



Benefits Investigation and Prescription Form



Complete and fax this form to 866-769-3903. For assistance, prescribers can call 844-4withMe (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 Benefits Investigation 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 via Janssen CarePath. 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 ▼	▼ TO BE COMPLETED BY PROVIDER ▼
1. Patient Information (Required)	5. Prior Authorization
FIRST NAME LAST NAME DOB (MM/DD/YYYY) GENDER ADDRESS CITY	Prior Authorization Form Assistance and Status Monitoring: STELARA with Me 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 with Me 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®.
STATEZIP CODEPHONEEMAIL	Ido NOT wish to receive Prior Authorization Form Assistance or Status Monitoring. This opt-out does not apply when the patient
2. Insurance Information (Required. Complete fields below OR provide a copy of insurance cards.)	is signed up to receive this product at no cost until their insurance covers the medication if delayed >5 business days or denied.
	\square Prior Authorization is already on file with the patient's plan for treatment with subcutaneous STELARA®.
MEDICAL INSURANCE (MI)MI POLICY#MI GROUP#	▼ COMPLETE IF REQUESTING BENEFITS INVESTIGATION ▼
MI CARDHOLDER FIRST NAMEMI CARDHOLDER LAST NAME	6. Benefits Investigation (For benefits investigation only. Do not prescribe these products together.)
MI DOB (MM/DD/YYYY) RELATIONSHIP TO CARDHOLDER	I would like to request a benefits investigation for STELARA® (ustekinumab). ☐ 1 single-dose 45 mg prefilled syringe ☐ 1 single-dose 90 mg prefilled syringe
PHARMACY INSURANCE (RX) RX PCN# RX GROUP#	☐ 1 single-dose 45 mg vial ☐ 2 single-dose 45 mg vials I would also like to request a benefits investigation for TREMFYA® (guselkumab) which is approved for adult
Rx CARDHOLDER FIRST NAME Rx CARDHOLDER LAST NAME	patients only. (Pharmacy Insurance information must be provided.)
Rx CARD/BIN#Rx DOB (MM/DD/YYYY)	☐ 1 single-dose 100 mg One-Press patient-controlled injector ☐ 1 single-dose 100 mg prefilled syringe SITE OF CARE ☐ Prescribing Physician's Office ☐ Non-prescribing Physician's Office ☐ Hospital Outpatient ☐ Other
SECONDARY INSURANCE (SI)SI POLICY#SI GROUP#	(Required if different from prescriber)
SI CARDHOLDER FIRST NAME SI CARDHOLDER LAST NAME SI DOB (MM/DD/YY YY)	PHYSICIAN FIRST NAMEPHYSICIAN LAST NAME CONTACT FIRST NAMECONTACT LAST NAME
▼ TO BE COMPLETED BY PROVIDER ▼	
3. Prescriber Information (Required)	SITE NAMESITE PTAN#
	SITE NPI#SITE TAX ID#
PRESCRIBER FIRST NAME PRESCRIBER LAST NAME	SITE ADDRESS SITE CITY
OFFICE CONTACT FIRST NAMEOFFICE CONTACT LAST NAME	
PRACTICE NAME PRACTICE TAX ID# PRACTICE NPI#	SITE STATESITE ZIP CODESITE PHONESITE FAX
PRACTICE NAME PRACTICE TAX ID# PRACTICE NPI#	▼ IF REQUESTING BENEFITS INVESTIGATION ONLY, DO NOT COMPLETE THIS SECTION ▼
OFFICE ADDRESSOFFICE CITY	7. Prescription Information
OFFICE STATE OFFICE ZIP CODE OFFICE PHONE OFFICE FAX	STELARA® Rx DIRECTIONS (Select all that apply.)
	VIAL STARTER DOSE for plaque psoriasis and active PREFILLED SYRINGE STARTER DOSE
4. Clinical Information (Required. This information requested is for benefits investigation purposes only.)	psoriatic arthritis (ages 6-17) weighing less than 60 kg 1 single-dose 45 mg SC prefilled syringe Week 0 Week 4
PRIMARY DIAGNOSIS:	□ 1 single-dose 45 mg vial at □ Week 0 □ Week 4 □ 1 single-dose 90 mg SC prefilled syringe □ Week 0 □ Week 4
PSORIASIS PSORIATIC ARTHROPATHY	VIAL MAINTENANCE THERAPY for plaque psoriasis PREFILLED SYRINGE MAINTENANCE THERAPY
L40.0 (Psoriasis vulgaris) L40.50 (Arthropathic psoriasis, unspecified) L40.53 (Psoriatic spondylitis)	and active psoriatic arthritis (ages 6-17) weighing less 1 single-dose 45 mg SC prefilled syringe every 12 weeks Refills #
Other ICD-10 Code	than 60 kg 1 single-dose 45 mg vial every 12 weeks Refills # 1 single-dose 90 mg SC prefilled syringe every 12 weeks Refills #
SECONDARY DIAGNOSIS: ICD-10 CODE	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
TB TEST DATEDATE OF DIAGNOSIS OR YEARS WITH DISEASE	purposes of transmitting this prescription to the appropriate pharmacy designated by me, the patient, or the patient's plan.
PATIENT WEIGHT Ib kg	Delay and Denial Support 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. See the program requirements on page 4. By enrolling
PRIOR MEDICATIONS (REQUIRED TO COMPLETE PRIOR AUTHORIZATION) ☐ Arava® ☐ Corticosteroids ☐ Cosentyx® ☐ Cyclosporine ☐ Enbrel® ☐ Humira® ☐ Methotrexate ☐ Otezla® ☐ Phototherapy	patients in STELARA with Me Delay and Denial Support, I certify that I agree to the program requirements and will take any necessary action described in the requirements for my patient.
Indicate the control of the control	PRESCRIBER SIGNATURE (DISPENSE AS WRITTEN) DATE

Please see accompanying full Prescribing Information and Medication Guides for STELARA® and TREMFYA®. Provide Medication Guides to your patients and encourage discussion.

