modifier to attest that no amount of drug was discarded and eligible for payment. The modifier should only be used for claims that bill for drugs from single-dose containers. The modifier would be placed on the same line as the drug code.¹¹

Please refer to page 12 of this guide for a list of modifiers that may apply.

- 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.

The fact that a drug, device, procedure, or service is assigned an HCPCS code and a payment rate does not imply coverage by the Medicare and/or Medicaid program, but indicates only how the product, procedure, or service may be paid if covered by the program. Fiscal Intermediaries (FIs)/Medicare Administrative Contractors (MACs) and/or State Medicaid program administration determine whether a drug, device, procedure, or other service meets all program requirements for coverage.

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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 for STELARA® [on pages 47 and 48](#).

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FOR PLAQUE PSORIASIS AND
PSORIATIC ARTHRITIS —
STELARA[®] 45 MG/0.5 ML VIAL
FOR SUBCUTANEOUS INJECTION

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 for STELARA[®] on [pages 47 and 48](#).

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INDICATIONS AND USAGE¹

STELARA® is indicated for the treatment of patients 6 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 may be weight-based. Induction and maintenance doses are administered by subcutaneous injection.

Table 1. STELARA® Subcutaneous Injection Dosing

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>Pediatric Patients (6-17 years old)</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 <i>Arthritis</i>	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 pediatric patients with psoriasis weighing less than 60 kg" for correlation between weight, dose, and injection volume.

There are two available dosage forms for subcutaneous injection:

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

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 for STELARA® on [pages 47 and 48](#).

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DOSING AND ADMINISTRATION¹ (cont'd)

This section of the Billing Guide will provide coding and product information related to the subcutaneous injection of the 45 mg/0.5 mL 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. 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 pediatric patients, it is recommended that STELARA® be administered by a healthcare provider. 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 [see [Medication Guide](#)].

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. For active psoriatic arthritis, weight should be considered only if patient has co-existent moderate-to-severe plaque psoriasis
- 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, ½-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 pediatric patients, it is recommended that STELARA® be administered by a healthcare provider. 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 [see [Medication 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®.

Please see Important Safety Information for STELARA® on [pages 47 and 48](#).

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CODING

ICD-10-CM Diagnosis Codes

ICD-10-CM diagnosis codes use 3 to 7 alpha and numeric characters to achieve the greatest level of specificity. Codes with 3 characters are included in ICD-10-CM as the heading of a category of codes that may be further subdivided by use of additional characters to provide greater detail. A 3-character code is to be used only if it is not further subdivided. A code is invalid if it has not been coded to the full number of characters required for that code, including the 7th character, if applicable.² Table 2 below lists possible ICD-10-CM diagnosis codes that you may consider for patients treated with STELARA®.

Table 2. ICD-10-CM Codes ³ 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.

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, 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.⁴ Although the FDA uses a 10-digit format when registering NDCs, payers often require an 11-digit NDC format on claim forms for billing purposes. It is important to confirm with your payer if an NDC is needed and the format the payer requires. 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

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 for STELARA® on [pages 47 and 48](#).

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CODING (cont'd)

NDC Units

The NDC unit of measure is determined by how the drug is supplied. In the outpatient setting, UN (unit) applies to drugs supplied in a vial in powder form, requiring reconstitution before administration, and ML (milliliters) applies to drugs supplied in liquid form.⁴ 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®:

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 components⁴:

- 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 information and assistance, please contact STELARA withMe at **844-4withMe (844-494-8463)** or visit Janssen CarePath at [JanssenCarePath.com/hcp/Stelara](https://www.janssen-carepath.com/hcp/Stelara).

Healthcare Common Procedure Code System (HCPCS) Level II Codes

Drugs are typically reported using product-specific HCPCS codes (e.g., 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 mg⁵

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.

The fact that a drug, device, procedure, or service is assigned an HCPCS code and a payment rate does not imply coverage by the Medicare and/or Medicaid program, but indicates only how the product, procedure, or service may be paid if covered by the program. Fiscal Intermediaries (FIs)/Medicare Administrative Contractors (MACs) and/or State Medicaid program administration determine whether a drug, device, procedure, or other service meets all program requirements for coverage.

