Ustekinumab

STELARA® (ustekinumab) and Ustekinumab

BILLING & CODING GUIDE

INDICATIONS

STELARA® (ustekinumab) and Ustekinumab are human interleukin-12 and -23 antagonists 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® and Ustekinumab are contraindicated in patients with clinically significant hypersensitivity to ustekinumab or excipients. Serious adverse reactions have been reported in STELARA® and Ustekinumab-treated patients, including bacterial, mycobacterial, fungal, and viral infections, malignancies, hypersensitivity reactions, Posterior Reversible Encephalopathy Syndrome (PRES), and noninfectious pneumonia. STELARA® and Ustekinumab should not be given to patients with any clinically important active infection. Patients should be evaluated for tuberculosis prior to initiating treatment with either STELARA® or Ustekinumab. Live vaccines should not be given to patients receiving either STELARA® or Ustekinumab. If PRES is suspected or if noninfectious pneumonia is confirmed, discontinue either STELARA® or Ustekinumab.

Please see related and other Important Safety Information on on pages 50 and 51.

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Johnson&Johnson

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Introduction

Reimbursement Support

Johnson & Johnson is committed to providing you with reimbursement information for STELARA® (ustekinumab) and Ustekinumab. This Billing Guide includes information regarding:

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

Information about STELARA® and Ustekinumab 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 JNJwithMe.com/hcp/stelara/.

This information is not a promise of coverage or payment. It is not intended to give reimbursement advice or increase reimbursement by any payer. The fact that a treatment is assigned a code and payment rate does not promise that it will be covered. Codes are used to describe products, procedures, or services on insurance claims. Payers use these codes with other information to figure out if treatment will be covered, and how much will be paid if covered. Legal requirements and plan information can be updated frequently. Contact the plan for more information about current coverage, reimbursement policies, restrictions, or requirements that may apply.

*CPT®, Current Procedural Terminology. CPT® is a registered trademark of the American Medical Association, 2025.

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Please see Important Safety Information for STELARA® and Ustekinumab on pages 50 and 51.

Please refer to the Dosage and Administration section of the accompanying full Prescribing Information and the Medication Guide for STELARA®, or the Dosage and Administration section of the accompanying full Prescribing Information and Medication Guide for Ustekinumab, for complete information on how to prepare and administer STELARA® or Ustekinumab.

Available formulations of STELARA® (ustekinumab) and Ustekinumab[1,2]

Single-dose vials for intravenous (IV) infusion*

*IV dose not approved for all indications.

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

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

Single-dose vials for subcutaneous injection

DOSE: 45 mg/0.5 mL VIAL

Coding for single-dose vials for subcutaneous injection is included in this billing guide for those plans continuing to provide coverage under a medical benefit.

Single-dose prefilled syringes for subcutaneous injection

45 mg/0.5 mL single-dose prefilled syringes

90 mg/mL single-dose prefilled syringes

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

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

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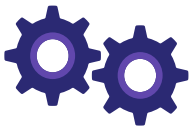
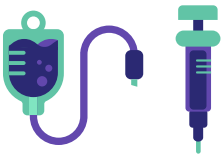
Ustekinumab is an Unbranded Biologic From the Makers of STELARA® (ustekinumab)

Ustekinumab from Johnson & Johnson is STELARA® without the brand name[1-3*]



Produced from the **same** cell line and at the **same** manufacturing sites as STELARA®

Approved for all of the **same** indications as STELARA® with the **same** safety and efficacy profile

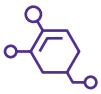


Available in the **same** strengths, **same** dosage forms, and **same** routes of administration as STELARA®

Has many of the **same** patient support programs as STELARA®

Understanding Unbranded Biologics

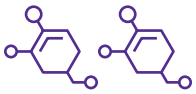
Ustekinumab is an unbranded biologic[3]



Brand-Name Biologic[4,5*]

Approved in a stand-alone BLA that demonstrates the product's safety and effectiveness

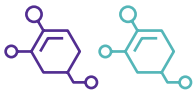
Produced through biotechnology in a living system (ie, a "cell line")



Unbranded Biologic[3]

Same product as the brand-name biologic* without the brand name, marketed under the **same** BLA

Produced using the same cell line as the brand-name biologic*



Biosimilar[5-7†]

Highly similar to brand-name biologic* with **no clinically meaningful differences** in terms of safety, purity, and potency (safety and effectiveness)

May be produced using the same or a different cell line

***"Brand-name" biologic refers to the FDA-approved reference biologic.**
†During the approval process, the FDA conducts a thorough evaluation that ensures that all biosimilars, including interchangeable biosimilars, are as safe and effective as their reference product and meet the FDA's high standards for approval.[6]

BLA, biologics license application; FDA, U.S. Food and Drug Administration.

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Ustekinumab

INDUCTION

For Crohn's Disease or Ulcerative Colitis

STELARA® (ustekinumab) and Ustekinumab intravenous (IV) use

Please see Important Safety Information for STELARA® and Ustekinumab on pages 50 and 51.

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Indications and usage[1,2]

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

Dosing and administration[1,2]

For the treatment of Crohn's disease or ulcerative colitis, STELARA® and Ustekinumab are administered in 2 phases: induction and maintenance. Table 1 summarizes the induction dose, provided as a single intravenous infusion.

Induction

Intravenous (IV) Induction: A single IV infusion dose of STELARA® or Ustekinumab using a weight-based dosage regimen administered over at least 1 hour (see Table 1).

Table 1: STELARA® and Ustekinumab Initial Intravenous Dosage

INDICATION	Patient Weight At Time of Dosing	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® or Ustekinumab 130 mg/26 mL (5 mg/mL) Vials for IV Infusion[1,2]

STELARA® or Ustekinumab 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® or Ustekinumab vials needed based on patient weight (Table 1). Each 26 mL vial of STELARA® or Ustekinumab 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® or Ustekinumab to be added (discard 26 mL sodium chloride for each vial of STELARA® or Ustekinumab 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® or Ustekinumab 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 8 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® or Ustekinumab concomitantly in the same IV line with other agents.
8. STELARA® and Ustekinumab do 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.

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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.[8] The table below lists possible ICD-10-CM diagnosis codes that you may consider for patients treated with STELARA® or Ustekinumab.

Table 2: ICD-10-CM Codes[9] for Consideration*

CROHN'S DISEASE	
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
ULCERATIVE COLITIS	
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.

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Coding (cont'd)

The initial dose of STELARA® or Ustekinumab 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 many private payers now also require the NDC for billing in addition to the HCPCS code, for healthcare provider claims and those of other service providers.[10] 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® or Ustekinumab to the 11-digit format, insert a leading zero into the middle sequence, as illustrated below.

Table 3: NDC for STELARA® or Ustekinumab (IV)

	FDA-Specified 10-Digit NDC (5-3-2 format)	11-Digit NDC (5-4-2 format)	Description
STELARA®	57894-054-27[2]	57894-0054-27	**130 mg vial** Single-use vial containing 130 mg/26 mL (5 mg/mL) of STELARA® or Ustekinumab for IV infusion
Ustekinumab	57894-444-01[1]	57894-0444-01	

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.[10] NDC units dispensed are based on the packaging and numeric quantity administered to the patient. Here are examples for 390-mg doses of STELARA® or Ustekinumab:

Table 4: STELARA® and Ustekinumab (IV) NDC Units

	Dose to Be Billed	NDC (11-Digit)	Packaging	NDC Unit of Measure	NDC Units
STELARA®	390 mg	57894-0054-27	130 mg/26 mL (5 mg/mL)(liquid)	ML	78
Ustekinumab	390 mg	57894-0444-01	130 mg/26 mL (5 mg/mL) vial (liquid)	ML	78

Accurate NDC coding typically requires the following components[10, 11]:

- 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

Examples

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

N457894005427 ML78

Coding format for 390-mg dose of Ustekinumab IV from single-dose vials:

N457894044401 ML78

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Coding (cont'd)

Healthcare Common Procedure Coding System (HCPCS) Level II Codes and NDCs

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 crossover 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 healthcare provider claims and those of other service providers.[10] 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® or Ustekinumab to the 11-digit format, insert a leading zero into the middle sequence, as illustrated below.

Table 5. HCPCS Code for STELARA® and Ustekinumab (IV)

Code	Description
J3358	Ustekinumab, for intravenous injection, 1 mg[12]

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

Each 1-mg dose of STELARA® or Ustekinumab (IV) equals 1 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® or Ustekinumab (IV) vials, milligrams, and HCPCS billing units.

Table 6. Vials, Doses, and Billing Units for STELARA® and Ustekinumab

Number of 130 mg/26 mL (5 mg/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 healthcare provider 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® or Ustekinumab Administration

Drug administration services are reported on claim forms in both the healthcare provider office (CMS-1500) and hospital outpatient (CMS-1450) sites of care using the CPT®* coding system. Payer policies for codes used to describe infusion services can vary. CPT codes that may apply to the administration of STELARA® or Ustekinumab (IV) include:

- **96365** - Intravenous infusion for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour[13]

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.[12]

- **96413** - Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug[13]

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.[13]

*CPT®, Current Procedural Terminology. CPT® is a registered trademark of the American Medical Association, 2025.

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 **STELARA withMe** 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 healthcare provider practice location is considered "nonfacility" (NF), allowing for the practice expenses to be included in the payment under the PFS. When professional services are performed in a facility (eg, hospital outpatient department), the practice does not incur the same expense (overhead, staff, equipment and supplies, etc); thus, payment under the PFS is generally lower for facility-based services than for NF.

The healthcare provider practice setting is indicated with POS code 11. To differentiate between on-campus and off-campus provider-based departments, CMS created POS code 19 and revised the POS code description for outpatient hospital (POS 22).

Professional services delivered in outpatient hospital settings must now specifically include the off-campus or on-campus POS on the claim form. Table 7 summarizes the potentially applicable POS codes.

Table 7. Place of Service Codes[14]

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, General[15]
- 0636 Pharmacy, drugs requiring detailed coding[15]

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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® or Ustekinumab IV use in healthcare provider offices and hospital outpatient departments (HOPDs).

Table 7. Place of Service Codes

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 healthcare provider or other qualified healthcare professional on the same day of the procedure or other service[13]	• Patient requires distinct E/M service in addition to the infusion procedure[13] • Must be substantiated by documentation that supports the relevant criteria for the reported E/M code[13] • Append the modifier to the appropriate E/M code[13]	✓ Required by Medicare	✓ Required by Medicare
PO†	Excepted services provided at an off-campus, outpatient, provider-based department of a hospital[12]	• To be reported on each claim line for excepted services furnished in an off-campus, provider-based department of a hospital and billed on an institutional claim[16]	N/A	✓ Required by Medicare
PN†	Non-excepted service provided at an off-campus, outpatient, provider-based department of a hospital[12]	• To be reported on each claim line for non-excepted services furnished in an off-campus provider-based department of a hospital and billed on an institutional claim[16]	N/A	✓ Required by Medicare
JW	Drug amount discarded/not administered to any patient[12]	• Applies only to the unused drug that is discarded after applicable dose has been administered from a single-use vial[11] • Append the modifier to the drug code on a line separate from that reporting the administered dose[11]	✓ Required by Medicare	✓ Required by Medicare
JZ	Zero drug amount discarded/not administered to any patient[12]	• To be used for single-dose containers or single-use packages when the entire amount has been administered to the patient (no wastage)[16]	✓ Required by Medicare	✓ Required by Medicare
TB	Drug or biological acquired with 340B pricing program discount, reported for informational purposes[12,16,17]	• Must be reported by all 340B covered entities submitting claims for separately payable drugs and biologicals[16] • To be reported on the same claim line as the drug HCPCS code for all 340B-acquired drugs[16]	N/A	✓ Required by Medicare

*CPT®, Current Procedural Terminology. CPT® is a registered trademark of the American Medical Association, 2025.

