Stelara withMe | Stelara® (ustekinumab)

Personalized help every step of the way

Starting on STELARA®? STELARA withMe is here to help. Receive personal support from a registered nurse (a real person!) for every step of your STELARA® treatment: from scheduling your one-time intravenous (IV) infusion to in-person self-injection training. We're also here to help you with prescription and cost support: from verifying coverage to looking for options that could make your treatment more affordable.

It's free and easy to enroll in STELARA withMe.


Actor Portrayal

You'll enjoy personalized support throughout your STELARA® treatment journey.

We're committed to making sure you have what you need, when you need it. Your treatment journey is about more than appointments and injections: it's about you feeling supported.

From now on, you can have a dedicated STELARA withMe Nurse Navigator. Just a phone call away. STELARA withMe is ready to help.

If you have any questions or need sign-up support, contact us at: 844-4-withMe (844-494-8463).

After signing up, you can expect a call from your STELARA withMe Nurse Navigator within 1 to 2 business days.

The program is limited to education about your Janssen medication, its administration, and/or the condition it treats. It is not intended to provide medical advice, replace a treatment plan you receive from your doctor or nurse, or serve as a reason for you to start or stay on treatment.

STELARA withMe can help you with:

- **Providing hands-on treatment education**
- **Understanding your insurance coverage and savings options**
- **Scheduling one-time IV infusion**
- **Receiving injection support**—Your doctor will review the injection process with you. Your doctor is the best person to help you understand what to expect. Your STELARA withMe Nurse Navigator is also available, after you have talked with your doctor, if you have questions about injections.

To get started, complete the Patient Authorization form and have your doctor submit it with the Enrollment and Prescription Form.

Please read the full Prescribing Information and Medication Guide for STELARA® and discuss any questions you have with your doctor.

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Stelara® (ustekinumab)

STELARA® (stel AR' a)

(ustekinumab) injection, for subcutaneous or intravenous use

WHAT IS STELARA® USED FOR?

STELARA® is a prescription medicine used to treat:

- adults and children 6 years and older with moderate or severe psoriasis who may benefit from taking injections or pills (systemic therapy) or phototherapy (treatment using ultraviolet light alone or with pills).
- adults 18 years and older with active psoriatic arthritis; STELARA® can be used alone or with methotrexate.
- adults 18 years and older with moderately to severely active Crohn's disease.
- adults 18 years and older with moderately to severely active ulcerative colitis.

It is not known if STELARA® is safe in children less than 6 years of age.

WHAT ARE THE MOST SERIOUS WARNINGS ABOUT STELARA®?

- STELARA® may lower the ability of your immune system to fight infections and may increase your risk of infections. Some people have serious infections while taking STELARA®, including tuberculosis (TB), and infections caused by bacteria, fungi, or viruses. Some people have to be hospitalized for treatment of their infection.
- Your doctor should check you for TB before starting STELARA®.
- If your doctor feels that you are at risk for TB, you may be treated with medicine for TB before you begin treatment with STELARA® and during treatment with STELARA®.
- Your doctor should watch you closely for signs and symptoms of TB during treatment with STELARA®.
- You should not start taking STELARA® if you have any kind of infection unless your doctor says it is okay.
- STELARA® may decrease the activity of your immune system and increase your risk for certain types of cancers. Tell your doctor if you have ever had any type of cancer. Some people who are receiving STELARA® and have risk factors for skin cancer have developed certain types of skin cancers. During your treatment with STELARA®, tell your doctor if you develop any new skin growths.
- Posterior Reversible Encephalopathy Syndrome (PRES) is a rare condition that affects the brain and can cause death. The cause of PRES is not known. If PRES is found early and treated, most people recover. Tell your doctor right away if you have any new or worsening medical problems including:
  - headache
  - confusion
  - seizures
  - vision problems

BEFORE TAKING STELARA®, TELL YOUR DOCTOR IF YOU:

- think you have an infection or have symptoms of an infection such as:
  - fever, sweat, or chills
  - weight loss
  - muscle aches
  - warm, red, or painful skin or sores on your body
  - cough
  - diarrhea or stomach pain
  - shortness of breath
  - burning when you urinate or urinate more often than normal
  - blood in phlegm
  - feel very tired
- are being treated for an infection or have any open cuts.
- get a lot of infections or have infections that keep coming back.
- have TB, or have been in close contact with someone with TB.

