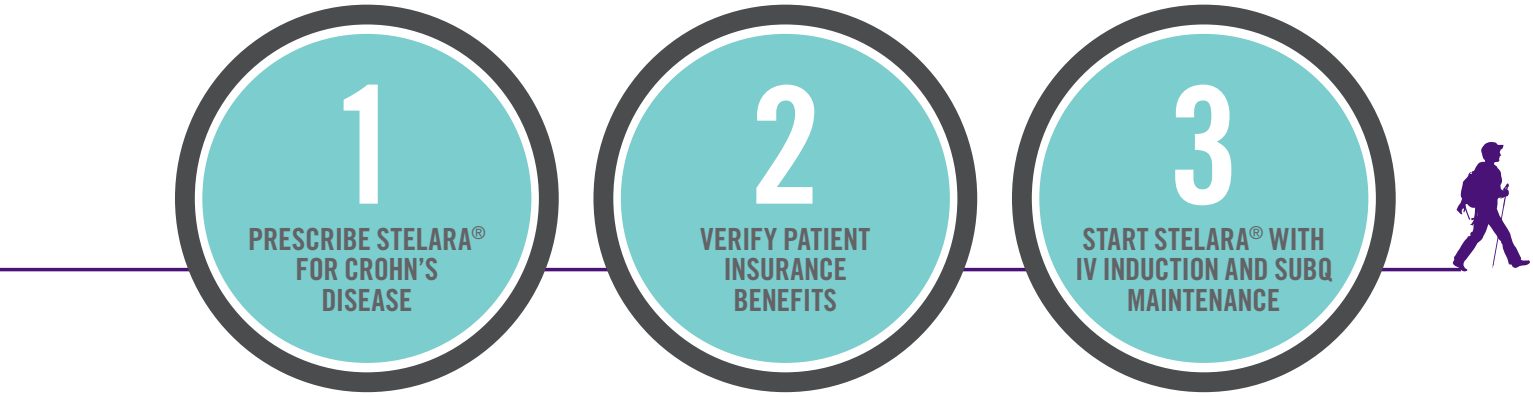
A GUIDE TO STARTING **STELARA®**



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

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 indication and related and other Important Safety Information within this guide.

Stelara® (ustekinumab)

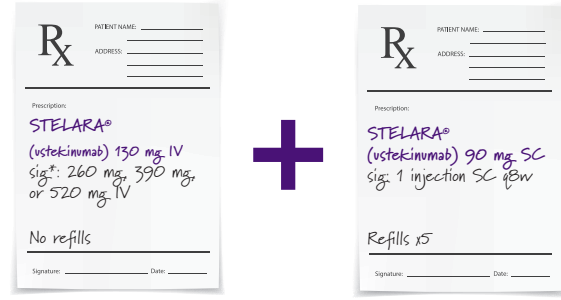
janssen Immunology

PHARMACEUTICAL COMPANIES OF Johnson & Johnson

1 Prescribe STELARA® for Crohn's Disease

Write 2 prescriptions for STELARA®[1]

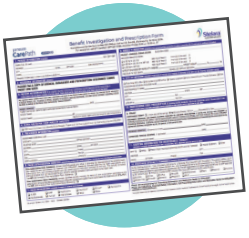
One for the single intravenous (IV) induction dose and 1 for subcutaneous (subQ) maintenance treatment.



*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).

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.

Please see indication and Important Safety Information within this guide.

Stelara® (ustekinumab)

janssen Immunology
PHARMACEUTICAL COMPANIES OF Johnson & Johnson

2 Verify Patient Insurance Benefits

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

STELARA® is available as a first-line biologic for many of your patients, with more than 118 million commercial patients covered through several national plans and PBMs.[2]*

STELARA® IV Induction

Verify medical benefit coverage†

NO

YES

Janssen CarePath can provide support during the exceptions and appeals process

Janssen CarePath

$5 per dose

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

The Janssen CarePath Savings Program for STELARA® allows patients to pay only $5 per dose.‡

STELARA® SubQ Maintenance

Verify pharmacy benefit coverage

YES

NO

Janssen Link

Obtain ongoing coverage for commercial patients without access

When commercial insurance is delayed (>5 days) or denied, your eligible patients will receive STELARA® at no cost. The Janssen Link program is ongoing until your patients receive coverage; if patient receives coverage within 90 days, this will be transitioned to commercial product.§

Separate financial support and access may be available for eligible patients without insurance coverage through the **Johnson & Johnson Patient Assistance Foundation, Inc**. Please visit www.jjpaf.org or call 800-652-6227 for more information.

*Includes UnitedHealthcare®, UHC West®, and OptumRx®; Aetna®; Anthem®; Express Scripts®; and Humana® (medical benefit); pharmacy benefit access as of July 1, 2015.

† In some instances, IV may be covered by pharmacy benefits.

‡ 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.

§ Please see JanssenCarePath.com for more details. Federal government-subsidized healthcare programs are not eligible.

Stelara® (ustekinumab)

3 Start STELARA® With a Single IV Induction and SubQ Maintenance

If your practice has infusion capabilities:

Order IV from a Specialty Distributor authorized to sell STELARA®

Schedule and complete infusion

The first dose of STELARA® is delivered as a single IV infusion using a weight-based dosage regimen

If your practice refers out for infusion:

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:

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

Stelara® (ustekinumab)

Indication

STELARA® (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

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.

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, 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 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

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®.

Please see Important Safety Information continued on next page.

Stelara® (ustekinumab)

Important Safety Information (cont'd)

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. 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®.

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 (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.

060385-160920

Stelara® (ustekinumab)

References

1. STELARA [prescribing information]. Horsham, PA: Janssen Biotech, Inc; 2016. **2.** Data on file. Janssen Biotech, Inc.

janssen Immunology
PHARMACEUTICAL COMPANIES OF Johnson & Johnson