Janssen CarePath UPDATE 9.19

Gastroenterologist Benefits Investigation and Prescription Form

Complete and fax this form to 866-769-3903. For assistance, call 877-CarePath (877-227-3728), Monday–Friday, 8:00 AM–8:00 PM ET

Stelara® (ustekinumab)

Janssen CarePath cannot accept any information without an executed Business Associate Agreement or Patient Authorization Form, which can be found at JanssenCarePath.com or as the last page of this document.

1. PATIENT INFORMATION (REQUIRED)

NAME (First, MI, Last) _____ SEX ☐ M ☐ F

ADDRESS _____

CITY _____ STATE _____ ZIP CODE _____ DOB (MM/DD/YYYY) _____

PRIMARY PHONE (best number to call 8:00 AM to 8:00 PM) _____

NURSE NAVIGATORS FROM JANSSEN CAREPATH (Patient Enrolled Program)

☐ YES! I (the patient) would like to enroll in the Nurse Navigator Program and will submit the attached enrollment form.

2. INSURANCE INFORMATION (REQUIRED. Complete fields below OR provide a copy of insurance cards.)

MEDICAL INSURANCE _____

CARDHOLDER _____

DATE OF BIRTH _____ POLICY# _____ GROUP# _____

PHARMACY INSURANCE _____ PCN# _____

CARDHOLDER _____ DATE OF BIRTH _____

PHARMACY ID _____ CARD/BIN# _____ GROUP# _____

SECONDARY INSURANCE _____ CARDHOLDER _____

DATE OF BIRTH _____ POLICY# _____ GROUP# _____

3. CLINICAL INFORMATION & PRIOR THERAPIES (REQUIRED. The information requested is for benefits investigation purposes only. Visit JanssenCarePath.com for ICD-10 codes or consult the ICD-10 code book for additional information.)

STELARA®—DIAGNOSIS

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

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

PRIOR MEDICATIONS (REQUIRED TO COMPLETE PRIOR AUTHORIZATION)

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

4. JANSSEN LINK PROGRAM

Janssen Link, a program offered by Janssen CarePath, is for eligible patients with commercial insurance who have been prescribed subcutaneous STELARA® for an on-label FDA-approved indication. It enables patients to receive subcutaneous STELARA® at no cost if the patient has commercial insurance that has delayed (>5 business days) or denied their treatment. See program requirements below and on back.

By enrolling patients in Janssen Link, I certify to not purchase the Janssen medication on behalf of Janssen Link patient participants, and not bill commercial payers for any part of the prescribed subcutaneous treatment. I also agree to complete and submit a form of coverage determination (ie, prior authorization or prior authorization with an exception) to the commercial insurance. If coverage is denied, then I agree to challenge the coverage denial with an exception, Letter of Medical Necessity or appeal. I also understand that Janssen CarePath will monitor prior authorization status.

PRESCRIBER SIGNATURE (NO STAMPS ALLOWED) _____ DATE _____

5. PRIOR AUTHORIZATION

Prior Authorization Form Assistance and Status Monitoring: Janssen CarePath 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. Janssen CarePath 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 be enrolled in Janssen Link.**
☐ **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®.**

6. PRESCRIBER INFORMATION (REQUIRED)

PRESCRIBER NAME (First, Last) _____

PRACTICE NAME _____ OFFICE CONTACT _____

ADDRESS _____

CITY _____ STATE _____ ZIP CODE _____

PHONE _____ FAX _____

TAX ID# _____ NPI# _____

7. SINGLE IV INDUCTION AND SITE OF INFUSION INFORMATION (Complete this section and provide induction dose information. If requesting benefits investigation or prescription for maintenance dose only, skip to Section 8.)

Please Investigate ☐ **PHARMACY & MEDICAL BENEFITS**

INFUSION INDUCTION DOSE

☐ 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

PATIENT WEIGHT _____ lb. _____ kg. DATE OF INFUSION INDUCTION DOSE _____

SITE OF INFUSION (REQUIRED IF DIFFERENT FROM PRESCRIBING MD's OFFICE)

☐ Non-prescribing MD's office ☐ Hospital outpatient ☐ Infusion center ☐ Other

PHYSICIAN OR INFUSION PROVIDER NAME _____

PRACTICE/FACILITY NAME _____

ADDRESS _____

CITY _____ STATE _____ ZIP _____

PHONE _____ FAX _____

NPI # _____ TAX ID # _____

8. MAINTENANCE DOSE INFORMATION (Complete this section if requesting benefits investigation, enrollment in Janssen Link AND/OR a prescription for maintenance dose.)

Please investigate STELARA® 90 mg single-use prefilled syringe ☐ **PHARMACY & MEDICAL BENEFITS**

Please investigate STELARA® 45 mg vials ☐ **PHARMACY & MEDICAL BENEFITS**

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.)

☐ 1 single-use prefilled syringe; **90 mg** SC every 8 weeks Refills # _____
☐ 2, 45 mg vials; **90 mg** SC every 8 weeks Refills # _____

DATE OF INFUSION INDUCTION DOSE (IF KNOWN) _____

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 Janssen CarePath 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.

PRESCRIBER SIGNATURE (Dispense as written) _____ DATE _____

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

By providing your information and information about your patient on the front of the Benefits Investigation and Prescription Form, you are requesting the services described on this form. The information you provide will only be used by Janssen Biotech, Inc., our affiliates, and our service providers involved in delivering these services. You may withdraw your request for these services by calling 877-CarePath (877-227-3728). Our Privacy Policy, available at **JanssenCarePath.com/Privacy-Policy**, governs the use of the information you provide. By providing the information and submitting this form, you indicate you read, understand, and agree to these terms.

