Accessing STELARA®

Your comprehensive guide to obtaining STELARA® for your appropriate patients

Specialty products like STELARA® may be covered for your patients under the medical benefit, the pharmacy benefit, or both. It's important to investigate both benefits to ensure seamless processing and timely delivery of STELARA® to your patients.

STELARA® 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.

STELARA® is indicated for the treatment of adult patients (18 years or older) with active psoriatic arthritis. STELARA® can be used alone or in combination with methotrexate (MTX).

STELARA®, available as 45 mg and 90 mg, is a subcutaneous injection intended for use under the guidance and supervision of a physician with patients who will be closely monitored and have regular follow-up. Patients may self-inject with STELARA® after physician approval and proper training. Patients should be instructed to follow the directions provided in the Medication Guide.[1]

Selected Safety Information

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

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

Please see related and other Important Safety Information for STELARA® on back.

Stelara® (ustekinumab)

Determining an individual patient's coverage for STELARA®

Health plans can cover prescription benefits in different ways for different patients, and the chart below helps explain how. The answers to the 3 questions below will help you determine how STELARA® is covered:

1 Are medical and pharmacy benefits managed together or separately?	2 Who is responsible for administering each benefit type?	3 What determines pharmacy coverage for STELARA®?
Scenario #1 (single card) 	• MCO (managed care organization) covers the medical and pharmacy benefit (please note, a PBM [pharmacy benefit manager] may still adjudicate claims).	MCO Formulary
Scenario #2 (two cards) 	• MCO covers only the medical benefit. • PBM covers pharmacy benefit following PBM National Formulary.	PBM National Formulary
Scenario #3 (two cards) 	• MCO covers only the medical benefit. • PBM covers pharmacy benefit following an individual health plan/ employer group custom formulary.	Health Plan/Employer Group Custom Formulary

Please ask your patients for both their medical and pharmacy benefit cards (if available) to help facilitate the benefit investigation process.

Stelara® (ustekinumab)

Understanding medical and pharmacy health plan benefits for STELARA®

Facilitating access to STELARA® begins with an understanding of some of the key differences between your patients' medical and pharmacy coverage. The chart below outlines the way these benefit types typically work.

MEDICAL BENEFIT

Provides coverage for medical procedures, hospital care, and healthcare provider (HCP)-administered medications[2]

- Customarily includes an annual patient out-of-pocket (OOP) maximum amount for the patient and/or family.[3]
- May include a deductible. Co-insurance and/or co-pay may apply to each procedure, treatment, or office visit until the OOP maximum is met.[4,5]
- Once the maximum annual OOP amount is met, the patient/family may have no further OOP cost for treatments for the rest of the year.[6,7]

PHARMACY (OR PRESCRIPTION) BENEFIT

Provides coverage for prescription drugs and self-administered medications[2]

- May not include an OOP maximum amount, but may include a pharmacy benefit upper limit.[3]
- A co-pay amount for each patient applies to every prescription drug purchase and self-administered medication.[4,5]
- A co-pay is generally required for each prescription fill and self-administered medication treatment throughout the year.[4,5]

Typical Medical Benefit

Typical Pharmacy Benefit

Because STELARA® may be covered by either the medical or pharmacy benefit, it's important to investigate both benefits to identify the coverage option that will ensure smooth administrative processing for your office and timely delivery of STELARA® to your appropriate patients. Checking both benefits works best for you and your patients!

Coverage requirements can differ between the medical and pharmacy benefits

As a specialty drug, STELARA® may be subject to precertification, prior authorization (PA), and/or other coverage requirements. Identifying patients' health plan requirements before submitting a STELARA® prescription to the specialty pharmacy provider (SPP) can help streamline the acquisition process significantly.

Medical benefit

Some medical benefit plans require precertification before approving coverage for STELARA®. This can take the form of a letter of medical necessity or other documentation that verifies that use of a prescribed drug meets a plan's approval criteria. Plan approval criteria may be based on internal medical policies or nationally recognized clinical guidelines.[8,9]

Pharmacy benefit

Pharmacy benefit plans may have a PA process for STELARA® to ensure that a patient meets coverage approval guidelines. These guidelines can include:

- Criteria for appropriate indication.[5]
- Duration of use limits.[5]
- Criteria for adequate response to therapy.[3]
- Requirements for previous trial and failure of other treatments.[3]

A note about SPPs and health plan coverage

Health plans may contract with an SPP and mandate that plan members use these contracted SPPs exclusively to obtain their medications.[3,4] Keep in mind that a patient's mandated or preferred SPP for the medical benefit may be different from the mandated or preferred SPP for the pharmacy benefit.