†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."[16]

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Other Coding Considerations (cont'd)

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

It may be necessary to provide E/M services on the same day as a drug administration procedure. Depending on the payer, E/M services that are medically necessary, separate and distinct from the drug administration procedure, 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 healthcare provider 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.***[18]

Thus, CPT® code 99211 cannot be paid on the same day as an office-based infusion of STELARA® or Ustekinumab. 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.[18]

Payer policies vary. For information and assistance, please contact STELARA withMe at **844-4withMe (844-494-8463)** or visit **STELARA withMe.**

CMS Discarded Drug Policy[11]

When a healthcare provider, 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

Medicare now requires 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.[19]

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 healthcare provider. Therefore, administration of the drug is payable if the drug would have been covered if the healthcare provider 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.[20] Payer policies may vary.

Please see Important Safety Information for STELARA® and Ustekinumab on pages 50 and 51.

Please refer to the Dosage and Administration section of the accompanying full Prescribing Information and the Medication Guide for STELARA®, or the Dosage and Administration section of the accompanying full Prescribing Information and Medication Guide for Ustekinumab, for complete information on how to prepare and administer STELARA® or Ustekinumab.

Ustekinumab

SAMPLE CLAIM FORMS

For Crohn's Disease or Ulcerative Colitis

STELARA® (ustekinumab) and Ustekinumab intravenous (IV) use

The following claim samples illustrate coding for intravenous (IV) use of STELARA® and Ustekinumab (J3357)

Please see Important Safety Information for STELARA® and Ustekinumab on pages 50 and 51.

Please refer to the Dosage and Administration section of the accompanying full Prescribing Information and the Medication Guide for STELARA®, or the Dosage and Administration section of the accompanying full Prescribing Information and Medication Guide for Ustekinumab, for complete information on how to prepare and administer STELARA® or Ustekinumab.

Sample claim forms

Healthcare Provider 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 1 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 1 processing system can handle both. Medicare Administrative Contractors may include a crosswalk between the ASC X12N 837I and the CMS-1450 on their websites.

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

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

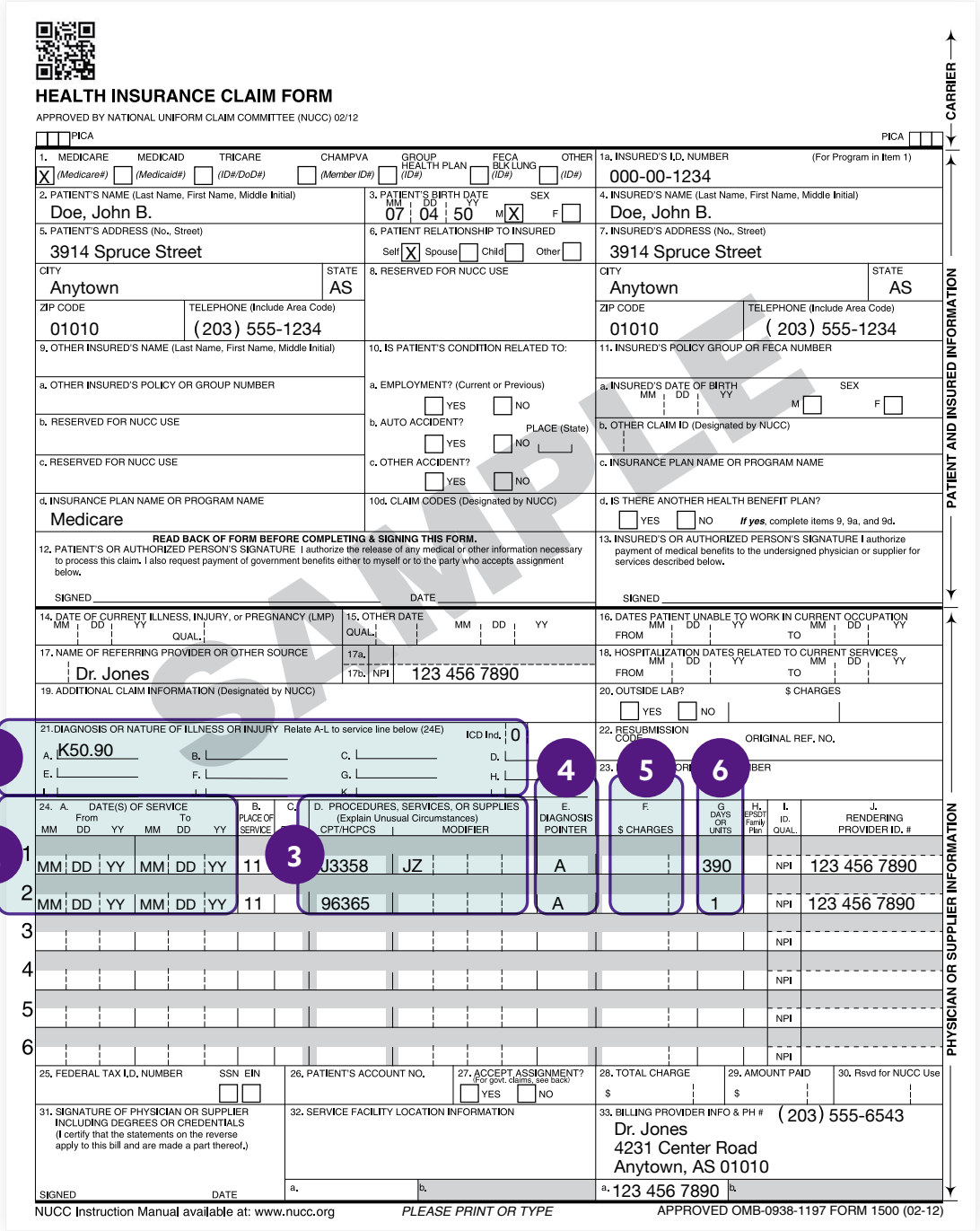
Please see Important Safety Information for STELARA® and Ustekinumab on pages 50 and 51.

Please refer to the Dosage and Administration section of the accompanying full Prescribing Information and the Medication Guide for STELARA®, or the Dosage and Administration section of the accompanying full Prescribing Information and Medication Guide for Ustekinumab, for complete information on how to prepare and administer STELARA® or Ustekinumab.

Sample claim forms (cont'd)

STELARA® or Ustekinumab for IV Use

Healthcare Provider Office Sample Claim Form (CMS-1500): 390-mg IV Induction Dose



HEALTH INSURANCE CLAIM FORM

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

PICA

1. MEDICARE [X] (Medicare#) MEDICAID [ ] (Medicaid#) TRICARE [ ] (ID#/DoD#) CHAMPVA [ ] (Member ID#) GROUP HEALTH PLAN [ ] (ID#) FECA BLK LUNG [ ] (ID#) OTHER [ ] (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: 07 04 50 SEX M [X] F [ ]

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 [X] Spouse [ ] Child [ ] Other [ ]

7. INSURED'S ADDRESS (No., Street): 3914 Spruce Street

CITY: Anytown STATE: AS

8. RESERVED FOR NUCC USE

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:

11. INSURED'S POLICY GROUP OR FECA NUMBER

a. OTHER INSURED'S POLICY OR GROUP NUMBER

a. EMPLOYMENT? (Current or Previous) YES [ ] NO [ ]

a. INSURED'S DATE OF BIRTH MM DD YY SEX M [ ] F [ ]

b. RESERVED FOR NUCC USE

b. AUTO ACCIDENT? YES [ ] NO [ ] PLACE (State)

b. OTHER CLAIM ID (Designated by NUCC)

c. RESERVED FOR NUCC USE

c. OTHER ACCIDENT? YES [ ] NO [ ]

c. INSURANCE PLAN NAME OR PROGRAM NAME

d. INSURANCE PLAN NAME OR PROGRAM NAME: Medicare

10d. CLAIM CODES (Designated by NUCC)

d. IS THERE ANOTHER HEALTH BENEFIT PLAN? YES [ ] NO [ ] If yes, complete items 9, 9a, and 9d.

READ BACK OF FORM BEFORE COMPLETING & SIGNING THIS FORM.

12. PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE I authorize the release of any medical or other information necessary to process this claim. I also request payment of government benefits either to myself or to the party who accepts assignment below.

SIGNED _____ DATE _____

13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE I authorize payment of medical benefits to the undersigned physician or supplier for services described below.

SIGNED _____

14. DATE OF CURRENT ILLNESS, INJURY, or PREGNANCY (LMP) MM DD YY QUAL.

15. OTHER DATE QUAL. MM DD YY

16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION MM DD YY FROM MM DD YY TO

17. NAME OF REFERRING PROVIDER OR OTHER SOURCE: Dr. Jones

17a.

17b. NPI 123 456 7890

18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES MM DD YY FROM MM DD YY TO

19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)

20. OUTSIDE LAB? YES [ ] NO [ ] $ CHARGES

21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E) ICD Ind. 0

A. K50.90 B. C. D. E. F. G. H.

22. RESUBMISSION CODE ORIGINAL REF. NO.

23. [illegible]BER

24. A. DATE(S) OF SERVICE From MM DD YY	To MM DD YY	B. PLACE OF SERVICE	C.	D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS	MODIFIER	E. DIAGNOSIS POINTER	F. $ CHARGES	G. DAYS OR UNITS	H. EPSDT Family Plan	I. ID. QUAL.	J. RENDERING PROVIDER ID. #
1 MM DD YY	MM DD YY	11		J3358	JZ	A		390		NPI	123 456 7890
2 MM DD YY	MM DD YY	11		96365		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? (For govt. claims, see back) YES [ ] NO [ ]

28. TOTAL CHARGE $

29. AMOUNT PAID $

30. Rsvd for NUCC Use

31. SIGNATURE OF PHYSICIAN OR SUPPLIER INCLUDING DEGREES OR CREDENTIALS (I certify that the statements on the reverse apply to this bill and are made a part thereof.)

SIGNED DATE

32. SERVICE FACILITY LOCATION INFORMATION

a. b.

33. BILLING PROVIDER INFO & PH # (203) 555-6543

Dr. Jones
4231 Center Road
Anytown, AS 01010

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

SAMPLE

1 2 3 4 5 6

Please see Important Safety Information for STELARA® and Ustekinumab on pages 50 and 51.

