**INDICATION**

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

**SELECTED IMPORTANT SAFETY INFORMATION**

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

Please see related and other Important Safety Information on page 4.
START WITH STELARA®
SO SIMPLE TRIAL PROGRAM

The STELARA® So Simple Trial Program provides pediatric patients requiring the 45-mg single-dose vial their first dose of STELARA® so they may determine with their provider if it is right for them.

1 FORM for easy enrollment

$0 COST to patient

3 Shipment can be authorized within 3 BUSINESS DAYS after prescription.*

This trial program is open to patients who have commercial insurance, government coverage, or no insurance coverage. However, there is no guarantee of continuous accessibility after the program ends.

*Shipment can be authorized within 3 business days of submitting a prescription, pending patient program opt-in and scheduling shipment.

Please see related Important Safety Information on page 4.

STAY WITH STELARA®
SUBMIT A COMPLETED PRIOR AUTHORIZATION FORM to the patient’s insurance company

FOR COMMERCIALLY INSURED PATIENTS

SUBMIT A COMPLETED PRIOR AUTHORIZATION FORM

11

$0

3

JANSSEN CAREPATH SAVINGS PROGRAM

Eligible patients pay $5 per injection with a $20,000 maximum program benefit per calendar year.

See full program requirements at Stelara.JanssenCarePathSavings.com.

Use the EXPRESS ENROLLMENT site at JanssenCarePathPortal.com/express to enroll eligible patients in the Janssen CarePath Savings Program.

INSURANCE COVERAGE APPROVED

JanssenLink
Patients will receive STELARA® at no cost until they receive insurance coverage approval.

See full program requirements at JanssenCarePath.com/HCP/Stelara/Insurance-Coverage/Janssen-Link.

COVERAGE DELAYED >5 BUSINESS DAYS OR DENIED

Both programs are unavailable to individuals who use any state or federal government-funded healthcare program to cover a portion of medication costs, such as Medicare, Medicaid, TRICARE, Department of Defense, or Veterans Administration.

STAY WITH STELARA®
FOR COMMERCIALLY INSURED PATIENTS

SUBMIT A COMPLETED PRIOR AUTHORIZATION FORM

to the patient’s insurance company

Click here for Prior Authorization information

JANSSEN CAREPATH SAVINGS PROGRAM

Eligible patients pay $5 per injection with a $20,000 maximum program benefit per calendar year.

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COVERAGE DELAYED >5 BUSINESS DAYS OR DENIED

Both programs are unavailable to individuals who use any state or federal government-funded healthcare program to cover a portion of medication costs, such as Medicare, Medicaid, TRICARE, Department of Defense, or Veterans Administration.

These programs are for medication only. Terms expire at the end of each program year and may change.

Please see related Important Safety Information on page 4.
HELP GET YOUR PEDIATRIC PATIENTS STARTED

THE STELARA® SO SIMPLE TRIAL OFFER IS AVAILABLE ONLY FOR THE 45-MG SINGLE-DOSE VIAL

OFFICE ROLE

To start therapy:
Submit the fully completed and signed Prescription Enrollment Form (PEF) to Janssen CarePath.
Adviser your patient’s caregiver to accept all phone calls from Wegmans Specialty Pharmacy.

To stay on therapy:
Submit completed Prior Authorization and any other documentation required by the insurance company to determine the patient’s insurance coverage.

Please see related Important Safety Information on page 4.

Enrollment starts with completing

1 FORM

IMPORTANT REMINDERS FOR CAREGIVERS TO ENROLL IN SO SIMPLE
FOR PATIENTS REQUIRING WEIGHT-BASED DOSING

CAREGIVER ROLE

Set an appointment for the child to receive the first injection of STELARA®.
Accept 2 important calls from Wegmans Specialty Pharmacy from 866-889-5660.

Call #1: Within 1 business day—to complete the So Simple Trial Program enrollment.
Call #2: Within 14-21 days after starting STELARA®—to confirm continuation of therapy and to learn about insurance coverage options.

Enrollment starts with your patients and their caregivers accepting

2 PHONE CALLS

Please see related Important Safety Information on page 4.
IMPORTANT SAFETY INFORMATION

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

Infections

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

Treatment with STELARÁ® 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 STELARÁ® 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 STELARÁ® and consider discontinuing STELARÁ® 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-Guérin (BCG) vaccinations.