INDICATIONS

STELARA® (ustekinumab) is indicated for the treatment of patients 6 years and older with active psoriatic arthritis.

STELARA® is indicated for the treatment of patients 6 years or older with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy.

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 aastroenteritis, 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®.

Posterior Reversible Encephalopathy Syndrome (PRES)

Two cases of posterior reversible encephalopathy syndrome (PRES), also known as Reversible Posterior Leukoencephalopathy Syndrome (RPLS), were reported in clinical trials. Cases have also been reported in postmarketing experience in patients with psoriasis, psoriatic arthritis and Crohn's disease. Clinical presentation included headaches, seizures, confusion, visual disturbances, and imaging changes consistent with PRES a few days to several months after ustekinumab initiation. A few cases reported latency of a year or longer. Patients recovered with supportive care following withdrawal of ustekinumab.

Monitor all patients treated with STELARA® for signs and symptoms of PRES. If PRES is suspected, promptly administer appropriate treatment and discontinue STELARA®.

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 presentations in cluded cough. The couple of the coupleinfiltrates 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 (23% and higher than that with placebo) in adults from psoriasis clinical studies for STELARA® 45 mq, STELARA® 90 mq, 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 arthralqia 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 accompanying full Prescribing Information and Medication Guide for STELARA®. Provide Medication Guide to your patients and encourage discussion.

0-82625v3

INDICATIONS

TREMFYA® (guselkumab) is indicated for the treatment of adults with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy. TREMFYA® is indicated for the treatment of adults with active psoriatic arthritis.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

TREMFYA® is contraindicated in patients with a history of serious hypersensitivity reaction to quselkumab or to any of the excipients.

WARNINGS AND PRECAUTIONS

Hypersensitivity Reactions

Serious hypersensitivity reactions, including anaphylaxis, have been reported with postmarket use of TREMFYA®. Some cases required hospitalization. If a serious hypersensitivity reaction occurs, discontinue TREMFYA® and initiate appropriate therapy.

Infections

TREMFYA® may increase the risk of infection. Treatment with TREMFYA® 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 prescribing TREMFYA® in patients with a chronic infection or a history of recurrent infection. Instruct patients receiving TREMFYA® to seek medical help if signs or symptoms of clinically important chronic or acute infection occur. If a patient develops a clinically important or serious infection, or is not responding to standard therapy, closely monitor and discontinue TREMFYA® until the infection resolves.

Pre-Treatment Evaluation for Tuberculosis (TB)

Evaluate patients for TB infection prior to initiating treatment with TREMFYA®. Initiate treatment of latent TB prior to administering TREMFYA®. Monitor patients for signs and symptoms of active TB during and after TREMFYA® treatment. Do not administer TREMFYA® to patients with active TB infection.

Immunizations

Prior to initiating TREMFYA®, consider completion of all age-appropriate immunizations according to current immunization guidelines. Avoid use of live vaccines in patients treated with TREMFYA®.

ADVERSE REACTIONS

Most common (≥1%) adverse reactions associated with TREMFYA® include upper respiratory infections, headache, injection site reactions, arthralgia, bronchitis, diarrhea, gastroenteritis, tinea infections, and herpes simplex infections.

The overall safety profile observed in patients with psoriatic arthritis is generally consistent with the safety profile in patients with plaque psoriasis, with the addition of bronchitis and neutrophil count decreased.

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

STELARA withMe Delay and Denial Support

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

Program Requirements

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 Janssen CarePath Business Associate Agreement and/or Patient Authorization on file. The Patient Authorization can be found on this Benefits Investigation and Prescription Form.

Please see accompanying full <u>Prescribing Information</u> and <u>Medication Guide</u> for STELARA®. Provide Medication Guide to your patients and encourage discussion.



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 866-769-3903 or mailed to STELARA withMe, 2250 Perimeter Park Drive, Suite 300, Morrisville, NC 27560

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 pharmacies that dispense and ship my medication and service providers for the patient support programs may be paid by Janssen for their services and data. This may include payment for sharing Protected Health Information and other data in connection with these programs, 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: STELARA withMe, 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 lanseen patient support programs:

(Signature of person legally authorized to sign for patient) Describe relationship to patient and authority to make medical decisions for patient:		janssen j
Ву:	Print Name:	Date:
f the patient cannot sign, patient's l	egally authorized representative must sign below:	
Patient sign here:		Date:
Patient name (print):		
Cell phone number:	issert patient support programs or to receive any other comm	difficultions i flave selected.
provided below. Message and da	essages. By selecting this option, I agree to receive text messa ta rates may apply. Message frequency varies. I understand I ar assen patient support programs or to receive any other comm	n not required to provide my permission to receive text
Permission for text communication	ns:	
or privacy rights and choices speciet https://www.janssen.com/us/p	fic to California residents, please see Janssen's California privac rivacy-policy#california	ty notice available
	unications relating to my Janssen medication. unications relating to other Janssen products and services.	