Please see Important Safety Information for STELARA® on back.

Preparing and submitting claims for STELARA®

Code Type	Code Number	Description
ICD-9	696.1 696.0	Plaque psoriasis Psoriatic arthritis
HCPCS	J3357	Injection, ustekinumab, 1 mg
Coding unit for STELARA®	Number of units provided	1 unit—one 45 mg/0.5 mL single-use prefilled syringe 1 unit—one 90 mg/1 mL single-use prefilled syringe
CPT®	96372	Therapeutic, prophylactic, or diagnostic injection, subcutaneous/intramuscular
NDC	57894-060-03 57894-061-03	45 mg/0.5 mL in a single-use prefilled syringe 90 mg/1 mL in a single-use, prefilled syringe

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

Glossary of health insurance terms

Co-insurance—Amount a beneficiary is required to pay for services after a deductible has been paid; usually a percentage of the amount an insurer will reimburse a medical provider for certain services.[6,7]

Co-pay—A predetermined fee that a plan member pays for healthcare services.[6]

Deductible—Predetermined dollar amount a patient must pay for medical expenses before insurance covers a portion of the costs.[6]

OOP maximum—The annual predetermined dollar amount a patient pays that is not paid by insurance. Once the OOP maximum amount is paid, the patient's insurance should cover all approved healthcare expenses at 100% for the remainder of the year. The OOP maximum may or may not include the deductible.[6,7]

References: 1. STELARA® Prescribing Information. Horsham, PA: Janssen Biotech, Inc. **2.** Challenges of reimbursing through the medical vs. pharmacy benefit. Midwest Business Group on Health (MBGH) Web site. http://www.specialtyxtoolkit.com/specialty-pharmacy-101/challenges-reimbursing-through-medical-vs-pharmacy-benefit. Accessed February 4, 2014. **3.** EMD Serono Speciality Digest, 9th ed. Managed care strategies for speciality pharmaceuticals. Published 2013. http://www.amcp.org/EMDSeronoSpecialtyDigest9th.pdf. Accessed February 27, 2014. **4.** Compare benefit options. BlueCross BlueShield Federal Employee Program Web site. http://fepblue.org/benefitplans/compare/index.jsp. Accessed February 4, 2014. **5.** Understanding specialty pharmacy management and cost control. Pharmaceutical Strategies Group (PSG) Web site. Published June 2010. http://www.psgconsults.com/Understanding_Specialty_Pharmacy_Management_and_Cost_Control_FINAL.pdf. Accessed February 4, 2014. **6.** Glossary. BlueCross BlueShield Association Web site. http://www.bcbs.com/glossary. Accessed February 4, 2014. **7.** Health insurance glossary. Healthinsurance.org Web site. http://www.healthinsurance.org/glossary/. Accessed February 4, 2014. **8.** Preauthorization and precertification. Cochlear Web site. http://www.cochlear.com/wps/wcm/connect/us/for-professionals/reimbursement-solutions/Self-help-Resources/Step-by-step-Guide/Preauthorization-Precertification. Accessed February 11, 2014. **9.** Participating provider precertification. Aetna Web site. http://www.aetna.com/healthcare-professionals/assets/documents/2014-precert-list.pdf. Accessed February 11, 2014.

Stelara® (ustekinumab)

IMPORTANT SAFETY INFORMATION

Infections

STELARA® (ustekinumab) may increase the risk of infections and reactivation of latent infections. Serious bacterial, fungal, and viral infections were reported. Infections requiring hospitalization included diverticulitis, cellulitis, pneumonia, appendicitis, cholecystitis, and sepsis. 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 mycobacteria, *Salmonella*, and *Bacillus Calmette-Guerin* (BCG) vaccinations. Serious infections and fatal outcomes have been reported in such patients. It is not known whether patients with pharmacologic blockade of IL-12/IL-23 from treatment with STELARA® 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.

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

Hypersensitivity Reactions

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

Reversible Posterior Leukoencephalopathy Syndrome (RPLS)

One case of RPLS has been reported in a STELARA®-treated patient. If RPLS is suspected, administer appropriate treatment and discontinue STELARA®.
RPLS is a neurological disorder, which is not caused by an infection or demyelination. RPLS can present with headache, seizures, confusion, and visual disturbances. RPLS has been associated with fatal outcomes.