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 for STELARA®** on [pages 47 and 48](#).

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CODING (cont'd)

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/0.5 mL vial	45 mg	45
Two 45 mg/0.5 mL 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 ⁶

Please refer to the summary of code modifiers on page 12 for details.

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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 for STELARA® on [pages 47 and 48](#).

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SAMPLE CLAIM FORMS

THE FOLLOWING CLAIM SAMPLES ILLUSTRATE
CODING FOR THE SUBCUTANEOUS
INJECTION OF STELARA[®] (J3357)

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 for STELARA[®] on [pages 47 and 48](#).

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SAMPLE CLAIM FORMS

STELARA® for Subcutaneous Injection 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 BENEFIT <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 MM DD YY SEX 07 01 50 M <input checked="" type="checkbox"/> <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	
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)		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? <input type="checkbox"/> YES <input type="checkbox"/> NO PLACE (State)	
c. RESERVED FOR NUCC USE		c. OTHER ACCIDENT? <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 _____		a. INSURED'S DATE OF BIRTH MM DD YY SEX b. OTHER CLAIM ID (Designated by NUCC) c. INSURANCE PLAN NAME OR PROGRAM NAME 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	
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 A-L to service line below (24E)		22. RESUBMISSION CODE ORIGINAL REF. NO.	
A. L40.50 B. C. D. E. F. G. H. I. J. K. L. ICD Ind. 0		23. PRIOR AUTHORIZATION NUMBER	
24. A. DATE(S) OF SERVICE From MM DD YY To MM DD YY B. PLACE OF SERVICE C. PHYSICIAN(S), SERVICE(S), OR SUPPLIER(S) (Explain Unusual Circumstances) D. DIAGNOSIS POINTER E. \$ CHARGES F. DAYS OR UNITS G. H. EPSTI (Only if P) I. ID. J. RENDERING PROVIDER ID. #		25. FEDERAL TAX I.D. NUMBER SSN EIN	
1 MM DD YY MM DD YY 11 J3357 JZ A 45 NPI 123 456 7890		26. PATIENT'S ACCOUNT NO. 27. ACCEPT ASSIGNMENT? (For govt. claims, see back) <input type="checkbox"/> YES <input type="checkbox"/> NO	
2 MM DD YY MM DD YY 11 96372 A 1 NPI 123 456 7890		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.)		32. SERVICE FACILITY LOCATION INFORMATION	
33. BILLING PROVIDER INFO & PH # (203) 555-6543 Dr. Jones 4231 Center Road Anytown, AS 01010		SIGNED _____ DATE _____ 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 for STELARA® on pages 47 and 48.

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SAMPLE CLAIM FORMS (cont'd)

STELARA® for Subcutaneous Injection 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.

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.⁷ 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. EPISODE Family Plan	I. ID. QUAL.	J. RENDERING PROVIDER ID. #	OF SUPPLIER INFORMATION
	From MM DD YY	To MM DD YY	(Explain Unusual Circumstances)		MODIFIER												
1	N457894006002 ML0.5								J3357	JZ	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

Modifiers

When it is necessary to discard the remainder of a single-use package/container after administering a dose of drug/biological to a Medicare patient, the program provides payment for the amount discarded as well as the dose administered. Medicare requires the modifier JW be appended to the discarded amount, billed on a separate line from the administered dose.¹⁰ Other payer policies may vary.*

If there is no discarded drug or wastage, use the JZ modifier to attest that no amount of drug was discarded and eligible for payment. The modifier should only be used for claims that bill for drugs from single-dose containers. The modifier would be placed on the same line as the drug code.¹¹

Please refer to page 12 of this guide for a list of modifiers that may apply.

- 3 **Item 24E**—Refer to the diagnosis for this service (see Item 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

The fact that a drug, device, procedure, or service is assigned an HCPCS code and a payment rate does not imply coverage by the Medicare and/or Medicaid program, but indicates only how the product, procedure, or service may be paid if covered by the program. Fiscal Intermediaries (FIs)/Medicare Administrative Contractors (MACs) and/or State Medicaid program administration determine whether a drug, device, procedure, or other service meets all program requirements for coverage.