Serious infections and fatal outcomes have been reported in such patients. The safety of STELARÁ® 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 STELARÁ® who had risk factors for developing non-melanoma skin cancer (NMSC). All patients receiving STELARÁ®, 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 STELARÁ®. If an anaphylactic or other clinically significant hypersensitivity reaction occurs, institute appropriate therapy and discontinue STELARÁ®.

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 STELARÁ® for signs and symptoms of PRES. If PRES is suspected, promptly administer appropriate treatment and discontinue STELARÁ®.

Immunizations

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

Concomitant Therapies

The safety of STELARÁ® in combination with other biologic immunosuppressive agents or phototherapy was not evaluated in clinical studies of psoriasis. Ultraviolet-induced skin cancers developed earlier and more frequently in mice. In psoriasis studies, the relevance of findings in mouse models for malignancy risk in humans is unknown. In psoriatic arthritis studies, concomitant methotrexate use did not appear to influence the safety or efficacy of STELARÁ®. In Crohn’s disease and ulcerative colitis induction studies, concomitant use of 6-mercaptopurine, azathioprine, methotrexate, and corticosteroids did not appear to influence the overall safety or efficacy of STELARÁ®.

Noninfectious Pneumonia

Cases of interstitial pneumonia, eosinophilic pneumonia, and cryptocogenic organizing pneumonia have been reported during post-approval use of STELARÁ®. 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 STELARÁ® and institute appropriate treatment.

Allergen Immunotherapy

STELARÁ® 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 psoriasis clinical studies for STELARÁ® 45 mg, STELARÁ® 90 mg, or placebo were: nasopharyngitis (8%, 7%, 8%), upper respiratory tract infection (5%, 4%, 5%), headache (5%, 5%, 3%), and fatigue (3%, 3%, 2%), respectively. The safety profile in pediatric patients with plaque psoriasis was similar to that of adults with plaque psoriasis. In psoriatic arthritis (PsA) studies, a higher incidence of arthralgia and nausea was observed in patients treated with STELARÁ® when compared with placebo (3% vs 1% for both). In Crohn’s disease induction studies, common adverse reactions (3% or more of patients treated with STELARÁ® and higher than placebo) reported through Week 8 for STELARÁ® 6 mg/kg intravenous single infusion or placebo included: vomiting (4% vs 3%). In the Crohn’s disease maintenance study, common adverse reactions (3% or more of patients treated with STELARÁ® and higher than placebo) reported through Week 44 for STELARÁ® 90 mg subcutaneous injection or placebo were: nasopharyngitis (11% vs 8%), injection site erythema (5% vs 0%), vulvovaginal candidiasis/mycotic infection (5% vs 1%), bronchitis (5% vs 3%), pruritus (4% vs 2%), urinary tract infection (4% vs 2%) and sinusitis (3% vs 2%). In the ulcerative colitis induction study, common adverse reactions (3% or more of patients treated with STELARÁ® and higher than placebo) reported through Week 8 for STELARÁ® 6 mg/kg intravenous single infusion or placebo included: nasopharyngitis (7% vs 4%). In the ulcerative colitis maintenance study, common adverse reactions (3% or more of patients treated with STELARÁ® and higher than placebo) reported through Week 44 for STELARÁ® 90 mg subcutaneous injection or placebo included: nasopharyngitis (24% vs 20%), headache (10% vs 4%), abdominal pain (7% vs 3%), influenza (5% 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 see the full Prescribing Information and Medication Guide for STELARÁ®. Provide the Medication Guide to your patients and encourage discussion.

INDICATIONS

STELARÁ® (ustekinumab) is indicated for the treatment of patients 6 years old or younger with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy.

STELARÁ®, 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 visits with a physician. In pediatric patients, it is recommended that STELARÁ® be administered by a healthcare provider. If a physician determines that it is appropriate, a patient may self-inject or a caregiver may inject STELARÁ® after proper training in subcutaneous injection technique. Patients should be instructed to follow directions provided in the Medication Guide.
For more information about Janssen CarePath, talk with your Janssen Representative.

Call a Janssen CarePath Care Coordinator at 877-CarePath (877-227-3728), Monday-Friday 8:00 AM to 8:00 PM ET

Sign Up or Log In to the Provider Portal at JanssenCarePathPortal.com

Visit JanssenCarePath.com