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Sample claim forms (cont'd)

STELARA® or Ustekinumab for IV Use

Healthcare Provider Office Sample Claim Form (CMS-1500): 390-mg IV Induction 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 24A**—If line item NDC information is required, it will be entered in the shaded portion of Item 24A.[13]

	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. #	
1	N457894005427 ML78																ER INFORMATION
	MM	DD	YY	MM	DD	YY			J3358	JZ	A		390		NPI	123 456 7890	
2																	
															NPI		

Payer requirements for NDC entries may vary.*

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

STELARA® or Ustekinumab
J3358 (Ustekinumab, for intravenous injection, 1 mg)

NOTE: Do not report STELARA® or Ustekinumab 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.[11] 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.[19]

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

5 **Item 24F—Indicate total charges.**

6 **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® or Ustekinumab 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.

*For information and assistance, please contact STELARA withMe at 844-4withMe (844-494-8463) or visit **STELARA withMe**.

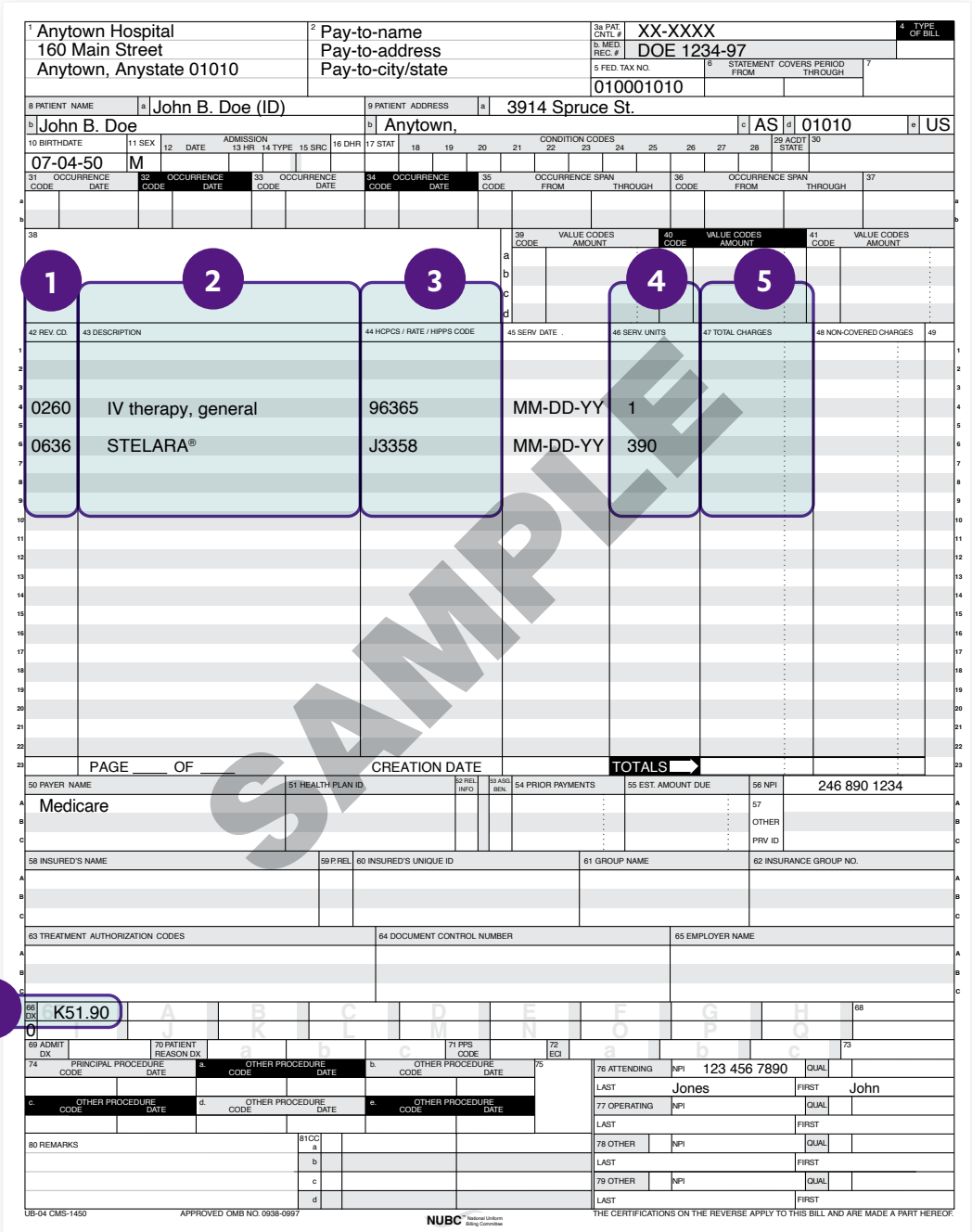
Please see Important Safety Information for STELARA® and Ustekinumab on pages 50 and 51.

Please refer to the Dosage and Administration section of the accompanying full Prescribing Information and the Medication Guide for STELARA®, or the Dosage and Administration section of the accompanying full Prescribing Information and Medication Guide for Ustekinumab, for complete information on how to prepare and administer STELARA® or Ustekinumab.

Sample claim forms (cont'd)

STELARA® or Ustekinumab for IV Use

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



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Sample claim forms (cont'd)

STELARA® or Ustekinumab 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 (eg, IV therapy, drug). If line item NDC information is required, it will be entered in the unshaded portions of Locator Box 43.[21] Payer requirements for NDC entries may vary.*

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

STELARA® or Ustekinumab
J3358 (Ustekinumab, for intravenous injection, 1 mg)

NOTE: Do not report STELARA® or Ustekinumab 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.[19]
- 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, provider-based department (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.[16]
- For informational purposes, the TB modifier must be reported for all 340B-acquired drugs.[15]

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® or Ustekinumab 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.

*For information and assistance, please contact STELARA withMe at 844-4withMe (844-494-8463) or visit **STELARA withMe**.

Please see Important Safety Information for STELARA® and Ustekinumab on pages 50 and 51.

Please refer to the Dosage and Administration section of the accompanying full Prescribing Information and the Medication Guide for STELARA®, or the Dosage and Administration section of the accompanying full Prescribing Information and Medication Guide for Ustekinumab, for complete information on how to prepare and administer STELARA® or Ustekinumab.

Ustekinumab

MAINTENANCE

For Crohn's Disease or Ulcerative Colitis

STELARA® (ustekinumab) and Ustekinumab subcutaneous injection

Please see Important Safety Information for STELARA® and Ustekinumab on pages 50 and 51.

Please refer to the Dosage and Administration section of the accompanying full Prescribing Information and the Medication Guide for STELARA®, or the Dosage and Administration section of the accompanying full Prescribing Information and Medication Guide for Ustekinumab, for complete information on how to prepare and administer STELARA® or Ustekinumab.

Indications and usage[1,2]

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

Dosing and administration[1,2]

Maintenance

The maintenance doses of STELARA® and Ustekinumab 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® or Ustekinumab Subcutaneous Dosage[1,2]

Indications	Dose	Frequency
Crohn's disease or ulcerative colitis	90 mg	• 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® or Ustekinumab for Subcutaneous Injection

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

If a healthcare provider determines that it is appropriate, a patient may self-inject or a caregiver may inject STELARA® or Ustekinumab 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® and Ustekinumab for Subcutaneous Injection

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

- Each vial of STELARA® and Ustekinumab for subcutaneous use contains 45 mg of ustekinumab in 0.5 mL. Determine the dose and number of STELARA® or Ustekinumab vials needed based on the indication
- Prior to administration, visually inspect STELARA® or Ustekinumab for particulate matter and discoloration. STELARA® and Ustekinumab are colorless to light yellow solutions and may contain a few small translucent or white particles. Do not use STELARA® or Ustekinumab if discolored or cloudy, or if other particulate matter is present. STELARA® and Ustekinumab do 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

Please see Important Safety Information for STELARA® and Ustekinumab on pages 50 and 51.

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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, many payers now also require the NDC for billing in addition to the HCPCS code, for healthcare provider claims and those of other service providers.[9] 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® or Ustekinumab to the 11-digit format, insert a leading zero into the middle sequence, as illustrated below.

Table 2: STELARA® and Ustekinumab Single-Dose Vial for Subcutaneous Injection NDCs

	FDA-Specified 10-Digit NDC (5-3-2 format)	11-Digit NDC (5-4-2 format)	Description
STELARA®	57894-060-02[2]	57894-0060-02	45-mg single-dose vial containing 45 mg of ustekinumab per 0.5 mL solution
Ustekinumab	57894-440-03[1]	57894-0440-03	

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.[9] NDC units dispensed are based on the packaging and numeric quantity administered to the patient. Here are examples for 90-mg doses of STELARA® or Ustekinumab:

Table 3: STELARA® and Ustekinumab (SC) NDC Units

	Dose to Be Billed	NDC (11-Digit)	Packaging	NDC Unit of Measure	NDC Units
STELARA®	90 mg	57894-0060-02	45 mg/0.5 mL vial x 2 vials	ML	1
Ustekinumab	90 mg	57894-0440-03	45 mg/0.5 mL vial x 2 vials	ML	1

Accurate NDC coding typically requires the following components[10,11]:

- 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

EXAMPLES:

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

N457894006002 ML1

Coding format for 90-mg dose of Ustekinumab from single-dose vials:

N457894044003 ML1

Please see Important Safety Information for STELARA® and Ustekinumab on pages 50 and 51.

Please refer to the Dosage and Administration section of the accompanying full Prescribing Information and the Medication Guide for STELARA®, or the Dosage and Administration section of the accompanying full Prescribing Information and Medication Guide for Ustekinumab, for complete information on how to prepare and administer STELARA® or Ustekinumab.

Coding (cont'd)

Healthcare Common Procedure Coding System (HCPCS) Level II Codes

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

Table 4. HCPCS Code for STELARA® and Ustekinumab

Code	Description
J3357	Ustekinumab, subcutaneous injection, 1 mg[12]

Thus, each 1-mg dose of STELARA® or Ustekinumab equals 1 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® and Ustekinumab vials, milligrams, and HCPCS billing units.

Table 5. STELARA® and Ustekinumab Single-Dose Vial 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® or Ustekinumab 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 healthcare provider 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® or Ustekinumab subcutaneous injection is:

Table 6. Potential CPT® Code for STELARA® or Ustekinumab for Subcutaneous Injection

Code	Description
96372	Therapeutic, prophylactic, or diagnostic injection; subcutaneous injection or intramuscular[13]

Please refer to the summary of code modifiers on page 13 for details.

Please see Important Safety Information for STELARA® and Ustekinumab on pages 50 and 51.

