Stelara Support™

The Janssen Biotech Support System

Getting patients started on STELARA®

Stelara® (ustekinumab)

3 STEPS after identifying patients appropriate for STELARA® (ustekinumab)

STEP 1: Determine the correct dose

STELARA® is administered by subcutaneous injection.[1]

Psoriatic Arthritis

- The recommended dose is 45 mg initially and 4 weeks later, followed by 45 mg every 12 weeks
- For patients with co-existent moderate-to-severe plaque psoriasis weighing >100 kg (220 lbs), the recommended dose is 90 mg initially and 4 weeks later, followed by 90 mg every 12 weeks

Plaque Psoriasis

- **For patients weighing ≤100 kg (220 lbs)**, the recommended dose is 45 mg initially and 4 weeks later, followed by 45 mg every 12 weeks
- **For patients weighing >100 kg (220 lbs)**, the recommended dose is 90 mg initially and 4 weeks later, followed by 90 mg every 12 weeks. In subjects weighing >100 kg (220 lbs), 45 mg was also shown to be efficacious. However, 90 mg resulted in greater efficacy in these subjects

STEP 2: Complete the Prescription Form

- Complete the Prescription Form for STELARA® including previous therapy, patient weight, insurance information, and dosage information

- **Request Pharmacy and Medical insurance cards**
  - Submit copies of Pharmacy and Medical insurance cards with the Prescription Form to specialty pharmacy or StelaraSupport™ for benefit verification
  - Request investigation of benefits most appropriate for patient
- Provide eligible commercially insured patients with the StelaraSupport™ Instant Savings Program card for activation

STEP 3: Receive STELARA®

- Once benefits are verified, the specialty pharmacy will coordinate shipment with you and your patient:
  - **To patient's home** or other convenient location, for patient self-injection
  - **To your office** or to a location convenient for your patient, for injection by a Healthcare Provider (HCP)
- Coordinate shipment with patient appointment/injection date or patient's next scheduled self-injection treatment, as appropriate

- **Please note:**
  - Instruct patients in proper storage and handling of STELARA®
  - Keep STELARA® refrigerated at 2°C to 8°C (36°F to 46°F). Keep the product in the original carton to protect from light until the time of use. Do not freeze. Do not shake. STELARA® does not contain a preservative; discard any unused portion[1]
  - 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

Please see coding and billing information on page 5.

1. STELARA® Prescribing Information. Janssen Biotech, Inc.

Indications

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 alone or in combination with methotrexate (MTX).

StelaraSupport™
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Selected Important Safety Information

STELARA® is an immunosuppressant and may increase the risk of infections, reactivation of latent infections, and malignancies. Serious adverse reactions have been reported in STELARA®-treated patients, including bacterial, fungal, and viral infections, malignancies, hypersensitivity reactions 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 on pages 7 and 8.

Patient Affordability

Alternative sources of financial support for STELARA® (ustekinumab) vary depending on the patient's insurance coverage.

Patients with commercial insurance

Provide eligible patients with StelaraSupport™ Instant Savings Program information and encourage immediate card activation.

- See StelaraSupport™ Instant Savings Program materials for additional information and program restrictions, or visit **www.STELARAinfo.com**

Patients with Medicare, Medicaid, TRICARE, or commercial insurance

Foundation Support may be available:

- **The Assistance Fund** 1-855-845-3663 theassistancefund.org
- **The HealthWell Foundation** 1-800-675-8416 healthwellfoundation.org
- **Patient Access Network Foundation** 1-866-316-7263 panfoundation.org
- **Patient Advocate Foundation** 1-866-512-3861 patientadvocate.org

Other resources

Johnson & Johnson Patient Assistance Foundation, Inc. (JJPAF) is committed to providing access to uninsured patients that lack the financial resources to pay for their medicines. If your patient needs STELARA®, and is uninsured and unable to pay for their medicine, please have them contact a JJPAF program specialist at 1-800-652-6227 or visit the foundation website at www.JJPAF.org to see if they might qualify for assistance.

For a complete list of alternative funding options, please direct your patients to JanssenPrescriptionAssistance.com/STELARA.