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*For information and assistance, please contact STELARA withMe at 844-4withMe (844-494-8463) or visit Janssen CarePath at [JanssenCarePath.com/hcp/Stelara](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 for STELARA® on pages 47 and 48.

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SAMPLE CLAIM FORMS (cont'd)

STELARA® Subcutaneous Injection 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 Locator Box 43.¹⁴ Payer requirements for NDC entries may vary.
- 3 **Locator Box 44**—Indicate appropriate CPT® and HCPCS codes.

STELARA®

J3357 - Ustekinumab, subcutaneous injection, 1 mg

Drug Administration

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

Modifiers

When it is necessary to discard the remainder of a single-use package/container after administering a dose of drug/biological to a Medicare patient, the program provides payment for the amount discarded as well as the dose administered. Medicare requires the modifier JW be appended to the discarded amount, billed on a separate line from the administered dose.¹⁰ Other payer policies may vary.*

If there is no discarded drug or wastage, use the JZ modifier to attest that no amount of drug was discarded and eligible for payment. The modifier should only be used for claims that bill for drugs from single-dose containers. The modifier would be placed on the same line as the drug code.¹¹

Please refer to page 12 of this guide for a list of modifiers that may apply.

- 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.

The fact that a drug, device, procedure, or service is assigned an HCPCS code and a payment rate does not imply coverage by the Medicare and/or Medicaid program, but indicates only how the product, procedure, or service may be paid if covered by the program. Fiscal Intermediaries (FIs)/Medicare Administrative Contractors (MACs) and/or State Medicaid program administration determine whether a drug, device, procedure, or other service meets all program requirements for coverage.

CPT®— Current Procedural Terminology. CPT® is a registered trademark of the American Medical Association, 2022.

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 for STELARA®** on [pages 47 and 48](#).

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COVERAGE CONSIDERATIONS

Factors That Influence Coverage

Third-party payers (e.g., commercial insurers, Medicare, Medicaid) will generally cover parenteral drugs for their approved U.S. Food and Drug Administration (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 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 (e.g., 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.
- Is the plan willing to grant in-network status when a service is otherwise out of network? In some cases (e.g., when there are no available in-network providers), health plans may grant in-network status for a provider and related services. In such cases, the provider accepts the in-network rate and the patient will be able to access in-network cost-sharing. It may be helpful to contact a payer to ask for a service to be converted to in-network status.
- 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 for STELARA® on [pages 47 and 48](#).

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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 for STELARA® [on pages 47 and 48](#).

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Stelara withMe

Once a decision has been made to prescribe STELARA®

STELARA withMe is here to support your patients

STELARA withMe provides a range of dedicated support and resources to help make it easier for patients as they begin, and continue, their STELARA® treatment journey.

STELARA withMe is limited to education for patients about STELARA®, its administration, and/or their disease, and is not intended to provide medical advice, replace a treatment plan from the patient's doctor or nurse, or provide case management 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®. Please see Important Safety Information for STELARA® on [pages 47 and 48](#).

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Once a decision has been made to prescribe STELARA®

STELARA withMe is all about dedicated support



Nurse Navigator*

A trained professional is available to patients to offer support and answer questions about STELARA®, including supplemental self-injection training, infusion support, coverage, and options for saving on treatment.

*Nurse Navigators do not provide medical advice.



Reimbursement Support

Your Field Reimbursement and Access Specialist (FRAS) provides in-office educational support and additional assistance to help patients have a positive experience throughout their STELARA® treatment journey.



Infusion Services

Infusion Services is intended to help patients transition from their single infusion to injection. Infusion Services utilizes Infusion Services Providers (ISPs) to coordinate patient continuity of care and support the overall patient experience by leveraging existing infrastructure and clinical experience.



Access and Affordability Support

We can help verify insurance coverage, provide reimbursement information, find financial assistance options, and offer ongoing support so you can help patients start and stay on STELARA®.