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Ustekinumab

SAMPLE CLAIM FORMS

For Crohn's Disease or Ulcerative Colitis

STELARA® (ustekinumab) and Ustekinumab subcutaneous injection

The following claim samples illustrate coding for the subcutaneous injection of STELARA® and Ustekinumab (J3357)

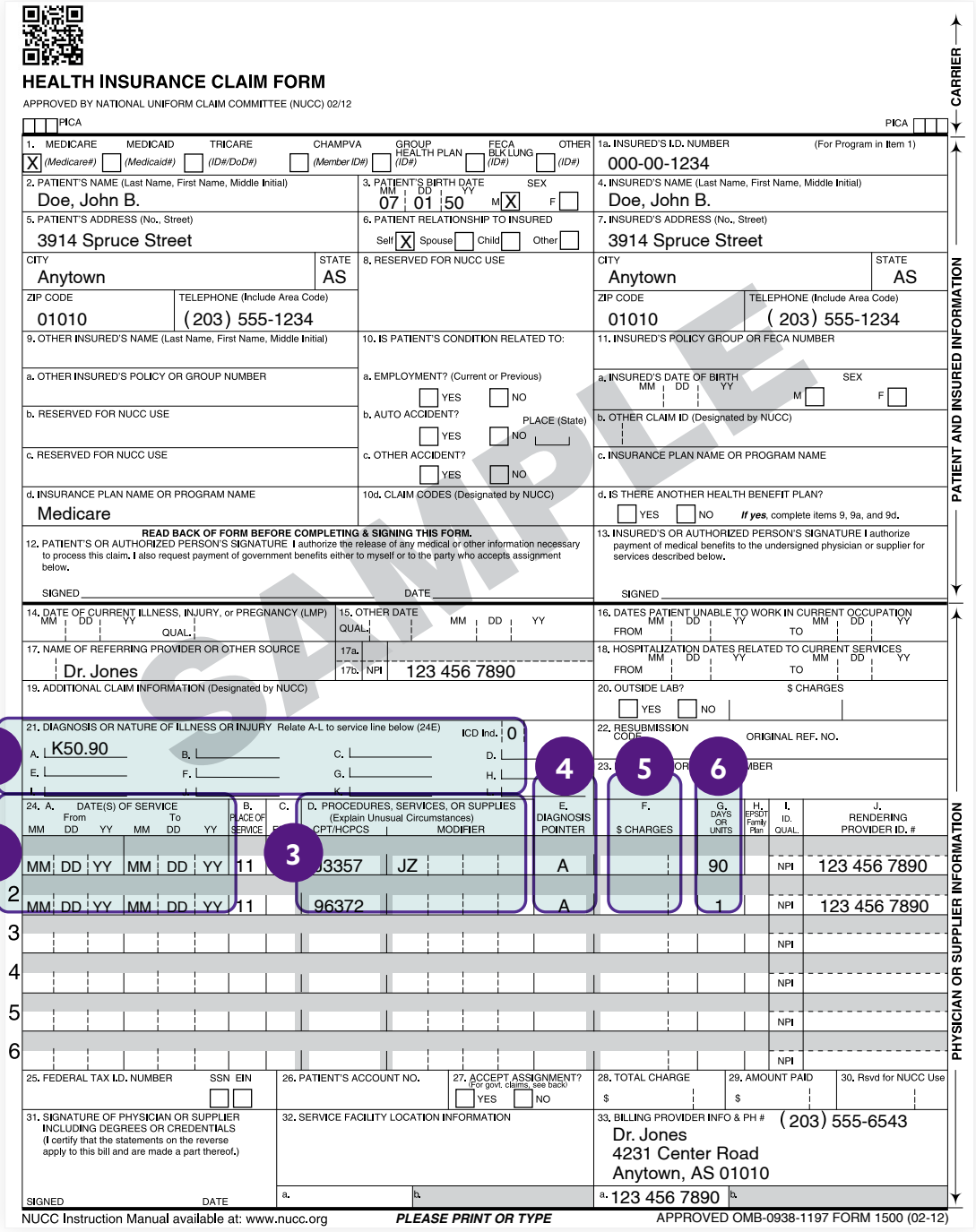
Please see Important Safety Information for STELARA® and Ustekinumab on pages 50 and 51.

Please refer to the Dosage and Administration section of the accompanying full Prescribing Information and the Medication Guide for STELARA®, or the Dosage and Administration section of the accompanying full Prescribing Information and Medication Guide for Ustekinumab, for complete information on how to prepare and administer STELARA® or Ustekinumab.

Sample claim forms

STELARA® or Ustekinumab Subcutaneous Injection for Maintenance

Healthcare Provider 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

PICA

1. MEDICARE [X] (Medicare#) MEDICAID [ ] (Medicaid#) TRICARE [ ] (ID#/DoD#) CHAMPVA [ ] (Member ID#) GROUP HEALTH PLAN [ ] (ID#) FECA BLK LUNG [ ] (ID#) OTHER [ ] (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: 07 01 50 SEX: M [X] F [ ]

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 [X] Spouse [ ] Child [ ] Other [ ]

7. INSURED'S ADDRESS (No., Street): 3914 Spruce Street

CITY: Anytown STATE: AS

8. RESERVED FOR NUCC USE

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:

11. INSURED'S POLICY GROUP OR FECA NUMBER

a. OTHER INSURED'S POLICY OR GROUP NUMBER

a. EMPLOYMENT? (Current or Previous) [ ] YES [ ] NO

a. INSURED'S DATE OF BIRTH SEX

b. RESERVED FOR NUCC USE

b. AUTO ACCIDENT? [ ] YES [ ] NO PLACE (State)

b. OTHER CLAIM ID (Designated by NUCC)

c. RESERVED FOR NUCC USE

c. OTHER ACCIDENT? [ ] YES [ ] NO

c. INSURANCE PLAN NAME OR PROGRAM NAME

d. INSURANCE PLAN NAME OR PROGRAM NAME: Medicare

10d. CLAIM CODES (Designated by NUCC)

d. IS THERE ANOTHER HEALTH BENEFIT PLAN? [ ] YES [ ] NO *If yes*, complete items 9, 9a, and 9d.

READ BACK OF FORM BEFORE COMPLETING & SIGNING THIS FORM.

12. PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE I authorize the release of any medical or other information necessary to process this claim. I also request payment of government benefits either to myself or to the party who accepts assignment below.

SIGNED _____ DATE _____

13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE I authorize payment of medical benefits to the undersigned physician or supplier for services described below.

SIGNED _____

14. DATE OF CURRENT ILLNESS, INJURY, or PREGNANCY (LMP) MM DD YY QUAL.

15. OTHER DATE QUAL. MM DD YY

16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION MM DD YY FROM TO

17. NAME OF REFERRING PROVIDER OR OTHER SOURCE: Dr. Jones

17a.

17b. NPI 123 456 7890

18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES MM DD YY FROM TO

19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)

20. OUTSIDE LAB? [ ] YES [ ] NO $ CHARGES

21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E) ICD Ind. 0

A. K50.90 B. C. D. E. F. G. H. I. J. K.

22. RESUBMISSION CODE ORIGINAL REF. NO.

23. OR NUMBER

24. A. DATE(S) OF SERVICE From MM DD YY To MM DD YY | B. PLACE OF SERVICE | C. 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. #

1	MM DD YY	MM DD YY	11		J3357	JZ	A		90		NPI	123 456 7890
2	MM DD YY	MM DD YY	11		96372		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? (For govt. claims, see back) [ ] YES [ ] NO

28. TOTAL CHARGE $

29. AMOUNT PAID $

30. Rsvd for NUCC Use

31. SIGNATURE OF PHYSICIAN OR SUPPLIER INCLUDING DEGREES OR CREDENTIALS (I certify that the statements on the reverse apply to this bill and are made a part thereof.)

SIGNED DATE

32. SERVICE FACILITY LOCATION INFORMATION

a. b.

33. BILLING PROVIDER INFO & PH # (203) 555-6543

Dr. Jones
4231 Center Road
Anytown, AS 01010

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

1 2 3 4 5 6

SAMPLE

Please see Important Safety Information for STELARA® and Ustekinumab on pages 50 and 51.

Please refer to the Dosage and Administration section of the accompanying full Prescribing Information and the Medication Guide for STELARA®, or the Dosage and Administration section of the accompanying full Prescribing Information and Medication Guide for Ustekinumab, for complete information on how to prepare and administer STELARA® or Ustekinumab.

Sample claim forms (cont'd)

STELARA® or Ustekinumab for SC Use

Healthcare Provider 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® or Ustekinumab (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.[14] For example:

	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. #
1	N457894006002 ML1															
	MM	DD	YY	MM	DD	YY			J3357	JZ	A		90		NPI	123 456 7890
2															NPI	
3															NPI	
4															NPI	

OR SUPPLIER INFORMATION

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.[11] 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.[19]

Please refer to page 13 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® or Ustekinumab 1 mg = 1 unit; STELARA® or Ustekinumab 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.

*For information and assistance, please contact STELARA withMe at 844-4withMe (844-494-8463) or visit **STELARA withMe**.

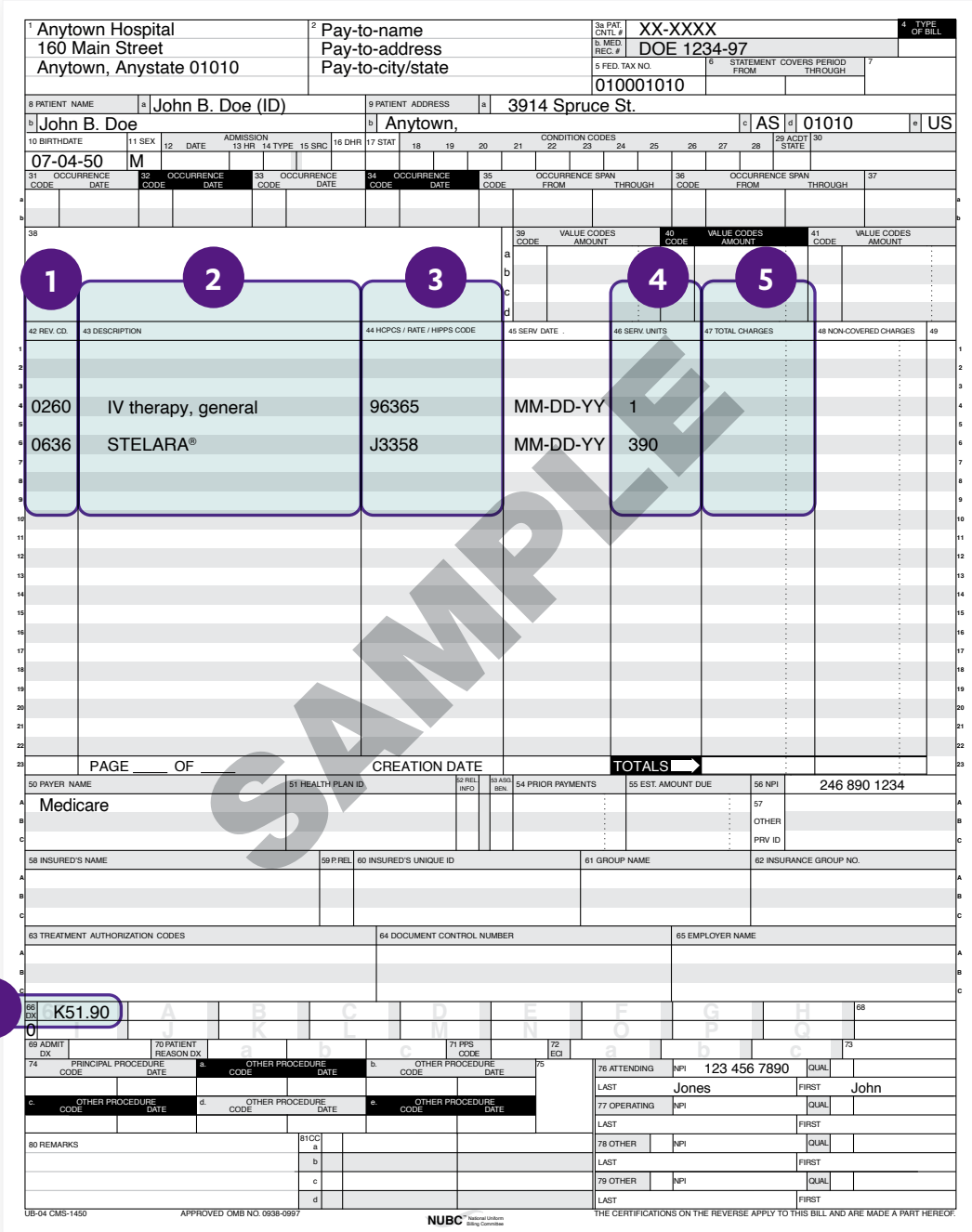
Please see Important Safety Information for STELARA® and Ustekinumab on pages 50 and 51.