After starting STELARA®, call your doctor right away if you have any symptoms of an infection (see above). These may be signs of infections such as chest infections, or skin infections or shingles that could have serious complications. STELARA® can make you more likely to get infections or make an infection that you have worse. People who have a genetic problem where the body does not make any of the proteins interleukin 12 (IL-12) and interleukin 23 (IL-23) are at a higher risk for certain serious infections. These infections can spread throughout the body and cause death. People who take STELARA® may also be more likely to get these infections.

WHAT DO I NEED TO TELL MY HEALTHCARE PROVIDER?

- See **"What is the most important information about STELARA®?"**
- If you ever had an allergic reaction to STELARA®. Ask your doctor if you are not sure.
- If you are allergic to latex. The needle cover on the prefilled syringe contains latex.
- If you have recently received or are scheduled to receive an immunization (vaccine). People who take STELARA® should not receive live vaccines. Tell your doctor if anyone in your house needs a vaccine. The viruses used in some types of vaccines can spread to people with a weakened immune system and can cause serious problems. **You should not receive the BCG vaccine during the one year before taking STELARA® or one year after you stop taking STELARA®.**
- If you have any new or changing lesions within psoriasis areas or on normal skin.
- If you are receiving or have received allergy shots, especially for serious allergic reactions. Allergy shots may not work as well for you during treatment with STELARA®. STELARA® may also increase your risk of having an allergic reaction to an allergy shot.
- If you receive or have received phototherapy for your psoriasis.
- If you have any other medical conditions.
- If you are pregnant or planning to become pregnant. It is not known if STELARA® will harm your unborn baby. You and your doctor should decide if you will take STELARA®.
- If you are breastfeeding or plan to breastfeed. It is thought that STELARA® passes into your breast milk.
- Talk to your doctor about the best way to feed your baby if you take STELARA®.

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Know the medicines you take. Keep a list of them to show your doctor and pharmacist when you get a new medicine.

WHO SHOULD NOT TAKE STELARA®?

Do not take STELARA® if you are allergic to ustekinumab or any of the ingredients in STELARA®.

HOW SHOULD I USE STELARA®?

- Use STELARA® exactly as prescribed by your doctor.
- **The needle cover on the STELARA® prefilled syringe contains latex. Do not handle the needle cover if you are sensitive to latex.**
- Adults with Crohn's disease and ulcerative colitis will receive the first dose of STELARA® through a vein in the arm (intravenous infusion) in a healthcare facility by a healthcare provider. It takes at least 1 hour to receive the full dose of medicine. You will then receive STELARA® as an injection under the skin (subcutaneous injection) 8 weeks after the first dose of STELARA®.
- Adults with psoriasis or psoriatic arthritis and children 6 years and older with psoriasis will receive STELARA® as an injection under the skin (subcutaneous injection) as described below.
- STELARA® is intended for use under the guidance and supervision of your doctor. In children 6 years and older, it is recommended that STELARA® be administered by a healthcare provider. If your doctor decides that you or a caregiver may give your injections of STELARA® at home, you should receive training on the right way to prepare and inject STELARA®. Your doctor will determine the right dose of STELARA® for you, the amount for each injection, and how often you should receive it. Do not try to inject STELARA® yourself until you or your caregiver have been shown how to inject STELARA® by your doctor or nurse.
- **Visit STELARAinfo.com to read the detailed Instructions for Use about how to prepare and inject a dose of STELARA® and how to properly throw away used needles and syringes.**

WHAT ARE THE POSSIBLE SIDE EFFECTS OF STELARA®?

