Indication
STEVAR® (ustekinumab) is indicated for the treatment of adult patients with moderately to severely active Crohn’s disease who have:
• failed or were intolerant to treatment with immunomodulators or corticosteroids, but never failed treatment with a tumor necrosis factor (TNF) blocker, or
• failed or were intolerant to treatment with one or more TNF blockers.

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

STEVAR® 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 STEVAR®. Live vaccines should not be given to patients receiving STEVAR®. If RPLS is suspected, discontinue STEVAR®.

Please see related and other Important Safety Information on pages 6 and 7.
Janssen CarePath Support for Adults With Moderately to Severely Active Crohn’s Disease

Janssen wants to help patients who have Crohn’s disease with the specific issues that they face in getting treatment. Four features of the Janssen CarePath Program are built with these patients in mind: the Benefit Investigation and Prescription Form, Janssen Link, Janssen CarePath Savings Program, and Nurse Navigators from Janssen CarePath.

Benefit Investigation and Prescription Form

The Benefit Investigation and Prescription Form is a gateway to ensuring your patient is covered to receive both the initial intravenous (IV) and maintenance subcutaneous (s.c.) doses of STELARA® for moderately to severely active Crohn’s disease.

Filling out the Benefit Investigation and Prescription Form eliminates the need to write 2 prescriptions and perform 2 separate benefits investigations. Once you complete and submit the form, our Care Coordinators can perform a dual benefits investigation, deliver prior authorization support and status monitoring, and provide information on exceptions and appeals.

Visit JanssenCarePath.com to see all the resources that are available.

See corresponding numbers on form at right:

1. Simplified Insurance Information
   - We verify Medical and Pharmacy Benefits with photocopies of your patient’s Primary Medical and Prescription insurance cards.

2. Nurse Navigator Support
   - Check the box and your patient will be contacted to opt in for personalized nurse support from Janssen CarePath.

3. Prior Authorization (PA) Services
   - We’re ready to assist you in completing the PA form, and status monitoring. Or opt out by checking the boxes.

4. Single IV Induction Dose
   - Information covers induction dose for your patient.

5. Required ‘DIAGNOSIS CODE’ is required to complete benefit investigation for IV induction and/or maintenance dose prescription.

6. Site of Infusion
   - Identify location for the single IV induction dose to facilitate benefit investigation, including confirmation of provider network status.

7. Maintenance Dose Prescription
   - Information covers maintenance dose prescription for your patient. If only requesting benefit investigation—Do not complete this section.

8. Shipping Information
   - Help ensure delivery of maintenance dose prescription with complete address and contact information.

9. Preferred Specialty Pharmacy (SP)
   - Select the patient’s preferred SP for prescription processing.
Janssen CarePath Support for Adults With Moderately to Severely Active Crohn’s Disease

Janssen Link
Additional Access Support
Ongoing coverage for commercial patients without access

Janssen Link connects patients with STELARA® subQ maintenance treatment at no cost if insurance coverage is delayed or denied.

Begins immediately after denial or 5 days after PA submission and continues until coverage is obtained or program year ends.

Coverage with Janssen Link is ongoing until your patients receive coverage or through the rest of the current program year; if patient receives coverage within 90 days, this will be transitioned to commercial product.*

How it works:
- You prescribe STELARA® for moderately to severely active Crohn’s disease
- You complete the Benefit Investigation and Prescription Form and fax it to 866-769-3903
- Your patients get the treatment you prescribed for as long as they need

Janssen CarePath Savings Program:
$5 Per Dose†
Keep treatment affordable at only $5 per dose† for a total cost of $35 per year (based on 1 IV and 6 subQ doses in the first year)

Enroll at STELARA.JanssenCarePathsavings.com

The Janssen CarePath Savings Program provides financial assistance to help patients with their out-of-pocket costs on their STELARA® medication, including: deductible, co-payment, and co-insurance costs. The Savings Program provides benefits when using either Medical or Pharmacy insurance coverage.

*Federal government-subsidized healthcare programs are not eligible.

†Subject to a $20,000 annual maximum benefit; per calendar year; for medication cost only; not available to patients who use any state or federal government-subsidized healthcare program to cover a portion of medication costs, such as Medicare, Medicaid, TRICARE, Department of Defense, or Veterans Administration; additional eligibility restrictions apply.

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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 6 and 7.
**Important Safety Information (cont’d)**

**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 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. 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 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 immunosuppressive agents or phototherapy was not evaluated in clinical studies of psoriasis, psoriatic arthritis, or Crohn’s disease. STELARA® may increase the risk of infections and reactivation of latent infections. Concomitant use of immunosuppressants such as azathioprine, mercaptopurine, or mycophenolate mofetil for the treatment of psoriasis may increase the risk of infections. Concomitant use of immunosuppressants in Crohn’s disease may increase the risk of infections and reactivation of latent infections.

**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 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%), headache (7% vs 5%), and fatigue (5% vs 4%). In the Crohn’s disease maintenance study, common adverse reactions (3% or more of patients treated with STELARA® when compared with placebo) reported through Week 44 were: nasopharyngitis (11% vs 8%), injection site erythema (5% vs 0%), and mycotic infection (5% vs 1%). In psoriatic arthritis studies, common adverse reactions (3% or more of patients treated with STELARA® when compared with placebo) reported through Week 44 were: nasopharyngitis (11% vs 8%), injection site erythema (5% vs 0%), mycotic infection (5% vs 1%), bronchitis (2% vs 3%), and pruritus (4% vs 2%). In psoriatic arthritis studies, common adverse reactions (3% or more of patients treated with STELARA® when compared with placebo) reported through Week 44 were: nasopharyngitis (11% vs 8%), injection site erythema (5% vs 0%), and mycotic infection (5% vs 1%).

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

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**Important Safety Information**

**Infections**

STELARA® (ustekinumab) may increase the risk of infections and reactivation of latent infections. Serious bacterial, fungal, and viral infections, some requiring hospitalization, were reported. In patients with psoriasis, serious infections included diverticulitis, cellulitis, pneumonia, appendicitis, cholecystitis, sepsis, osteomyelitis, viral infections, gastroenteritis and urinary tract infections. In patients with psoriatic arthritis, serious infections included cholecystitis. In patients with Crohn’s disease, serious or other clinically significant infections included anal abscess, gastroenteritis, ophthalmic herpes, pneumonia, and Listeria meningitis.

**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.**

**Connect your patients with a Nurse Navigator today!**

Go to STELARAhcp.com for the Nurse Navigator Enrollment Form. Provide it to your patients to be completed and submitted to Janssen CarePath.

**Please see Important Safety Information continued on next page.**
Janssen CarePath: Resources for Your Patients With Crohn’s Disease

Ensuring adults with moderately to severely active Crohn’s disease can start and stay on STELARA®

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Please see related and other Important Safety Information inside.