A GUIDE TO STARTING STELARA®

For the treatment of adults with moderately to severely active Crohn’s disease who have failed or were intolerant to conventional therapy (but never failed treatment with a tumor necrosis factor [TNF] blocker) or have failed or were intolerant to treatment with one or more TNF blockers.

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, one case of Reversible Posterior Leukoencephalopathy Syndrome (RPLS), and noninfectious pneumonia.

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 or if noninfectious pneumonia is confirmed, discontinue STELARA®.

Please see related and other Important Safety Information within this guide.
Prescribe STELARA® for Crohn’s Disease

Write 2 prescriptions for STELARA®¹
One for the single intravenous (IV) induction dose and 1 for subcutaneous (subQ) maintenance treatment.

Perform 2 benefits investigations
Perform both the medical and pharmacy benefits investigations at the same time—the time of prescription—in order to continually support access to treatment.

Complete and submit the Benefit Investigation and Prescription Form
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.†

Complete and submit the Nurse Navigators from Janssen CarePath Enrollment Form
Nurse Navigators serve as a single point of contact for patients during their treatment journey. Once you’ve prescribed STELARA®, Nurse Navigators will reach out to your patients and provide personalized benefits coverage and cost support communications, consistent communications during IV induction, and live subQ injection training. Talk to your Janssen Biotech, Inc., sales representative for more details.

*The single IV infusion dose and number of vials are determined using a weight-based dosage regimen: STELARA® 260 mg (55 kg or less), STELARA® 390 mg (more than 55 kg to 85 kg), or STELARA® 520 mg (more than 85 kg).

† 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, Inc. 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, they and Janssen Biotech, Inc. 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, Inc. 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, Inc. assumes no responsibility for, and does not guarantee the quality, scope, or availability of the services including but not limited to reimbursement support services, coordination of prescription fulfillment, patient education, and other support services. Each provider, not Janssen Biotech, Inc., 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.

Please see the full Indication and related and other Important Safety Information within this guide.
Verify Patient Insurance Benefits

Simultaneously verify benefits for the initial STELARA® infusion and maintenance injections

As of January 2017, STELARA® is available on approximately 70% of commercial plans requiring no biological step edits* with open access through several national plans and pharmacy benefit managers (PBMs).†‡

Janssen CarePath can provide support during the exceptions and appeals process

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$5 per dose

Enroll patients in co-pay savings program to help keep treatment affordable

The Janssen CarePath Savings Program for STELARA® allows eligible commercially insured patients to pay $5 per dose.§

Janssen Link connects your commercially insured patients to their prescribed treatment when commercial insurance is delayed (>5 days) or denied.¶ Eligible¶ patients will receive STELARA® at no cost and ongoing support through the rest of the current program year if an approval decision has not been made after 90 days.

This program is not available to individuals 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, or any other federal or state healthcare plan, including pharmaceutical assistance programs. TRICARE® is a registered trademark of the Department of Defense (DoD), DHA.

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* Requiring no step edits indicates a drug will be given first-line biologic access and will not require stepping through other biologic therapies.
† Including UnitedHealthcare® (UHC), UHC West®, OptumRx®, Aetna®, Anthem®, Express Scripts® National Preferred/Basic, and Humana® (medical benefit only) as of July 1, 2017.
‡ Step edits required by biologic-naive patients only.
§ $20,000 maximum program 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 (DoD), or Veterans Administration (VA); see full eligibility requirements at JanssenCarePath.com. TRICARE® is a registered trademark of the DoD, DHA.
¶ Commercial insurance has been delayed >5 business days, or denied the treatment prescribed. Please see full eligibility requirements at JanssenCarePath.com/hcp/stelara/insurance-coverage/janssen-link.
§ Payer must have a biologic fail/first policy in place; patient must verbally “opt-in” to participate.
Start STELARA® With a Single IV Induction and SubQ Maintenance

The first dose of STELARA® is delivered as a single IV infusion using a weight-based dosage regimen administered over at least one hour.

Determine preferred location for infusion (Don’t have one? Visit www.2infuse.com to locate one)

Refer patient to preferred location for infusion

Confirm with the infusion site and patient that infusion has taken place

When your patient is ready for maintenance treatment, Janssen CarePath will send the prescription for first and subsequent injections to the Specialty Pharmacy of your choice:

Order IV from a Specialty Distributor authorized to sell STELARA®

Schedule and complete infusion

Specialty Pharmacy sends the first STELARA® subQ dose to your office or directly to your patient

Patient receives the first STELARA® subQ injection in your office or self-administers at home (after training from your office or a Nurse Navigator)

Specialty Pharmacy sends subsequent maintenance doses directly to patient as prescribed

Maintenance dosing of STELARA® consists of a 90-mg subQ injection every 8 weeks after the induction dose

Please see the full Indication and related and other Important Safety Information within this guide.
**Indication**

STEMLAR® (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.

**Important Safety Information**

**Infections**

STEMLAR® (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 STEMLAR® 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 STEMLAR® 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 STEMLAR® and consider discontinuing STEMLAR® 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 STEMLAR® may be susceptible to these types of infections. Appropriate diagnostic testing should be considered, e.g., tissue culture, stool culture, as dictated by clinical circumstances.

**Pre-Treatment Evaluation of Tuberculosis (TB)**

Evaluate patients for TB prior to initiating treatment with STEMLAR®. Do not administer STEMLAR® to patients with active tuberculosis infection. Initiate treatment of latent TB before administering STEMLAR®. Closely monitor patients receiving STEMLAR® for signs and symptoms of active TB during and after treatment.

**Malignancies**

STEMLAR® is an immunosuppressant and may increase the risk of malignancy. Malignancies were reported among patients who received STEMLAR® in clinical studies. The safety of STEMLAR® 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 STEMLAR® who had risk factors for developing non-melanoma skin cancer (NMSC). All patients receiving STEMLAR®, 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**

STEMLAR® is contraindicated in patients with clinically significant hypersensitivity to ustekinumab or excipients. Hypersensitivity reactions, including anaphylaxis and angioedema, have been reported with STEMLAR®. If an anaphylactic or other clinically significant hypersensitivity reaction occurs, institute appropriate therapy and discontinue STEMLAR®.

**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 STEMLAR®. 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.

Please see Important Safety Information 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 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 MTX use did not appear to influence the safety or efficacy of STELARA®. In Crohn’s disease 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 adolescents with plaque psoriasis through Week 60 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 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%).

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

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For Crohn’s Disease:
STELARA® for intravenous infusion is available as a 130 mg/26 mL (5 mg/mL) single-dose vial. It must be diluted, prepared, and infused by a healthcare professional for Crohn’s disease.

STELARA®, available as 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.1

References