*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 codes are supplied for informational purposes only and this information does not represent any statement, promise, or guarantee by Janssen Biotech, Inc., about coverage, levels of reimbursement, payment, or charge. Please consult with your payer organization(s) for local or actual coverage, reimbursement policies, and determination processes. Please consult with your counsel or reimbursement specialist for any reimbursement or billing questions specific to your institution.

Benefits Verification

Knowing the differences between Pharmacy and Medical coverage can be beneficial.

- Helps facilitate smoother, more efficient administrative processing
- Helps ensure that patients have appropriate access to the medications they need

Remember, check both Pharmacy and Medical insurance coverage cards.

Pharmacy benefit coverage for STELARA®

Coverage for prescription biologic medications may vary from the medical benefit:

- Coverage requirements may vary
- Patient out-of-pocket requirement may vary
- Distribution may be through the specialty pharmacy, retail pharmacy, or mail order

Medical benefit coverage for STELARA®

Coverage for medical procedures, hospital care, and Healthcare Provider–administered medications may vary from the pharmacy benefit:

- Coverage requirements may vary
- Patient out-of-pocket requirement may vary
- Distribution may be through the specialty pharmacy or Buy and Bill

Preparing & submitting claims for STELARA®*

Code Type	Code Number	Description
ICD-9	696.0 696.1	Psoriatic arthritis Plaque psoriasis
ICD-10	**L40** L40.50 L40.51 L40.52 L40.53 L40.54 L40.59 L40.0 L40.1 L40.2 L40.3 L40.4 L40.8 L40.9	**Psoriasis** Arthropathic psoriasis, unspecified Distal interphalangeal psoriatic arthropathy Psoriatic arthritis mutilans Psoriatic spondylitis Psoriatic juvenile arthropathy Other psoriatic arthropathy Psoriasis vulgaris Generalized pustular psoriasis Acrodermatitis continua Pustulosis palmaris et plantaris Guttate psoriasis Other psoriasis Psoriasis, unspecified
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 leading 0 should be added to the middle set of numbers.

We help make access easy

Support for you

- Single point of contact for answers to your questions about coverage
- Assistance with benefit investigation, and the prior authorization and appeal process
- Easy-to-use, time-saving enhanced provider portal

Support for your patients

- One-to-one counseling on insurance benefits and cost-sharing requirements
- StelaraSupport™ Instant Savings Program for eligible patients
- Nurse support available 7 days a week
- Safe Returns™ for proper disposal of prefilled syringes at no cost
- Medication reminders

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

Patient insurance benefit investigation is provided as a service by The Lash Group, Inc., under contract for Janssen Biotech, Inc. In this regard, The Lash Group, Inc., assists healthcare professionals in the determination of whether treatment could be covered by the applicable third-party payer based on coverage guidelines provided by the payer and patient information provided by the healthcare provider under appropriate authorization following the provider's exclusive determination of medical necessity.

Importantly, insurance verification is the ultimate responsibility of the provider. Third-party reimbursement is affected by many factors. Therefore, The Lash Group, Inc., and Janssen Biotech make no representation or guarantee that full or partial insurance reimbursement or any other payment will be available. This information is provided as an information service only. While The Lash Group, Inc., tries to provide correct information, it and Janssen Biotech make no representations or warranties, expressed or implied, as to the accuracy of the information. In no event shall The Lash Group, Inc., or Janssen Biotech or its employees or agents be liable for any damages resulting from or relating to the services. All providers and other users of this information agree that they accept responsibility for the use of this service.

Janssen Biotech assumes no responsibility for, and does not guarantee the quality, scope, or availability of the services including but not limited to reimbursement support services, patient education, and other support services. Each provider, not Janssen Biotech, is responsible for the services they provide. These support services have no independent value to providers apart from the product and are included within the cost of the product.

Janssen Biotech, Inc.

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Indications

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

Important Safety Information

Infections

STELARA® may increase the risk of infections and reactivation of latent infections. Serious bacterial, fungal, and viral infections, some requiring hospitalization, were reported. Serious infections included diverticulitis, cellulitis, pneumonia, appendicitis, cholecystitis, sepsis, osteomyelitis, viral infections, gastroenteritis 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 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).

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

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