STELARA® may cause serious side effects, including:

- See **"What is the most important information about STELARA®?"**
- **Serious allergic reactions.** Serious allergic reactions can occur with STELARA®. Stop using STELARA® and get medical help right away if you have any of the following symptoms of a serious allergic reaction:
  - feeling faint
  - swelling of your face, eyelids, tongue, or throat
  - chest tightness
  - skin rash
- **Lung inflammation.** Cases of lung inflammation have happened in some people who receive STELARA®, and may be serious. These lung problems may need to be treated in a hospital. Tell your doctor right away if you develop shortness of breath or a cough that doesn't go away during treatment with STELARA®.

COMMON SIDE EFFECTS OF STELARA® INCLUDE:

Nasal congestion, sore throat, and runny nose, upper respiratory infections, fever, headache, tiredness, itching, nausea and vomiting, redness at the injection site, vaginal yeast infections, urinary tract infections, sinus infection, bronchitis, diarrhea, stomach pain, and joint pain.

These are not all of the possible side effects with STELARA®. For more information, ask your healthcare provider.

WHAT SHOULD I KNOW ABOUT THIS BRIEF SUMMARY?

This information is not complete. To get more information:

- Talk to your doctor.
- Visit **STELARAinfo.com** to obtain the FDA-approved product labeling, Medication Guide, and Instructions for Use.
- Call the FDA at 1-800-FDA-1088 to report side effects.

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Janssen Patient Support Program Patient Authorization Form

Patients should read the Patient Authorization, check the desired permission boxes, and return both pages of the Form to Janssen Patient Support Program.

- **Download a copy, print, check the desired boxes, and sign. Your healthcare provider may scan the completed Form and upload on Provider Portal, or completed Form may be faxed to 844-250-7193 or mailed to Janssen CarePath, 2250 Perimeter Park Drive, Suite 300, Morrisville, NC 27560**
- **You may be able to eSign a digital Form in your healthcare provider's office or on your Patient Account at MyJanssenCarePath.com**

Patient Name: _____ **Email Address:** _____

I give permission for each of my "Healthcare Providers" (eg, my physicians, pharmacists, specialty pharmacies, other healthcare providers, and their staff) and "Insurers" (eg, my health insurance plans) to share my Protected Health Information as described on this Form.

My "Protected Health Information" includes any and all information related to my medical condition, treatment, prescriptions, and health insurance coverage.

The following person(s) or class of person(s) are given permission to receive and use my Protected Health Information (collectively "Janssen"):

- Johnson & Johnson Health Care Systems Inc., its affiliated companies, agents, and representatives
- Providers of other sources of funding, including foundations and co-pay assistance providers
- Service providers for the patient support programs, including subcontractors or healthcare providers helping Janssen run the programs
- Service providers maintaining, transmitting, de-identifying, aggregating, or analyzing data from Janssen patient support programs

Also, I give permission to Janssen to receive, use, and share my Protected Health Information in order to:

- see if I qualify for, sign me up for, contact me about, and provide services relating to Janssen patient support programs, including in-home services
- manage the Janssen patient support programs
- give me educational and adherence materials, information, and resources related to my Janssen medication in connection with Janssen patient support programs
- communicate with my Healthcare Providers regarding access to, reimbursement for, and fulfillment of my Janssen medication, and to tell my Healthcare Provider that I am participating in Janssen patient support programs
- verify, assist with, and coordinate my coverage for my Janssen medication with my Insurers and Healthcare Providers
- coordinate prescription or treatment location and associated scheduling
- conduct analysis to help Janssen evaluate, create, and improve its products, services, and customer support for patients prescribed Janssen medications
- share and give access to information created by the Janssen patient support programs that may be useful for my care

I understand that my Protected Health Information may be shared by Janssen for the uses written in this Form to:

- My Insurers
- My Healthcare Providers
- Any of the persons given permission to receive and use my Protected Health Information as mentioned above
- Any individual I give permission as an additional contact

Janssen and the other data recipients listed on this Form may share information about me as permitted on this Form or if any information that specifically identifies me is removed. I understand that Janssen will use reasonable efforts to keep my information private but once my Protected Health Information is disclosed as allowed on this Form, it may no longer be protected by federal privacy laws.