Specialty Pharmacy Enhanced Services

Specialty pharmacies provide enhanced product fulfillment and patient support services.

Enhanced services provided by each specialty pharmacy may vary.

Janssen Biotech, Inc., does not endorse the use of any pharmacies in particular. The information provided represents no statement, promise, or guarantee of Janssen Biotech, Inc., concerning levels of reimbursement, payment, or charge. Please consult specific payer organizations with regard to local or actual coverage, reimbursement policies, and determination processes.

Enroll your patients in STELARA withMe at stelarawithme.com/hcp

STELARA withMe is limited to education for patients about STELARA®, its administration, and/or their disease, and is not intended to provide medical advice, replace a treatment plan from the patient's doctor or nurse, or provide case management 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®. Please see **Important Safety Information for STELARA®** on [pages 47 and 48](#).

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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. Download a sample letter template at [JanssenCarePath.com/hcp/Stelara](https://www.janssen-carepath.com/hcp/stelara).

[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 or name of individual responsible for prior authorization],

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, including dose and duration, response to those interventions
- Description of patient's recent symptoms/condition
- Site of medical service—include site type (eg, inpatient, hospital outpatient, outpatient clinic, private practice, or other) and rationale (eg, compliance or closely monitoring patients)
- Rationale for not using drugs that are on the plan's formulary
- Summary of your professional opinion of the patient's likely prognosis or disease progression without treatment with STELARA®

Note: Exercise your medical judgment and discretion when providing a diagnosis and characterization of the patient's medical condition.]

Rationale for Treatment
 [Insert summary statement for rationale for treatment such as: Considering the patient's history, condition, and the full Prescribing Information supporting 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 Healthcare Provider's 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 for STELARA® on pages 47 and 48.

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APPENDIX (cont'd)

Sample Format Exception Letter: Crohn's Disease or Ulcerative Colitis

Letter templates for [Crohn's Disease](#) or [Ulcerative Colitis](#) available for download at JanssenCarePath.com/hcp/Stelara.

[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 or name of individual responsible for prior authorization],

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, including dose and duration, response to those interventions
- Description of patient's recent symptoms/condition
- Site of medical service—include site type (eg, inpatient, hospital outpatient, outpatient clinic, private practice, or other) and rationale (eg, compliance or closely monitoring patients)
- Rationale for not using drugs that are on the plan's formulary
- Summary of your professional opinion of the patient's likely prognosis or disease progression without treatment with STELARA®

Note: Exercise your medical judgment and discretion when providing a diagnosis and characterization of the patient's medical condition.]

Rationale for Treatment

[Insert summary statement for rationale for treatment such as: Considering the patient's history, condition, and the full Prescribing Information supporting 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 Healthcare Provider's 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 for STELARA® on [pages 47 and 48](#).

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APPENDIX (cont'd)

Psoriatic Arthritis Sample Format Exception Letter

Letter template available for download at JanssenCarePath.com/hcp/Stelara.

[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 or name of individual responsible for prior authorization],

I am writing to request a **formulary exception** for the above-mentioned patient to receive treatment with STELARA® [45 mg vial, 45 mg prefilled syringe, or 90 mg prefilled syringe] 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, including dose and duration, response to those interventions
- Description of patient's recent symptoms, including if patient has co-existent moderate-to-severe plaque psoriasis
- Site of medical service—include site type (eg, inpatient, hospital outpatient, outpatient clinic, private practice, or other) and rationale (eg, compliance or closely monitoring). Note: STELARA® for active psoriatic arthritis may be administered at home if deemed appropriate by the patient's Healthcare Provider
- Rationale for not using drugs that are on the plan's formulary
- Summary of your professional opinion of the patient's likely prognosis or disease progression without treatment with STELARA®

Note: Exercise your medical judgment and discretion when providing a diagnosis and characterization of the patient's medical condition.]

Rationale for Treatment

[Insert summary statement for rationale for treatment such as: Considering the patient's history, condition, and the full Prescribing Information supporting 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 Healthcare Provider's 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 for STELARA® on pages 47 and 48.

