

START YOUR PATIENTS ON STELARA® WITH THE 3 STEPS BELOW



STEP 1: Coverage & Benefits

- Verify medical and pharmacy benefit coverage for intravenous (IV) and subcutaneous (subQ) maintenance doses
- Submit benefit investigations for IV and subQ prescriptions
- Enroll patient in STELARA withMe



STEP 2: IV Induction Dose

- Submit prior authorization with Letter of Medical Necessity, if required
- Schedule IV infusion or coordinate site of care



STEP 3: SubQ Maintenance Dose

- Confirm medical or pharmacy benefit coverage
- Submit prior authorization with Letter of Medical Necessity, if required
- Administer in-office injection or educate patient on how to proceed with self-injection



DEDICATED SUPPORT

Contact your **Field Reimbursement and Access Specialist (FRAS)** for questions about getting patients started on STELARA®

INDICATIONS

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

STELARA® is indicated for the treatment of adult patients with moderately to severely active ulcerative colitis.

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®.

(See next page for additional Important Safety Information)

Please see Important Safety Information throughout. Please click to see the full [Prescribing Information](#) and [Medication Guide](#) for STELARA®. Provide the Medication Guide to your patients and encourage discussion.



IMPORTANT SAFETY INFORMATION

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

Infections

STELARA® 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, ophthalmic herpes zoster, pneumonia, and *Listeria* meningitis. In patients with ulcerative colitis, these included gastroenteritis, ophthalmic herpes zoster, pneumonia, and listeriosis.

Treatment with STELARA® 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 STELARA® 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 STELARA® and consider discontinuing STELARA® 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 STELARA® may be susceptible to these types of infections. Appropriate diagnostic testing should be considered (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 STELARA®. Do not administer STELARA® to patients with active tuberculosis infection. Initiate treatment of latent TB before administering STELARA®. Closely monitor patients receiving STELARA® for signs and symptoms of active TB during and after treatment.

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

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

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

(See next page for additional Important Safety Information)



Immunizations

Prior to initiating therapy with STELARA[®], patients should receive all age-appropriate 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 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 STELARA[®]. 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 STELARA[®].

Noninfectious Pneumonia

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

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 ($\geq 3\%$ and higher than that with placebo) in adults from psoriasis clinical studies 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. 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 STELARA[®] 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 STELARA[®] and higher than placebo) reported through Week 8 for STELARA[®] 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 STELARA[®] and higher than placebo) reported through Week 44 for STELARA[®] 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 STELARA[®] and higher than placebo) reported through Week 8 for STELARA[®] 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 STELARA[®] and higher than placebo) reported through Week 44 for STELARA[®] 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 see the full [Prescribing Information](#) and [Medication Guide](#) for STELARA[®]. Provide the Medication Guide to your patients and encourage discussion.

Stelara withMe DEDICATED SUPPORT FOR YOUR PATIENTS



Nurse Navigators

Our registered nurses are just a phone call away. Nurse Navigators can answer questions about STELARA®, from how to self-inject to how to make the medication more affordable.



Access and Affordability

STELARA withMe can help verify insurance coverage for your patients, provide reimbursement information, find financial assistance options for eligible patients, and provide ongoing support to help patients start and stay on STELARA®.



Infusion Services

Infusion Services is intended to help patients transition from their single infusion to injection. Infusion Services utilizes Infusion Service Providers (ISPs) to coordinate patient continuity of care and support the overall patient experience by leveraging existing infrastructure and clinical experience.



Delay and Denial Support

STELARA withMe offers eligible patients subcutaneous STELARA® **at no cost** until their commercial insurance covers the medication. Patients may be eligible if there is a delay of more than 5 business days or a denial of treatment from their insurance.*



To enroll patients, visit stelarawithme.com/healthcare-professionals

STELARA withMe is limited to education for patients about STELARA®, its administration, and/or their disease, and is not intended to provide medical advice, replace a treatment plan from the patient's doctor or nurse, or provide case management services.

Information about your patient's insurance coverage, cost support options, and treatment support is given by service providers for STELARA withMe via Janssen CarePath. The information you get does not require you or your patient to use any Janssen product. Because the information we give you comes from outside sources, STELARA withMe cannot promise the information will be complete. STELARA withMe cost support is not for patients in the Johnson & Johnson Patient Assistance Foundation.

* Additional eligibility and program enrollment information is available from your FRAS.