Immunizations

Prior to initiating therapy with STELARA®, patients should receive all 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. In psoriasis studies, the relevance of findings in mouse models for malignancy risk in humans is unknown. In psoriatic arthritis studies, concomitant MTX use did not appear to influence the safety or efficacy of STELARA®.

Allergen Immunotherapy

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

Most Common Adverse Reactions

The most common adverse reactions (≥3% and higher than that with placebo) in psoriasis 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. In psoriatic arthritis (PsA) studies, a higher incidence of arthralgia and nausea was observed in patients treated with STELARA® when compared with placebo (3% vs 1% for both).

003173-130920

Please see accompanying full Prescribing Information and Medication Guide for STELARA®. Provide the Medication Guide to your patients and encourage discussion.

Janssen Biotech, Inc.

 3/14 009947-140207

janssen
PHARMACEUTICAL COMPANIES
OF Johnson & Johnson

Accessing STELARA®: A step-by-step guide

My STELARA® contact is:

_____

_____

_____

START

STELARA® is prescribed to the appropriate patient

Collect patient information, including both pharmacy and medical benefit cards

- Provide patient with the StelaraSupport™ Instant Savings Program brochure and encourage them to enroll in the StelaraSupport™ program for cost assistance, refill management and reminders, and nurse support
- Set expectations with patient regarding procurement process

Complete Prescription Information and StelaraSupport™ Enrollment Form (PEF) or Specialty Pharmacy Provider (SPP) intake form

Send the following to StelaraSupport™ or SPP for benefits verification:

- PEF or intake form
- Copies of pharmacy and medical benefit cards

Be sure to ask that both pharmacy and medical benefits are checked

StelaraSupport™/SPP begins benefits verification. Is prior authorization (PA) or precertification required?

NO

Benefits verification completed

YES

Work with StelaraSupport™ or SPP to complete PA or precertification requirements

Submit PA or precertification to payer

Is PA or precertification approved?

NO

Contact your StelaraSupport™ coordinator, SPP contact, or Janssen sales representative to discuss next steps and options

YES

SPP contacts patient to collect co-pay.

Important: Remind patient that he/she needs to take call from SPP or product will not be shipped

Also, if appropriate, encourage patient to enroll in the StelaraSuppport™ Instant Savings Program and activate co-pay card by the time they speak with the SPP

Confirm/coordinate shipment of STELARA®.

Remind patient to coordinate with SPP to confirm shipping to:

- Your office for injection, or to a location convenient for the patient, for injection by an HCP.
- Patient's home or other convenient location for patient self-injection.

Shipment should be coordinated with patient's appointment/injection date or patient's next scheduled self-injection treatment, as appropriate

STELARA® is administered.

Stelara® (ustekinumab)

StelaraSupport™—one-to-one support for access to treatment

We'll streamline the benefit investigation process

- Explanation of benefits to you and your patient.
- Assistance with the PA and appeal process, if requested.
- Preferred SPP option.
- Coordination of prescription information with a specialty pharmacy for processing and delivery of medication.
- Explanation of patient's medical and pharmacy benefits.
- Identification of alternate funding sources for patient OOP costs.
- Verification of pharmacy benefits within 1 hour.*

We'll support the prior authorization process, if requested†

- Research your patient's health plan for PA requirements and forms.
- Pre-populate the payer's PA form with your patient's information.‡
- Monitor status of the PA submission, if requested.
- Notify your office in the month prior to PA expiration.

We'll offer helpful resources at the online provider portal

- 24-hour access to your patient's information.
- Annual reverification of benefits confirms patients' coverage.
- Specialty Pharmacy Provider Reminder Tool.
- Refill Management and PA Expiration reports.
- Email alerts to changes in patient status.

StelaraSupport™
The Janssen Biotech Support System

1-877-STELARA (1-877-783-5272)
Monday–Friday, 8:00 AM–8:00 PM ET

One-to-one support for access to treatment

* Pharmacy benefits investigation for STELARA® typically completed within 1 hour. Benefits investigation for pharmacy and medical benefits for STELARA® typically completed within 48 hours.
† We do not fill out any information that requires the medical judgment of the prescriber and only the prescriber can determine whether to pursue a PA.
‡ The physician must opt in by checking the corresponding box on the PEF.

Please see Important Safety Information for STELARA® within this piece.

Stelara® (ustekinumab)