Please refer to the Dosage and Administration section of the accompanying full Prescribing Information and the Medication Guide for STELARA®, or the Dosage and Administration section of the accompanying full Prescribing Information and Medication Guide for Ustekinumab, for complete information on how to prepare and administer STELARA® or Ustekinumab.

Sample claim forms (cont'd)

STELARA® or Ustekinumab (Subcutaneous Injection for Maintenance)

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



1	2	3	4	5
42 REV. CD.	43 DESCRIPTION	44 HCPCS / RATE / HIPPS CODE	45 SERV. DATE	46 SERV. UNITS	47 TOTAL CHARGES	48 NON-COVERED CHARGES
0260	IV therapy, general	96365	MM-DD-YY	1		
0636	STELARA®	J3358	MM-DD-YY	390		

Please see Important Safety Information for STELARA® and Ustekinumab on pages 50 and 51.

Please refer to the Dosage and Administration section of the accompanying full Prescribing Information and the Medication Guide for STELARA®, or the Dosage and Administration section of the accompanying full Prescribing Information and Medication Guide for Ustekinumab, for complete information on how to prepare and administer STELARA® or Ustekinumab.

Sample claim forms (cont'd)

STELARA® or Ustekinumab 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.[21] Payer requirements for NDC entries may vary.

3. **Locator Box 44**—Indicate appropriate CPT® and HCPCS codes.

   STELARA® or Ustekinumab (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.[11] 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.[19]

   Please refer to page 13 of this guide for a list of modifiers that may apply.

4. **Locator Box 46**—Enter the number of units:
   • 96372—Enter 1 unit for the subcutaneous injection
   • J3357—Enter the amount of drug in HCPCS units according to dose; 1 mg = 1 unit, each STELARA® or Ustekinumab 90 mg = 90 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.

Please see Important Safety Information for STELARA® and Ustekinumab on pages 50 and 51.

Please refer to the Dosage and Administration section of the accompanying full Prescribing Information and the Medication Guide for STELARA®, or the Dosage and Administration section of the accompanying full Prescribing Information and Medication Guide for Ustekinumab, for complete information on how to prepare and administer STELARA® or Ustekinumab.

INDUCTION AND MAINTENANCE

For Plaque Psoriasis or Psoriatic Arthritis

STELARA® (ustekinumab) and Ustekinumab subcutaneous injection

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.

Please see Important Safety Information for STELARA® and Ustekinumab on pages 50 and 51.

Please refer to the Dosage and Administration section of the accompanying full Prescribing Information and the Medication Guide for STELARA®, or the Dosage and Administration section of the accompanying full Prescribing Information and Medication Guide for Ustekinumab, for complete information on how to prepare and administer STELARA® or Ustekinumab.

Indications and usage for plaque PsO[1,2]

STELARA® and Ustekinumab are indicated for the treatment of adults and pediatric patients 6 years of age and older with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy.

Dosing and administration for plaque PsO[1,2]

STELARA® and Ustekinumab dosing may be weight-based. Induction and maintenance doses are administered by subcutaneous injection.

Table 1: STELARA® and Ustekinumab Subcutaneous Injection Dosing for Adult Patients With Plaque PsO

Patient Weight	Induction	Maintenance	STELARA® Vials (45 mg/0.5 mL Vials)
100 kg or less	45 mg at Week 0 and Week 4	45 mg every 12 weeks thereafter	1 vial
More than 100 kg	90 mg at Week 0 and Week 4	90 mg every 12 weeks thereafter	2 vials

Table 2: STELARA® and Ustekinumab Subcutaneous Injection Dosing for Pediatric Patients (6 to 17 Years Old) With Plaque PsO

Patient Weight	Induction	Maintenance	STELARA® Vials (45 mg/0.5 mL Vials)
Less than 60 kg*	0.75 mg/kg at Week 0 and Week 4	0.75 mg/kg every 12 weeks thereafter	<1 vial*
60 kg – 100 kg	45 mg at Week 0 and Week 4	45 mg every 12 weeks thereafter	1 vial
More than 100 kg	90 mg at Week 0 and Week 4	90 mg every 12 weeks thereafter	2 vials

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.

*For pediatric patients weighing less than 60 kg, see table 2 in the prescribing information; withdraw the appropriate volume from the single-dose vial.

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 see Important Safety Information for STELARA® and Ustekinumab on pages 50 and 51.

Please refer to the Dosage and Administration section of the accompanying full Prescribing Information and the Medication Guide for STELARA®, or the Dosage and Administration section of the accompanying full Prescribing Information and Medication Guide for Ustekinumab, for complete information on how to prepare and administer STELARA® or Ustekinumab.

Indications and usage for PsA[1,2]

STELARA® and Ustekinumab are indicated for the treatment of patients 6 years and older with active psoriatic arthritis.

Dosing and administration for PsA[1,2]

STELARA® and Ustekinumab dosing may be weight-based. Induction and maintenance doses are administered by subcutaneous injection.

Table 1: STELARA® and Ustekinumab Subcutaneous Injection Dosing for Adult Patients With PsA

Patient Weight	Induction	Maintenance	STELARA® Vials (45 mg/0.5 mL Vials)
All adult patients* (see exception below)	45 mg at Week 0 and Week 4	45 mg every 12 weeks thereafter	1 vial
Patients with co-existent moderate-to-severe plaque psoriasis weighing more than 100 kg	90 mg at Week 0 and Week 4	90 mg every 12 weeks thereafter	2 vials

Table 2: STELARA® and Ustekinumab Subcutaneous Injection Dosing for Pediatric Patients (6 to 17 Years Old) With PsA

Patient Weight	Induction	Maintenance	STELARA® Vials (45 mg/0.5 mL Vials)
Less than 60 kg†	0.75 mg/kg Week 0 and Week 4	0.75 mg/kg every 12 weeks thereafter	<1 vial*
60 kg – 100 kg	45 mg Week 0 and Week 4	45 mg every 12 weeks thereafter	1 vial
More than 100 kg with co-existent moderate-to-severe plaque psoriasis	90 mg Week 0 and Week 4	90 mg every 12 weeks thereafter	2 vials

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.

*Please refer to complete **Prescribing Information** for STELARA® or complete **Prescribing Information** for Ustekinumab, Table 2, for correlation between weight, dose, and injection volume.

†For pediatric patients weighing less than 60 kg, see table 2 in the prescribing information; withdraw the appropriate volume from the single-dose vial.

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 see Important Safety Information for STELARA® and Ustekinumab on pages 50 and 51.

Please refer to the Dosage and Administration section of the accompanying full Prescribing Information and the Medication Guide for STELARA®, or the Dosage and Administration section of the accompanying full Prescribing Information and Medication Guide for Ustekinumab, for complete information on how to prepare and administer STELARA® or Ustekinumab.

Dosing and administration: general considerations[1,2]

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® or Ustekinumab for Subcutaneous Injection

STELARA® and Ustekinumab are intended for use under the guidance and supervision of a healthcare provider. STELARA® or Ustekinumab should only be administered to patients who will be closely monitored and have regular follow-up visits with a healthcare provider. 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® or Ustekinumab be administered by a healthcare provider. If a healthcare provider determines that it is appropriate, a patient may self-inject or a caregiver may inject STELARA® or Ustekinumab after proper training in subcutaneous injection technique. Instruct patients to follow the directions provided in the **Medication Guide**.

General Considerations for Healthcare Provider Administration of STELARA® or Ustekinumab

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

- Each vial of STELARA® and Ustekinumab for subcutaneous use contains 45 mg of ustekinumab in 0.5 mL. Determine the dose and number of STELARA® or Ustekinumab vials needed based on the indication and patient weight. For adult patients with active psoriatic arthritis, weight should be considered only if patient has co-existent moderate-to-severe plaque psoriasis. For pediatric patients (6 to 17 years old) with psoriatic arthritis, please refer to **table 2** for weight-based dosing and administration
- Prior to administration, visually inspect STELARA® and Ustekinumab for particulate matter and discoloration. STELARA® and Ustekinumab are colorless to light yellow solutions and may contain a few small translucent or white particles. Do not use STELARA® or Ustekinumab if discolored or cloudy, or if other particulate matter is present. STELARA® and Ustekinumab do not contain preservatives; therefore, discard any unused product remaining in the vial
- Draw required dose using the Instructions for Use
- It is recommended that each injection be administered at a different anatomic location (such as upper arms, gluteal regions, thighs, or any quadrant of abdomen) than the previous injection, and not into areas where the skin is tender, bruised, erythematous, or indurated. When using the single-dose vial, a 1 mL syringe with a 27 gauge, 1/2 inch needle is recommended

Please see Important Safety Information for STELARA® and Ustekinumab on pages 50 and 51.

Please refer to the Dosage and Administration section of the accompanying full Prescribing Information and the Medication Guide for STELARA®, or the Dosage and Administration section of the accompanying full Prescribing Information and Medication Guide for Ustekinumab, for complete information on how to prepare and administer STELARA® or Ustekinumab.

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.[8] The table below lists possible ICD-10-CM diagnosis codes that you may consider for patients treated with STELARA® or Ustekinumab.

