

2010 Coding and Billing for STELARA™ (ustekinumab)

Coding Information and Sample CMS-1500 and UB-04 Forms

Depending upon Medicare and individual private payer policies, some combination of the following codes may be appropriate for describing provision of therapy with STELARA™ on physician office and hospital outpatient claims.

Please pay special attention to the “CPT® and HCPCS Codes” for the full section of codes that may be used in 2010 for Medicare and some private payers.

Physician Offices

Location on CMS-1500 Form

Diagnosis Code: ICD-9

696.1 Plaque psoriasis

Procedures, Services, and Supplies Code: CPT® and HCPCS

Private payer policies regarding the use of code 96372 may vary. Consult local payer for coding policy.

96372^{1*} Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular[†]

Code for STELARA™: HCPCS

J3590[‡] Unclassified biologic

NOTE: Medi-Cal (California Medicaid) requires use of J3590 and the 11-digit NDC code 57894-0060-03 (45 mg single-use prefilled syringe) or 57894-0061-03 (90 mg single-use prefilled syringe) or 57894-0060-02 (45 mg single-use vial) on all claims.

Coding Units for STELARA™

Number of units provided

1 unit—one 45 mg single-use prefilled syringe;
1 unit—one 90 mg single-use prefilled syringe
1 unit—one 45 mg vial; 2 units—two 45 mg vials

Codes for STELARA™: NDC (10-digit format)

57894-060-03 STELARA™ single-use prefilled syringe, 45 mg
57894-061-03 STELARA™ single-use prefilled syringe, 90 mg
57894-060-02 STELARA™ single-use vial, 45 mg

NOTE: To convert a 10-digit NDC to an 11-digit NDC, a leading 0 should be added to the middle set of numbers.

Item 21

Inclusion in the CPT® codebook does not represent endorsement by the American Medical Association (AMA) of any particular diagnostic or therapeutic procedure. Inclusion or exclusion of a procedure does not imply any health insurance coverage or reimbursement policy.

Item 24D

To the right of Item 24D[§]

Item 24G

Item 19[¶]

Hospital Outpatient Departments

Location on UB-04 Form

Diagnosis Code: ICD-9

696.1 Plaque psoriasis

Procedures, Services, and Supplies Code: CPT® and HCPCS

Private payer policies regarding the use of code 96372 may vary. Consult local payer for coding policy.

96372^{2*} Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular[†]

Procedure Code: ICD-9

99.29 Injection or infusion of other therapeutic or prophylactic substance

Revenue Codes: AHA[†]

0510 Clinic visit—general classification

0636[#] Drugs requiring detailed coding

Codes for STELARA™: HCPCS

J3590[‡] Unclassified biologic

C9261^{3**} Injection, ustekinumab, 1 mg (Medicare)

NOTE: Medi-Cal (California Medicaid) requires use of J3590 and the 11-digit NDC code 57894-0060-03 (45 mg single-use prefilled syringe) or 57894-0061-03 (90 mg single-use prefilled syringe) or 57894-0060-02 (45 mg single-use vial) on all claims.

Coding Units for STELARA™

Number of units provided

1 unit—one 45 mg single-use prefilled syringe;
1 unit—one 90 mg single-use prefilled syringe
1 unit—one 45 mg vial; 2 units—two 45 mg vials

Codes for STELARA™: NDC (10-digit format)

57894-060-03 STELARA™ single-use prefilled syringe, 45 mg
57894-061-03 STELARA™ single-use prefilled syringe, 90 mg
57894-060-02 STELARA™ single-use vial, 45 mg

NOTE: To convert a 10-digit NDC to an 11-digit NDC, a leading 0 should be added to the middle set of numbers.

Locator Box 66

Inclusion in the CPT® codebook does not represent endorsement by the American Medical Association (AMA) of any particular diagnostic or therapeutic procedure. Inclusion or exclusion of a procedure does not imply any health insurance coverage or reimbursement policy.

Locator Box 44

Locator Box 74

Locator Boxes 42 and 43

Locator Box 44[§] or Electronic Comment Field (if available)

Locator Box 46

Locator Box 80

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This document is presented for informational purposes only and is not intended to provide reimbursement or legal advice. Laws, regulations, and policies concerning reimbursement are complex and are updated frequently. While we have made an effort to be current as of the issue date of this document, the information may not be as current or comprehensive when you view it. Similarly, all CPT® and HCPCS codes are supplied for informational purposes only and this information does not represent any statement, promise or guarantee by Centocor Ortho Biotech Inc. about coverage, levels of reimbursement, payment or charge. Please consult with your payer organization(s) for local or actual coverage and reimbursement policies and determination processes. Please consult with your counsel or reimbursement specialist for any reimbursement or billing questions specific to your institution.

* Append HCPCS modifier “-76” to the CPT® code 96372 to indicate repeat procedure or service by same physician.