Janssen Patient Support Program Patient Authorization Form

I understand that I am not required to sign this Form. My choice about whether to sign will not change how my Healthcare Providers or Insurers treat me. If I do not sign this Form, or cancel or remove my permission later, I understand I will not be able to participate or receive assistance from Janssen's patient support programs.

I understand that my Healthcare Providers may be paid by Janssen for sharing my Protected Health Information with Janssen as allowed on this Form.

This Form will remain in effect 10 years from the date of signature, except where state law requires a shorter time, or until I am no longer participating in any Janssen patient support programs. Information collected before that date may continue to be used for the purposes set forth in this Form.

I understand that I may cancel the permissions given by this Form at any time by letting Janssen know in writing at: Janssen CarePath, 2250 Perimeter Park Drive, Suite 300, Morrisville, NC 27560.

I can also cancel my permission by letting my Healthcare Providers and Insurers know in writing that I do not want them to share any information with Janssen.

I further understand that if I cancel my permission it will not affect how Janssen uses and shares my Protected Health Information received by Janssen prior to my cancellation.

I understand I may request a copy of this Form.

Permission for communications outside of Janssen patient support programs:

☐ Yes, I would like to receive communications relating to my Janssen medication.

☐ Yes, I would like to receive communications relating to other Janssen products and services.

For privacy rights and choices specific to California residents, please see Janssen's California privacy notice available at **https://www.janssen.com/us/privacy-policy#california**

Permission for text communications:

☐ Yes, I would like to receive text messages. By selecting this option, I agree to receive text messages as allowed by this Form to the cell phone number provided below. Message and data rates may apply. Message frequency varies. I understand I am not required to provide my permission to receive text messages to participate in the Janssen patient support programs or to receive any other communications I have selected.

Cell phone number: _____

Patient name (print): _____

Patient sign here: _____ **Date:** _____

If the patient cannot sign, patient's legally authorized representative must sign below:

By: _____ **Date:** _____

(Signature of person legally authorized to sign for patient)

Describe relationship to patient and authority to make medical decisions for patient:

_____

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UPDATE 03.22

Enrollment and Prescription Form

Complete and fax this form to 866-769-3903. For assistance, prescribers can call 844-4-withMe (844-494-8463), Monday–Friday, 8:00 AM–8:00 PM ET

Please be sure to have your patient complete the Patient Authorization Form and submit it with this completed Enrollment and Prescription Form.

The information you provide will be used by Janssen Biotech, Inc., our affiliates, and our service providers for your patient's enrollment and participation in STELARA withMe. Our Privacy Policy governs the use of the information you provide. By submitting this form, you indicate that you read, understand, and agree to these terms.

▼ TO BE COMPLETED BY PATIENT OR PROVIDER ▼

1. Patient Information (Required)

NAME (First, M, Last) _____ DOB (MM/DD/YYYY) _____ GENDER _____

ADDRESS _____ CITY _____

STATE _____ ZIP CODE _____ PHONE _____ EMAIL ADDRESS _____

As part of your patient's enrollment in STELARA withMe, they will have access to a dedicated Nurse Navigator at no cost to them. After submitting this form, your patient can expect a call from their STELARA withMe Nurse Navigator within 1 to 2 business days.