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APPENDIX (cont'd)

Plaque Psoriasis Sample Format Exception Letter

Letter template available for download at [JanssenCarePath.com/hcp/Stelara](https://www.janssencarepath.com/hcp/stelara).

[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 or name of individual responsible for prior authorization],

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, including dose and duration, response to those interventions
- Description of patient's recent symptoms/condition
- Site of medical service—include site type (eg, inpatient, hospital outpatient, outpatient clinic, private practice, or other) and rationale (eg, compliance or closely monitoring patients)
- Rationale for not using drugs that are on the plan's formulary
- Summary of your professional opinion of the patient's likely prognosis or disease progression without treatment with STELARA®

Note: Exercise your medical judgment and discretion when providing a diagnosis and characterization of the patient's medical condition.]

Rationale for Treatment

[Insert summary statement for rationale for treatment such as: Considering the patient's history, condition, and the full Prescribing Information supporting 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 Healthcare Provider's 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 patients 6 years and older with active psoriatic arthritis.

STELARA® (ustekinumab) is indicated for the treatment of patients 6 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.

STELARA® (ustekinumab) is indicated for the treatment of adult patients with moderately to severely active ulcerative colitis.

IMPORTANT SAFETY INFORMATION

STELARA® (ustekinumab) is contraindicated in patients with clinically significant hypersensitivity to ustekinumab or to any of the excipients.

Infections

STELARA® may increase the risk of infections and reactivation of latent infections. Serious bacterial, mycobacterial, fungal, and viral infections requiring hospitalization or otherwise clinically significant infections were reported. In patients with psoriasis, these included diverticulitis, cellulitis, pneumonia, appendicitis, cholecystitis, sepsis, osteomyelitis, viral infections, gastroenteritis, and urinary tract infections. In patients with psoriatic arthritis, this included cholecystitis. In patients with Crohn's disease, these included anal abscess, gastroenteritis, ophthalmic herpes zoster, pneumonia, and *Listeria* meningitis. In patients with ulcerative colitis, these included gastroenteritis, ophthalmic herpes zoster, pneumonia, and listeriosis.

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 (eg, tissue culture, stool culture) as dictated by clinical circumstances.

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 for STELARA® on pages 47 and 48.

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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

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®.

Posterior Reversible Encephalopathy Syndrome (PRES)

Two cases of posterior reversible encephalopathy syndrome (PRES), also known as Reversible Posterior Leukoencephalopathy Syndrome (RPLS), were reported in clinical trials. Cases have also been reported in postmarketing experience in patients with psoriasis, psoriatic arthritis and Crohn's disease. Clinical presentation included headaches, seizures, confusion, visual disturbances, and imaging changes consistent with PRES a few days to several months after ustekinumab initiation. A few cases reported latency of a year or longer. Patients recovered with supportive care following withdrawal of ustekinumab.

Monitor all patients treated with STELARA® for signs and symptoms of PRES. If PRES is suspected, promptly administer appropriate treatment and discontinue STELARA®.

Immunizations

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



IMPORTANT SAFETY INFORMATION (cont'd)

Concomitant Therapies

The safety of STELARA® in combination with other biologic 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 methotrexate use did not appear to influence the safety or efficacy of STELARA®. In Crohn's disease and ulcerative colitis induction 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 pediatric patients with plaque psoriasis 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 for STELARA® 90 mg subcutaneous injection or placebo 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%). In the ulcerative colitis induction study, 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: nasopharyngitis (7% vs 4%). In the ulcerative colitis maintenance study, common adverse reactions (3% or more of patients treated with STELARA® and higher than placebo) reported through Week 44 for STELARA® 90 mg subcutaneous injection or placebo included: nasopharyngitis (24% vs 20%), headache (10% vs 4%), abdominal pain (7% vs 3%), influenza (6% vs 5%), fever (5% vs 4%), diarrhea (4% vs 1%), sinusitis (4% vs 1%), fatigue (4% vs 2%), and nausea (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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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 for STELARA® on pages 47 and 48.

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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 for STELARA® on pages 47 and 48.

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