STEPS TO STARTING WITH STELARA® UC+CD

FOR IV INDUCTION AND SUBQ MAINTENANCE DOSES

START HERE

- Connect with a Sales Representative or Access and Reimbursement Specialist to understand coverage
- Submit a Benefits Investigation and Prescription Form for intravenous (IV) induction and subcutaneous (subQ) maintenance doses (medical and pharmacy benefit)
- Offer Janssen CarePath Patient Support and transfer patient to 877-CarePath
- Partner patients with dedicated Nurse Navigators

Next for Patients With COMMERCIAL INSURANCE

STEP 1: IV INDUCTION DOSE PA

- Submit prior authorization (PA) for IV induction dose
  - —Proactively include a Letter of Medical Necessity and Prescribing Information for UC for the first 90 days
- ✓Approved: Schedule the infusion
- ×Denied: Appeal the decision

STEP 2: IV INDUCTION DOSE ADMINISTRATION

- Administer IV induction dose
- Check with plan for subQ PA requirements

STEP 3: SUBQ MAINTENANCE DOSE PA

- Determine medical or pharmacy benefit based on coverage
- Submit PA for subQ maintenance doses after administration of IV induction dose
  - —Proactively include a Letter of Medical Necessity and Prescribing Information for UC for the first 90 days
- ✓Approved: Specialty pharmacy to fill
- ×Denied: Appeal the decision and enroll patient in Janssen Link

STEP 4: SUBQ MAINTENANCE DOSES

- Enroll patient in Janssen CarePath Savings Program
- Pharmacy benefit: Specialty pharmacy to fill
- Medical benefit: Buy and bill for in-office administration

Next for Patients With GOVERNMENT INSURANCE

BUY AND BILL ACCOUNTS

STEP 1: IV INDUCTION DOSE

- Medical benefit
- No PA required

STEP 2: SUBQ MAINTENANCE DOSES

- Determine medical or pharmacy benefit based on coverage

Indications

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

STELARA® (ustekinumab) 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, one case of Reversible Posterior Leukoencephalopathy Syndrome (RPLS), 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 RPLS is suspected or if noninfectious pneumonia is confirmed, discontinue STELARA®.

Please see Important Safety Information for STELARA® inside.

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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®.

Reversible Posterior Leukoencephalopathy Syndrome (RPLS)

One case of reversible posterior leukoencephalopathy syndrome (RPLS) was observed in clinical studies of psoriasis and psoriatic arthritis. No cases of RPLS were observed in clinical studies of Crohn's disease or ulcerative colitis. 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.

Important Safety Information for STELARA® continued on next page.

Important Safety Information (cont'd)

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 (≥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 see full Prescribing Information and Medication Guide for STELARA® within the pocket. Provide the Medication Guide to your patients and encourage discussion.

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Stelara® (ustekinumab)

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Stelara® (ustekinumab)

PATIENT SUPPORT FOR STELARA®

ACCESS AND REIMBURSEMENT SPECIALISTS

- Educate about STELARA® coverage at the national and local levels
- Discuss affordability options
- Respond to questions about the exceptions and appeals process

Contact your local Access and Reimbursement Specialist

THE NURSE NAVIGATOR PROGRAM*

- Offer patients treatment education, including infusion options
- Provide subQ-injection training and support
- Connect patients to a specialist for cost and insurance coverage support

Visit Nurse4STELARA.com to enroll your patients in the program

*The Nurse Navigator program is limited to education for patients about their Janssen therapy, its administration, and/or their disease. It is intended to supplement a patient's understanding of their therapy, and is not intended to provide medical advice, replace a treatment plan from the patient's doctor or nurse, provide case management services, or serve as a reason to prescribe.

FOR COMMERCIALLY INSURED PATIENTS

INSURANCE COVERAGE APPROVED

Janssen CarePath SAVINGS PROGRAM

Eligible patients pay $5 per dose.
$20,000 maximum program benefit per calendar year.

See full program requirements at
Stelara.JanssenCarePathSavings.com

COVERAGE DELAYED >5 BUSINESS DAYS OR DENIED

Janssen Link

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

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

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.

Call a Janssen CarePath Care Coordinator at **877-CarePath (877-227-3728)**, **Monday-Friday, 8:00 AM to 8:00 PM ET**. Multilingual phone support available.
Sign up or log in to the Provider Portal at **JanssenCarePathPortal.com**
Visit **JanssenCarePath.com/hcp/Stelara**

Please see Important Safety Information for STELARA® inside.