2. Insurance Information (Required. Complete fields below OR provide a copy of insurance cards.)

Medical Insurance _____ POLICY# _____ GROUP# _____

CARDHOLDER _____ DOB (MM/DD/YYYY) _____

Pharmacy Insurance _____ PCN# _____ GROUP# _____

CARDHOLDER _____ CARD/BIN# _____ DOB (MM/DD/YYYY) _____

Secondary Insurance _____ POLICY# _____ GROUP# _____

CARDHOLDER _____ DOB (MM/DD/YYYY) _____

▼ TO BE COMPLETED BY PROVIDER ▼

3. Prescriber Information (Required)

PRESCRIBER NAME (First, Last) _____ OFFICE CONTACT _____

PRACTICE NAME _____ TAX ID# _____ NPI# _____

ADDRESS _____ CITY _____

STATE _____ ZIP CODE _____ PHONE _____ FAX _____

4. Clinical Information (Required. The information requested is for benefits investigation purposes only.)

STELARA®—DIAGNOSIS

DATE OF DIAGNOSIS OR YEARS WITH DISEASE _____ PREVIOUS TB TEST (DATE) _____

- ☐ K50.00 (Crohn's Disease of small intestine, without complications)
- ☐ K51.90 (Ulcerative Colitis, unspecified, without complications)
- ☐ K50.80 (Crohn's Disease of both small and large intestine, without complications)
- ☐ K51.00 (Ulcerative [chronic] Pancolitis, without complications)
- ☐ K50.90 (Crohn's Disease, unspecified, without complications)
- ☐ K51.80 (Other Ulcerative Colitis, without complications)
- ☐ Other ICD-10 Code _____

PRIOR MEDICATIONS (REQUIRED TO COMPLETE PRIOR AUTHORIZATION)

☐ 5-ASA ☐ 6-MP ☐ Azathioprine ☐ Azulfidine® ☐ Cimzia® ☐ Corticosteroids ☐ Cyclosporine
☐ Entyvio® ☐ Humira® ☐ Methotrexate ☐ Tysabri® ☐ Xeljanz® ☐ Zeposia® ☐ None ☐ Other _____

5. Prior Authorization

Prior Authorization Form Assistance and Status Monitoring: STELARA withMe assists your office in providing the requirements of the patient's health plan related to prior authorization for treatment with STELARA®. Assistance includes obtaining the health plan–specific prior authorization form, and providing it based upon the patient-specific information provided on this form. The partially completed prior authorization form will be provided to your office for possible completion and submission in the office's sole discretion. STELARA withMe also actively monitors the status of prior authorization submission to the patient's plan and provides status updates to your office with respect to this patient's prior authorization for treatment with STELARA®.

- ☐ **I do NOT wish to receive Prior Authorization Form Assistance or Status Monitoring. This opt-out does not apply if you are requesting the patient to be signed up to receive this product at no cost until their insurance covers the medication if delayed >5 business days or denied.**
- ☐ **Prior Authorization is already on file with the patient's plan for treatment with STELARA® IV.**
- ☐ **Prior Authorization is already on file with the patient's plan for treatment with subcutaneous STELARA®.**

▼ COMPLETE IF REQUESTING BENEFITS INVESTIGATION FOR INDUCTION DOSE ▼

6. Single IV Induction Information

Please Investigate ☐ **Pharmacy & Medical Benefits**

DATE OF INFUSION INDUCTION DOSE (Required) _____

Patient Weight _____ lb _____ kg

- ☐ 55 kg or less — 260 mg (2 x 130 mg/26 mL vials) at Week 0
- ☐ more than 55 kg to 85 kg — 390 mg (3 x 130 mg/26 mL vials) at Week 0
- ☐ more than 85 kg — 520 mg (4 x 130 mg/26 mL vials) at Week 0

SITE OF INFUSION (REQUIRED IF DIFFERENT FROM PRESCRIBER'S OFFICE)

☐ Non-prescriber's office ☐ Hospital outpatient ☐ Infusion center ☐ Other

PHYSICIAN OR INFUSION PROVIDER NAME _____

PRACTICE/FACILITY NAME _____ NPI # _____ TAX ID # _____

ADDRESS _____ CITY _____

STATE _____ ZIP CODE _____ PHONE _____ FAX _____

▼ COMPLETE IF REQUESTING BENEFITS INVESTIGATION FOR MAINTENANCE DOSE ▼

7. Maintenance Dose Information

Please investigate ☐ **Pharmacy & Medical Benefits** ☐ **90 mg/mL single-use prefilled syringe** ☐ **45 mg/0.5 mL vials**

SHIPPING INFORMATION FOR MAINTENANCE THERAPY (Required to complete benefits investigation even if not prescribing. NOTE: Shipments cannot be sent to P.O. Boxes)

SHIP TO: ☐ Office ☐ Patient (Payer may require pharmacy benefit use only if selected) ☐ Hospital outpatient ☐ Other

ADDRESS _____ CITY _____

STATE _____ ZIP CODE _____ PHONE _____ FAX _____

Rx STELARA® MAINTENANCE THERAPY (Do not complete this section if requesting benefits investigation only.)