† These codes are not intended to be reported by the physician in the facility setting.

‡ Requires a Treatment Authorization Request (TAR) and must be billed with an invoice for pricing. Providers must also document the following on the TAR: medical necessity for using the drug; name, dosage, strength, and unit price of the medication.

§ If the NDC is used in item 24D or Form Locator 44, the “units of measure” will likely be 1 unit = one 45 mg single-use prefilled syringe or 1 unit = one 90 mg single-use prefilled syringe or 1 unit = one 45 mg single-use vial. Please consult with your local payer for additional guidance.

¶ In some cases, physician offices may choose to provide additional detail by providing the NDC in Item 19.

¶ This is not an all-inclusive list of revenue codes. Use of revenue codes will vary by institution.

Use revenue code 0636 to align HCPCS J3590 with appropriate category on the hospital cost report.

** If using code C9261, be sure to indicate the appropriate number of units in Locator Box 46. 45 units = one 45 mg single-use prefilled syringe or one 45 mg vial; 90 units = one 90 mg single-use prefilled syringe or two 45 mg vials.

Please see Indication and Important Safety Information for STELARA™ on reverse.

INDICATION

STELARA™ (ustekinumab) is indicated for the treatment of adult patients (18 years or older) with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy.

IMPORTANT SAFETY INFORMATION FOR STELARA™

Infections

STELARA™ may increase the risk of infections and reactivation of latent infections. Serious bacterial, fungal, and viral infections were reported. Infections requiring hospitalization included cellulitis, diverticulitis, osteomyelitis, gastroenteritis, pneumonia, and urinary tract infections. STELARA™ should not be given to patients with a clinically important active infection and should not be administered until the infection resolves or is adequately treated. Instruct patients to seek medical advice if signs or symptoms suggestive of an infection occur. Exercise caution when considering use of STELARA™ in patients with a chronic infection or a history of recurrent infection.

Theoretical Risk for Vulnerability to Particular Infections

Individuals genetically deficient in IL-12/IL-23 are particularly vulnerable to disseminated infections from mycobacterium, *Salmonella*, and *Bacillus Calmette-Guerin* (BCG) vaccinations. Serious infections and fatal outcomes have been reported in such patients. It is not known whether patients with pharmacologic blockade of IL-12/IL-23 from treatment with STELARA™ will be susceptible to these types of infections. Consider appropriate diagnostic testing as dictated by clinical circumstances.

Pre-Treatment Evaluation of Tuberculosis (TB)

Evaluate patients for TB prior to initiating treatment with STELARA™. STELARA™ should not be given to patients with active TB. Initiate treatment of latent TB before administering STELARA™. Patients should be monitored closely for signs and symptoms of active TB during and after treatment with STELARA™.

Malignancies

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

Reversible Posterior Leukoencephalopathy Syndrome (RPLS)

One case of RPLS has been reported in a STELARA™-treated patient. If RPLS is suspected, discontinue STELARA™ and administer appropriate treatment.

RPLS is a neurological disorder, which is not caused by an infection or demyelination. RPLS can present with headache, seizures, confusion, and visual disturbances. RPLS has been associated with fatal outcomes.

Immunizations

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

Concomitant Therapies

The safety of STELARA™ in combination with other immunosuppressive agents or phototherapy has not been evaluated. Ultraviolet-induced skin cancers developed earlier and more frequently in mice genetically manipulated to be deficient in both IL-12 and IL-23 or IL-12 alone. The relevance of these findings in mouse models for malignancy risk in humans is unknown.

Most Common Adverse Reactions

The most common adverse reactions (≥3% and higher than that with placebo) in clinical trials for STELARA™ 45 mg, STELARA™ 90 mg, or placebo were: nasopharyngitis (8%, 7%, 8%), upper respiratory tract infection (5%, 4%, 5%), headache (5%, 5%, 3%), and fatigue (3%, 3%, 2%), respectively.

Please see accompanying Full Prescribing Information and Medication Guide for STELARA™.

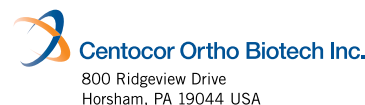
one call...for benefits investigation and billing and reimbursement support for STELARA™



1-888-ACCESS-1 (222-3771)
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single-source support for access to treatment with STELARA™

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1. Medicare Program: Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2010. 74 *Federal Register* 62136 (2009). 2. Medicare Program: Changes to the Hospital Outpatient Prospective Payment System and CY 2010 Payment Rates; Changes to the Ambulatory Surgical Center Payment System and CY 2010 Payment Rates. 74 *Federal Register* 60852 (2009). 3. Centers for Medicare & Medicaid Services web site. April 10, 2010 HCPCS C-codes. Available at: http://www.cms.hhs.gov/HCPSCReleaseCodeSets/Q2_HCPCS_Quarterly_Update.asp.

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