Table 2: ICD-10-CM Codes[8] for Consideration*

	PSORIATIC ARTHRITIS
L40.50	Arthropathic psoriasis, unspecified
L40.51	Distal interphalangeal psoriatic arthropathy
L40.52	Psoriatic arthritis mutilans
L40.53	Psoriatic spondylitis
L40.54	Psoriatic juvenile arthropathy
L40.59	Other psoriatic arthropathy
	PSORIASIS
L40.0	Psoriasis vulgaris (Plaque psoriasis)

*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, many private payers now also require the NDC for billing in addition to the HCPCS code for healthcare provider claims and those of other service providers.[10] 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® or Ustekinumab to the 11-digit format, insert a leading zero into the middle sequence, as illustrated below.

Table 3: NDC for STELARA® or Ustekinumab (SC)

	10-Digit NDC	11-Digit NDC	Description
STELARA®	57894-060-02	57894-0060-02	45-mg vial Single-dose vial containing 45 mg of ustekinumab per 0.5 mL solution
Ustekinumab	57894-440-03	57894-0440-03	

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.

Please see Important Safety Information for STELARA® and Ustekinumab on pages 50 and 51.

Please refer to the Dosage and Administration section of the accompanying full Prescribing Information and the Medication Guide for STELARA®, or the Dosage and Administration section of the accompanying full Prescribing Information and Medication Guide for Ustekinumab, for complete information on how to prepare and administer STELARA® or Ustekinumab.

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.[5] 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® and Ustekinumab:

Table 4: NDC Units for STELARA® and Ustekinumab (SC)

	Dose to be Billed	NDC (11-Digit)	Packaging	NDC Unit of Measure	NDC Units
STELARA®	90 mg	57894-0060-02	45 mg/0.5 mL vial x 2 vials	ML	1
Ustekinumab	90 mg	57894-0440-03	45 mg/0.5 mL vial x 2 vials	ML	1
STELARA®	45 mg	57894-0060-02	45 mg/0.5 mL vial	ML	0.5
Ustekinumab	45 mg	57894-0440-03	45 mg/0.5 mL vial	ML	0.5

Accurate NDC coding typically requires the following components[10,11]:

- 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

Coding format for 90-mg dose of Ustekinumab from single-dose vials:
N457894044003 ML1

EXAMPLE:
Coding format for 45-mg dose of STELARA® from single-dose vials:
N457894006002 ML0.5

Coding format for 45-mg dose of Ustekinumab from single-dose vials:
N457894044003 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 **STELARA withMe**.

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.

Please see Important Safety Information for STELARA® and Ustekinumab on pages 50 and 51.

Please refer to the Dosage and Administration section of the accompanying full Prescribing Information and the Medication Guide for STELARA®, or the Dosage and Administration section of the accompanying full Prescribing Information and Medication Guide for Ustekinumab, for complete information on how to prepare and administer STELARA® or Ustekinumab.

Coding (cont'd)

Healthcare Common Procedure Code System (HCPCS) Level II Codes

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

Table 5. HCPCS Code for STELARA® and Ustekinumab

Code	Description
J3357	Ustekinumab, subcutaneous injection, 1 mg[12]

Thus, each 1-mg dose of STELARA® or Ustekinumab 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® or Ustekinumab 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.

Table 6. STELARA® and Ustekinumab 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® or Ustekinumab 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 healthcare provider 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® and Ustekinumab subcutaneous injection is:

Table 7. Potential CPT® Code for STELARA® or Ustekinumab 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 13 for details.

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.

Please see Important Safety Information for STELARA® and Ustekinumab on pages 50 and 51.

Please refer to the Dosage and Administration section of the accompanying full Prescribing Information and the Medication Guide for STELARA®, or the Dosage and Administration section of the accompanying full Prescribing Information and Medication Guide for Ustekinumab, for complete information on how to prepare and administer STELARA® or Ustekinumab.

SAMPLE CLAIM FORMS

For Plaque Psoriasis or Psoriatic Arthritis

STELARA® (ustekinumab) and Ustekinumab subcutaneous injection

The following claim samples illustrate coding for the subcutaneous injection of STELARA® and Ustekinumab (J3357)

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.

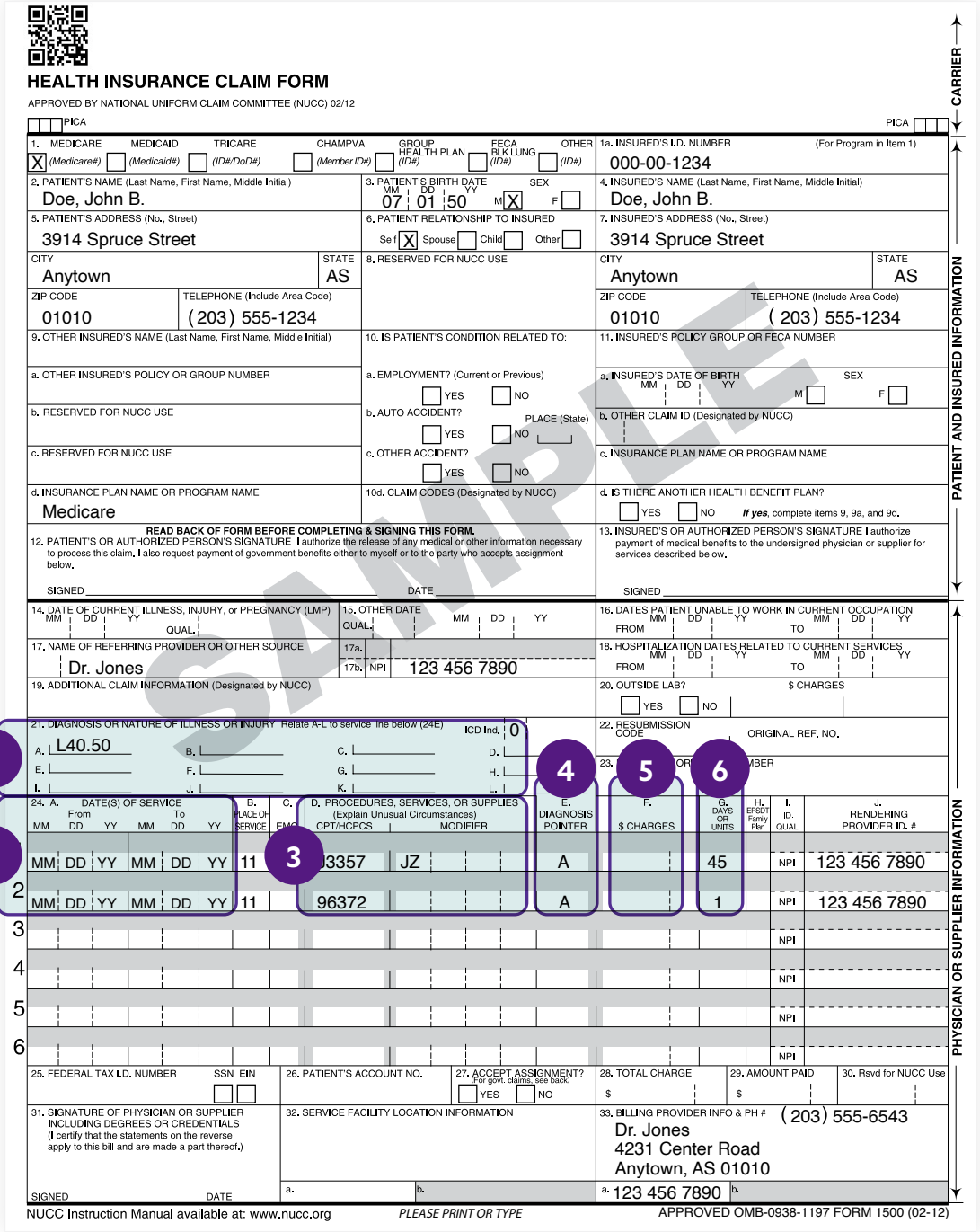
Please see Important Safety Information for STELARA® and Ustekinumab on pages 50 and 51.

Please refer to the Dosage and Administration section of the accompanying full Prescribing Information and the Medication Guide for STELARA®, or the Dosage and Administration section of the accompanying full Prescribing Information and Medication Guide for Ustekinumab, for complete information on how to prepare and administer STELARA® or Ustekinumab.

Sample claim forms

STELARA® or Ustekinumab for Subcutaneous Injection

Healthcare Provider Office Sample Claim Form: CMS-1500



HEALTH INSURANCE CLAIM FORM

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

PICA

1. MEDICARE [X] (Medicare#) MEDICAID [ ] (Medicaid#) TRICARE [ ] (ID#/DoD#) CHAMPVA [ ] (Member ID#) GROUP HEALTH PLAN [ ] (ID#) FECA BLK LUNG [ ] (ID#) OTHER [ ] (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: 07 01 50 SEX: M [X] F [ ]

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 [X] Spouse [ ] Child [ ] Other [ ]

7. INSURED'S ADDRESS (No., Street): 3914 Spruce Street

CITY: Anytown STATE: AS

8. RESERVED FOR NUCC USE

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:

11. INSURED'S POLICY GROUP OR FECA NUMBER

a. OTHER INSURED'S POLICY OR GROUP NUMBER

a. EMPLOYMENT? (Current or Previous) [ ] YES [ ] NO

a. INSURED'S DATE OF BIRTH SEX

b. RESERVED FOR NUCC USE

b. AUTO ACCIDENT? [ ] YES [ ] NO PLACE (State)

b. OTHER CLAIM ID (Designated by NUCC)

c. RESERVED FOR NUCC USE

c. OTHER ACCIDENT? [ ] YES [ ] NO

c. INSURANCE PLAN NAME OR PROGRAM NAME

d. INSURANCE PLAN NAME OR PROGRAM NAME: Medicare

10d. CLAIM CODES (Designated by NUCC)

d. IS THERE ANOTHER HEALTH BENEFIT PLAN? [ ] YES [ ] NO *If yes*, complete items 9, 9a, and 9d.

READ BACK OF FORM BEFORE COMPLETING & SIGNING THIS FORM.

12. PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE I authorize the release of any medical or other information necessary to process this claim. I also request payment of government benefits either to myself or to the party who accepts assignment below.

SIGNED _____ DATE _____

13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE I authorize payment of medical benefits to the undersigned physician or supplier for services described below.

SIGNED _____

14. DATE OF CURRENT ILLNESS, INJURY, or PREGNANCY (LMP) MM DD YY QUAL.

15. OTHER DATE QUAL. MM DD YY

16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION MM DD YY FROM MM DD YY TO

17. NAME OF REFERRING PROVIDER OR OTHER SOURCE: Dr. Jones

17a.

17b. NPI 123 456 7890

18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES MM DD YY FROM MM DD YY TO

19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)

20. OUTSIDE LAB? [ ] YES [ ] NO $ CHARGES

21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E) ICD Ind. 0

A. L40.50 B. C. D. E. F. G. H. I. J. K. L.

22. RESUBMISSION CODE ORIGINAL REF. NO.

23. PRIOR AUTHORIZATION NUMBER

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. #
1 MM DD YY	MM DD YY	11		93357	JZ	A		45		NPI	123 456 7890
2 MM DD YY	MM DD YY	11		96372		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? (For govt. claims, see back) [ ] YES [ ] NO

28. TOTAL CHARGE $

29. AMOUNT PAID $

30. Rsvd for NUCC Use

31. SIGNATURE OF PHYSICIAN OR SUPPLIER INCLUDING DEGREES OR CREDENTIALS (I certify that the statements on the reverse apply to this bill and are made a part thereof.)