DATE OF INFUSION INDUCTION DOSE (If known) _____

☐ 1 single-use prefilled syringe; **90 mg** SC every 8 weeks Refills # _____

☐ Two 45 mg vials; **90 mg** SC every 8 weeks Refills # _____

PRESCRIBER SIGNATURE (NO STAMPS ALLOWED) REQUIRED TO VALIDATE PRESCRIPTION: I certify that therapy with STELARA® is medically necessary for this patient. I will be supervising the patient's treatment accordingly, and I have reviewed the current STELARA® Prescribing Information. I authorize STELARA withMe to act on my behalf for the limited purposes of transmitting this prescription to the appropriate pharmacy designated by me, the patient, or the patient's plan.

When commercial insurance coverage is delayed >5 business days or denied, STELARA withMe offers eligible patients subcutaneous STELARA® at no cost until their commercial insurance covers the medication. Only available for 90 mg single-use prefilled syringe. See the program requirements on the next page.

By enrolling patient for this support, I certify that I agree to the program requirements and will take any necessary action described in the requirements for my patient.

PRESCRIBER SIGNATURE (Dispense as written) _____ DATE _____

Please read the full Prescribing Information and Medication Guide for STELARA® and discuss any questions you have with your doctor.

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Information about your patient's insurance coverage, cost support options, and treatment support is given by service providers for STELARA withMe. 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 is not for patients in the Johnson & Johnson Patient Assistance Foundation.

STELARA withMe offers eligible patients subcutaneous STELARA® (ustekinumab) **at no cost** until their commercial insurance covers the medication. See program requirements below.

To be eligible, patient must have:

1. a subcutaneous STELARA® prescription for an on-label, FDA-approved indication
2. commercial insurance with biologics coverage
3. a delay of more than 5 business days or a denial of treatment from their insurance.

In addition, for patient to be eligible, Prescriber must submit:

4. a program enrollment form*
5. a coverage determination form (ie, prior authorization or prior authorization with exception) to the commercial insurance. If coverage is denied, Prescriber must also submit a Letter of Formulary Exception, Letter of Medical Necessity, or appeal within 90 days of patient becoming eligible for patient to stay in the program.

Patient is not eligible if:

1. patient uses any state or federal government-funded healthcare program to cover medication costs. Examples of these programs are Medicare, Medicaid, TRICARE, Department of Defense, and Veterans Administration
2. prior authorization is denied due to missing information on coverage determination form, use for a non-FDA-approved indication, or invalid clinical rationale.

Patient is eligible until commercial insurance covers the medication. Program requires periodic verification of insurance coverage status to confirm continued eligibility.

Program covers the cost of therapy only—not associated administration cost. Prescriber cannot bill commercial insurance plan for any part of the prescribed subcutaneous treatment. Patient cannot submit the value of the free product as a claim for payment to any health plan. Program good only in the United States and its territories. Void where prohibited, taxed, or limited by law. Program terms may change.

Participating prescribers authorize STELARA withMe to:

1. conduct a benefits investigation and confirm prior authorization requirements
2. provide prior authorization form assistance and status monitoring, including the exceptions and appeals processes
3. refer eligible patients to Wegmans Specialty Pharmacy for further program support and shipment of medication
4. support the transition of patients to commercial product if the medication is covered
5. check insurance coverage status during the program.

*STELARA withMe cannot accept any information without an executed Business Associate Agreement and/or Patient Authorization on file. The Patient Authorization can be found on this form, or patient can create an account on **MyJanssenCarePath.com** and electronically sign a patient authorization there.

Please read the full Prescribing Information and Medication Guide for STELARA® and discuss any questions you have with your doctor.

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PHARMACEUTICAL COMPANIES OF
Johnson & Johnson