SIGNED DATE

32. SERVICE FACILITY LOCATION INFORMATION

a. b.

33. BILLING PROVIDER INFO & PH # (203) 555-6543

Dr. Jones
4231 Center Road
Anytown, AS 01010

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

SAMPLE

1 2 3 4 5 6

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.

Please see Important Safety Information for STELARA® and Ustekinumab on pages 50 and 51.

Please refer to the Dosage and Administration section of the accompanying full Prescribing Information and the Medication Guide for STELARA®, or the Dosage and Administration section of the accompanying full Prescribing Information and Medication Guide for Ustekinumab, for complete information on how to prepare and administer STELARA® or Ustekinumab.

Sample claim forms (cont'd)

STELARA® or Ustekinumab for Subcutaneous Injection

Healthcare Provider 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® or Ustekinumab (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.[13] For example:

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. #
1 N457894006002 ML0.5															
MM	DD	YY	MM	DD	YY			J3357	JZ	A		45		NPI	123 456 7890
2														NPI	
3														NPI	
4														NPI	

OR SUPPLIER INFORMATION

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.[19] 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.[19]

Please refer to page 13 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® or Ustekinumab 1 mg = 1 unit
STELARA® or Ustekinumab 45 mg = 45 units
STELARA® or Ustekinumab 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.

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.

*For information and assistance, please contact STELARA withMe at 844-4withMe (844-494-8463) or visit **STELARA withMe**.

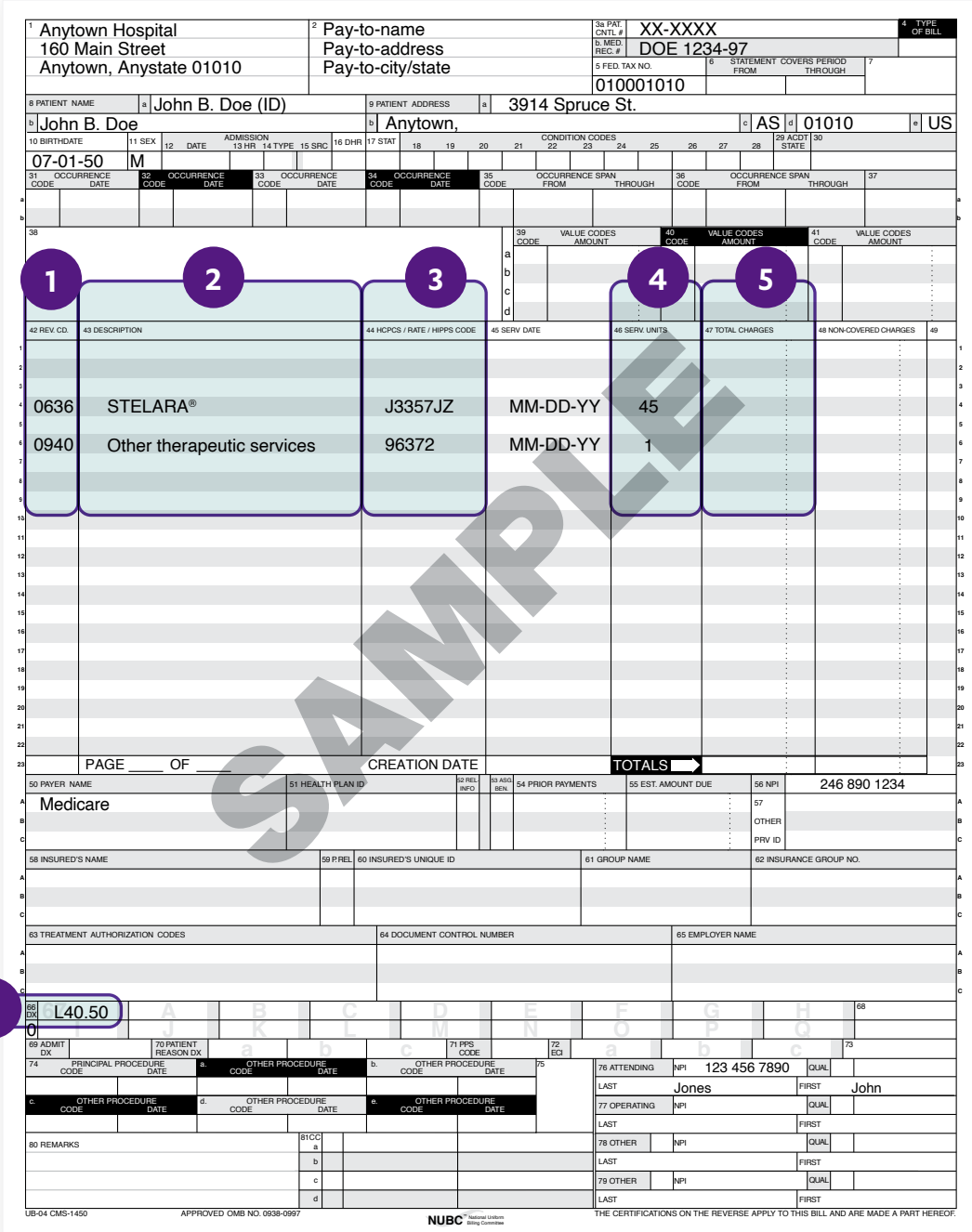
Please see Important Safety Information for STELARA® and Ustekinumab on pages 50 and 51.

Please refer to the Dosage and Administration section of the accompanying full Prescribing Information and the Medication Guide for STELARA®, or the Dosage and Administration section of the accompanying full Prescribing Information and Medication Guide for Ustekinumab, for complete information on how to prepare and administer STELARA® or Ustekinumab.

Sample claim forms (cont'd)

STELARA® or Ustekinumab for Subcutaneous Injection

HOPD Sample Claim Form: CMS-1450 (UB-04)



1 Anytown Hospital
160 Main Street
Anytown, Anystate 01010

2 Pay-to-name
Pay-to-address
Pay-to-city/state

3a PAT. CNTL. # XX-XXXX
b. MED. REC. # DOE 1234-97
4 TYPE OF BILL
5 FED. TAX NO. 010001010
6 STATEMENT COVERS PERIOD FROM THROUGH
7

8 PATIENT NAME a John B. Doe (ID)
b John B. Doe
9 PATIENT ADDRESS a 3914 Spruce St.
b Anytown, c AS d 01010 e US
10 BIRTHDATE 07-01-50
11 SEX M
12 DATE
ADMISSION 13 HR 14 TYPE 15 SRC
16 DHR
17 STAT
CONDITION CODES 18 19 20 21 22 23 24 25 26 27 28
29 ACDT STATE
30

31 OCCURRENCE CODE DATE
32 OCCURRENCE CODE DATE
33 OCCURRENCE CODE DATE
34 OCCURRENCE CODE DATE
35 OCCURRENCE SPAN CODE FROM THROUGH
36 OCCURRENCE SPAN CODE FROM THROUGH
37

38
39 VALUE CODES CODE AMOUNT
40 VALUE CODES CODE AMOUNT
41 VALUE CODES CODE AMOUNT

1 2 3 4 5

42 REV. CD.	43 DESCRIPTION	44 HCPCS / RATE / HIPPS CODE	45 SERV. DATE	46 SERV. UNITS	47 TOTAL CHARGES	48 NON-COVERED CHARGES	49
0636	STELARA®	J3357JZ	MM-DD-YY	45			
0940	Other therapeutic services	96372	MM-DD-YY	1			

PAGE ____ OF ____ CREATION DATE TOTALS

50 PAYER NAME Medicare
51 HEALTH PLAN ID
52 REL. INFO
53 ASG. BEN.
54 PRIOR PAYMENTS
55 EST. AMOUNT DUE
56 NPI 246 890 1234
57 OTHER PRV ID

58 INSURED'S NAME
59 P REL
60 INSURED'S UNIQUE ID
61 GROUP NAME
62 INSURANCE GROUP NO.

63 TREATMENT AUTHORIZATION CODES
64 DOCUMENT CONTROL NUMBER
65 EMPLOYER NAME

6
66 DX L40.50
0
68
69 ADMIT DX
70 PATIENT REASON DX
71 PPS CODE
72 ECI
73

74 PRINCIPAL PROCEDURE CODE DATE
a. OTHER PROCEDURE CODE DATE
b. OTHER PROCEDURE CODE DATE
75
c. OTHER PROCEDURE CODE DATE
d. OTHER PROCEDURE CODE DATE
e. OTHER PROCEDURE CODE DATE

76 ATTENDING NPI 123 456 7890 QUAL LAST Jones FIRST John
77 OPERATING NPI QUAL LAST FIRST
78 OTHER NPI QUAL LAST FIRST
79 OTHER NPI QUAL LAST FIRST

80 REMARKS
81CC a b c d

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

SAMPLE

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.

Please see Important Safety Information for STELARA® and Ustekinumab on pages 50 and 51.

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Sample claim forms (cont'd)

STELARA® or Ustekinumab 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.[20] Payer requirements for NDC entries may vary.

3. **Locator Box 44**—Indicate appropriate CPT® and HCPCS codes.

   STELARA® or Ustekinumab
   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.[11] 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.[19]

   Please refer to page 13 of this guide for a list of modifiers that may apply.

4. **Locator Box 46**—Enter the number of HCPCS units: STELARA® or Ustekinumab 1 mg = 1 unit; STELARA® or Ustekinumab 45 mg = 45 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.

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.

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Please see Important Safety Information for STELARA® and Ustekinumab on pages 50 and 51.

Please refer to the Dosage and Administration section of the accompanying full Prescribing Information and the Medication Guide for STELARA®, or the Dosage and Administration section of the accompanying full Prescribing Information and Medication Guide for Ustekinumab, for complete information on how to prepare and administer STELARA® or Ustekinumab.

Coverage considerations

Factors That Influence Coverage

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

Medical Necessity

When third-party payers review 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 healthcare provider's statement or Letter of Medical Necessity
- Supporting literature (eg, peer-reviewed studies and compendia monographs)
- Full Prescribing Information
- Availability of other treatment alternatives

Medical necessity refers to a decision by a health plan that a treatment, test, or procedure is necessary for health or to treat a diagnosed medical problem. Health insurance companies provide coverage only for health-related services that they define or determine to be medically necessary.

Medicare National Coverage Determinations (NCDs) 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 an "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 (eg, when there 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 healthcare provider make the referral for specialty care. Failing to obtain appropriate referrals or pre-authorization can result in non-payment by the plan.

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.

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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 (eg, 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 (eg, events leading to current condition, results of previous therapies, expected clinical progression, etc)
- expressing willingness to collaborate (eg, 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.

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.

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Please refer to the Dosage and Administration section of the accompanying full Prescribing Information and the Medication Guide for STELARA®, or the Dosage and Administration section of the accompanying full Prescribing Information and Medication Guide for Ustekinumab, for complete information on how to prepare and administer STELARA® or Ustekinumab.

Stelara withMe

Once a decision has been made to prescribe STELARA® (ustekinumab) or Ustekinumab

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® or Ustekinumab treatment journey.

The patient support and resources provided by STELARA withMe are not intended to give medical advice, replace a treatment plan from the patient's healthcare provider, offer services that would normally be performed by the provider's office, or serve as a reason to prescribe STELARA® or Ustekinumab.

Please see Important Safety Information for STELARA® and Ustekinumab on pages 50 and 51.

Please refer to the Dosage and Administration section of the accompanying full Prescribing Information and the Medication Guide for STELARA®, or the Dosage and Administration section of the accompanying full Prescribing Information and Medication Guide for Ustekinumab, for complete information on how to prepare and administer STELARA® or Ustekinumab.

Once a decision has been made to prescribe STELARA® (ustekinumab) or Ustekinumab

STELARA withMe is all about dedicated support

Nurse Navigator*

Once enrolled, a dedicated Nurse Navigator—a registered nurse— is available to patients to offer support and answer questions about STELARA® and Ustekinumab, including supplemental self-injection training, infusion support, coverage, and options for saving on treatment.

*Nurse Navigators do not provide medical advice.

Access and Affordability Support

We can help verify insurance coverage, provide reimbursement information, find cost support options, enroll eligible patients in the Savings Program, and offer ongoing support so you can help patients start and stay on STELARA® or Ustekinumab.

Reimbursement Support

Your Field Reimbursement Manager (FRM) provides in-office educational support and additional assistance to help patients throughout their STELARA® or Ustekinumab treatment journey.

For support resources, visit **JNJwithMe.com/hcp/stelara/**.

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

The patient support and resources provided by STELARA withMe are not intended to give medical advice, replace a treatment plan from the patient's healthcare provider, offer services that would normally be performed by the provider's office, or serve as a reason to prescribe STELARA® or Ustekinumab.

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Please refer to the Dosage and Administration section of the accompanying full Prescribing Information and the Medication Guide for STELARA®, or the Dosage and Administration section of the accompanying full Prescribing Information and Medication Guide for Ustekinumab, for complete information on how to prepare and administer STELARA® or Ustekinumab.

Appendix

Sample Letter of Medical Necessity

Some payers and other formulary decision makers may require that treating healthcare providers complete a Letter of Medical Necessity before patients can receive a specific therapy. Download a sample letter template at **STELARA withMe**, or you may create a customized letter in the Provider Portal at **Portal.JNJwithMe.com**.

[Insert Physician Letterhead]

[Insert Name of Medical Director]
[Insert Payer Name]
[Insert Address]
[Insert City, State ZIP]

Re: Member Name: [Insert Member Name]
Member Number: [Insert Member Number]
Group Number: [Insert Group Number]

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]

Please see Important Safety Information for STELARA® and Ustekinumab on pages 50 and 51.

Please refer to the Dosage and Administration section of the accompanying full Prescribing Information and the Medication Guide for STELARA®, or the Dosage and Administration section of the accompanying full Prescribing Information and Medication Guide for Ustekinumab, for complete information on how to prepare and administer STELARA® or Ustekinumab.

Appendix

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

Letter templates for **Crohn's Disease** or **Ulcerative Colitis** are available for download, or you may create a customized letter in the Provider Portal at **Portal.JNJwithMe.com**.

[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]

[Insert Physician Letterhead]

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

REQUEST: Authorization for treatment with STELARA® (ustekinumab)
DIAGNOSIS: [Insert Diagnosis] [Insert ICD]
DOSE AND FREQUENCY: [Insert Dose & Frequency]
REQUEST TYPE: ☐ Standard ☐ EXPEDITED

Dear [Insert Name of Medical Director]:

I am writing to request a **formulary exception** for the above-mentioned patient to receive treatment with STELARA® for ulcerative colitis. 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: hospital outpatient, outpatient clinic, private practice, or other
- 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 of 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 warranted, appropriate, and medically necessary, and should be a covered and reimbursed service.]

[You may consider including documents that provide additional clinical information to support the recommendation for STELARA® for this patient, such as the full Prescribing Information, peer-reviewed journal articles, or clinical guidelines.]

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

Sincerely,

[Insert Physician Name and Participating Provider Number]

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

Please see Important Safety Information for STELARA® and Ustekinumab on pages 50 and 51.

Please refer to the Dosage and Administration section of the accompanying full Prescribing Information and the Medication Guide for STELARA®, or the Dosage and Administration section of the accompanying full Prescribing Information and Medication Guide for Ustekinumab, for complete information on how to prepare and administer STELARA® or Ustekinumab.

Appendix

Psoriatic Arthritis Sample Format Exception Letter

Letter template available for download at **STELARA withMe**, or you may create a customized letter in the Provider Portal at **Portal.JNJwithMe.com**.

[Insert Physician Letterhead]

[Insert Name of Medical Director]
[Insert Payer Name]
[Insert Address]
[Insert City, State ZIP]

Re: Member Name: [Insert Member Name]
Member Number: [Insert Member Number]
Group Number: [Insert Group Number]

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]

Please see Important Safety Information for STELARA® and Ustekinumab on pages 50 and 51.

Please refer to the Dosage and Administration section of the accompanying full Prescribing Information and the Medication Guide for STELARA®, or the Dosage and Administration section of the accompanying full Prescribing Information and Medication Guide for Ustekinumab, for complete information on how to prepare and administer STELARA® or Ustekinumab.

Appendix

Plaque Psoriasis Sample Format Exception Letter

Letter template available for download at **STELARA withMe**, or you may create a customized letter in the Provider Portal at **Portal.JNJwithMe.com**.

[Insert Physician Letterhead]

[Insert Name of Medical Director]
[Insert Payer Name]
[Insert Address]
[Insert City, State ZIP]

Re: Member Name: [Insert Member Name]
Member Number: [Insert Member Number]
Group Number: [Insert Group Number]

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]

Please see Important Safety Information for STELARA® and Ustekinumab on pages 50 and 51.

Please refer to the Dosage and Administration section of the accompanying full Prescribing Information and the Medication Guide for STELARA®, or the Dosage and Administration section of the accompanying full Prescribing Information and Medication Guide for Ustekinumab, for complete information on how to prepare and administer STELARA® or Ustekinumab.

IMPORTANT SAFETY INFORMATION

INDICATIONS

STELARA® (ustekinumab) and Ustekinumab are indicated for the treatment of patients 6 years and older with active psoriatic arthritis.

STELARA® (ustekinumab) and Ustekinumab are indicated for the treatment of patients 6 years and older with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy.

STELARA® (ustekinumab) and Ustekinumab are indicated for the treatment of adult patients with moderately to severely active Crohn's disease.

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

IMPORTANT SAFETY INFORMATION

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

Infections

STELARA® and Ustekinumab 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 plaque 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 either STELARA® or Ustekinumab 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 either STELARA® or Ustekinumab 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 either STELARA® or Ustekinumab and discontinue either STELARA® or Ustekinumab 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 either STELARA® or Ustekinumab may be susceptible to these types of infections. Consider diagnostic testing, eg, tissue culture, stool culture, as dictated by clinical circumstances.

Pre-Treatment Evaluation of Tuberculosis (TB)

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

Malignancies

STELARA® and Ustekinumab are immunosuppressants and may increase the risk of malignancy. Malignancies were reported among patients who received either STELARA® or Ustekinumab in clinical trials. The safety of STELARA® and Ustekinumab 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 either STELARA® or Ustekinumab who had risk factors for developing non-melanoma skin cancer (NMSC). All patients receiving either STELARA® or Ustekinumab, 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® and Ustekinumab. If an anaphylactic or other clinically significant hypersensitivity reaction occurs, institute appropriate therapy and discontinue either STELARA® or Ustekinumab.

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 either STELARA® or Ustekinumab for signs and symptoms of PRES. If PRES is suspected, promptly administer appropriate treatment and discontinue either STELARA® or Ustekinumab.

(Continued on next page)

Please see Important Safety Information for STELARA® and Ustekinumab on pages 50 and 51.

Please refer to the Dosage and Administration section of the accompanying full Prescribing Information and the Medication Guide for STELARA®, or the Dosage and Administration section of the accompanying full Prescribing Information and Medication Guide for Ustekinumab, for complete information on how to prepare and administer STELARA® or Ustekinumab.

IMPORTANT SAFETY INFORMATION

Immunizations

Prior to initiating therapy with STELARA® and Ustekinumab, patients should receive all age-appropriate immunizations as recommended by current immunization guidelines. Patients being treated with either STELARA® or Ustekinumab should avoid receiving live vaccines. Avoid administering BCG vaccines during treatment with either STELARA® or Ustekinumab or for one year prior to initiating treatment or one year following discontinuation of treatment. Caution is advised when administering live vaccines to household contacts of patients receiving either STELARA® or Ustekinumab because of the potential risk for shedding from the household contact and transmission to patient. Non-live vaccinations received during a course of either STELARA® or Ustekinumab may not elicit an immune response sufficient to prevent disease.

Noninfectious Pneumonia

Cases of interstitial pneumonia, eosinophilic pneumonia, and cryptogenic organizing pneumonia have been reported during post-approval use of STELARA® and Ustekinumab. 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 either STELARA® or Ustekinumab and institute appropriate treatment.

Allergen Immunotherapy

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

Most Common Adverse Reactions

The most common adverse reactions (≥3% and higher than that with placebo) in adults from plaque psoriasis clinical trials for STELARA® and Ustekinumab 45 mg, STELARA® and Ustekinumab 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) trials, a higher incidence of arthralgia and nausea was observed in patients treated with STELARA® and Ustekinumab when compared with placebo (3% vs 1% for both). In Crohn's disease induction trials, common adverse reactions (3% or more of patients treated with STELARA® and Ustekinumab and higher than placebo) reported through Week 8 for STELARA® and Ustekinumab 6 mg/kg intravenous single infusion or placebo included: vomiting (4% vs 3%). In the Crohn's disease maintenance trial, common adverse reactions (3% or more of patients treated with STELARA® and Ustekinumab and higher than placebo) reported through Week 44 for STELARA® and Ustekinumab 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 trial, common adverse reactions (3% or more of patients treated with STELARA® and Ustekinumab and higher than placebo) reported through Week 8 for STELARA® and Ustekinumab 6 mg/kg intravenous single infusion or placebo included: nasopharyngitis (7% vs 4%). In the ulcerative colitis maintenance trial, common adverse reactions (3% or more of patients treated with STELARA® and Ustekinumab and higher than placebo) reported through Week 44 for STELARA® and Ustekinumab 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 click to read the full Prescribing Information and Medication Guide for STELARA® and the full Prescribing Information and Medication Guide for Ustekinumab. Provide the Medication Guide to your patients and encourage discussion.

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Please see Important Safety Information for STELARA® and Ustekinumab on pages 50 and 51.

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Please see Important Safety Information for STELARA® and Ustekinumab on pages 50 and 51.

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