Patient insurance benefits investigation and other Janssen CarePath program offerings are provided by third-party service providers for Janssen CarePath, under contract with Johnson & Johnson Health Care Systems Inc. on behalf of Janssen Pharmaceuticals, Inc., Janssen Biotech, Inc., and Janssen Products, LP (Janssen). Janssen CarePath is not available to patients participating in the Patient Assistance Program offered by Johnson & Johnson Patient Assistance Foundation. The availability of information and assistance may vary based on the Janssen medication, geography and other program differences. Janssen CarePath assists healthcare providers (HCPs) 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 HCP under appropriate authorization following the provider's exclusive determination of medical necessity. This information and assistance are made available as a convenience to patients, and there is no requirement that patients or HCPs use any Janssen product in exchange for this information or assistance. Janssen assumes no responsibility for and does not guarantee the quality, scope, or availability of the information and assistance provided. The third-party service providers, not Janssen, are responsible for the information and assistance provided under this program. Each HCP and patient is responsible for verifying or confirming any information provided. All claims and other submissions to payers should be in compliance with all applicable requirements.

Janssen Link enables eligible patients to receive subcutaneous STELARA® at no cost until they receive coverage. See program requirements below and on front.

Janssen Link Program Requirements

- Patient has been prescribed subcutaneous STELARA® for an on-label FDA-approved indication
- Patient has commercial insurance that has delayed (>5 business days) or denied their treatment
- Patient does not use any state or federal government-funded healthcare program to cover a portion of medication costs, such as Medicare, Medicaid, TRICARE, Department of Defense, or Veterans Administration
- Patient cannot submit the value of the free product as a claim for payment to any third-party payer
- Patient is not eligible if the prior authorization is denied due to missing information on coverage determination form, use for a non-FDA-approved indication or invalid clinical rationale
- Patient must contact Janssen CarePath if the patient switches from commercial health insurance coverage to a government-funded healthcare program at any point during the program year

How Janssen Link Works

- Program covers cost of therapy only—not associated administration cost
- No portion of the value of the free product will count towards the patient's applicable out-of-pocket cost-sharing obligations
- Program year runs March 1 – February 28
- Janssen CarePath reserves the right to cancel or modify Janssen Link at any time

By participating in Janssen Link, I authorize Janssen CarePath to:

- Conduct a benefits investigation and confirm prior authorization (PA) requirements
- Provide PA form assistance and status monitoring, including the exceptions and appeals processes
- Coordinate shipment of subcutaneous STELARA® from the program Specialty Pharmacy to eligible patients at no charge until they have coverage or until the end of the current program year
- Support the transition of patients to commercial product if a favorable coverage determination is made within 90 days of the PA submission
- Conduct verification of insurance coverage in January of each year for patients enrolled in the program and any time for patients who have coverage change throughout the program year to confirm eligibility criteria are met for continued participation

janssen
PHARMACEUTICAL COMPANIES OF
Johnson & Johnson

Janssen CarePath

Nurse Navigators from Janssen CarePath

Enroll now for your Dedicated Nurse Navigator

A Nurse Navigator serves as a partner throughout your treatment journey

Stelara® (ustekinumab)

E-mail to: mynurse@janssennurse.com

Fax to: 800-870-6237

Mail to: Nurse Navigators from Janssen CarePath
500 Atrium Drive, 3rd Floor, Somerset, NJ 08873

***REQUIRED INFORMATION**

1. PATIENT INFORMATION

☐ Mr ☐ Mrs ☐ Ms ☐ Miss

*FIRST NAME _____

*LAST NAME _____

STREET ADDRESS _____ APT/UNIT _____

CITY _____ STATE _____ ZIP CODE _____

*PHONE _____ ☐ Mobile ☐ Home ☐ Office ☐ Other

SECONDARY PHONE _____

Okay to leave message? ☐ Yes ☐ No Okay to text? ☐ Yes ☐ No

*EMAIL ADDRESS _____ DOB (MM/DD/YYYY)_____

I authorize the following individual to act as my personal representative in this program

Relationship to you

_____ _____

E-MAIL ADDRESS _____

*PHONE _____ ☐ Mobile ☐ Home ☐ Office ☐ Other

SECONDARY PHONE _____

2. PHYSICIAN INFORMATION

☐ Doctor ☐ Nurse Practitioner ☐ Physician Assistant

NAME _____

STREET ADDRESS _____

CITY _____ STATE _____

ZIP CODE _____ PHONE _____

3. PATIENT AUTHORIZATION (SIGNATURE REQUIRED)

My signature on the Nurse Navigator Enrollment Form confirms I authorize each of my physicians and Specialty Pharmacies ("healthcare providers") to disclose my protected health information, including information related to my medical condition, treatment, and prescriptions, to Janssen Biotech, Inc., its affiliated companies, agents, and representatives, including other service providers supporting Janssen access programs for healthcare providers and patients (STELARA® and Nurse Navigators from Janssen CarePath, together "Janssen Biotech") for the purposes described below.

Specifically, I authorize Janssen Biotech to receive, use, and disclose my protected health information in order to (i) enroll me in and contact me about Nurse Navigators from Janssen CarePath; (ii) provide me with educational materials, information, and services related to Nurse Navigators from Janssen CarePath; (iii) speak and otherwise communicate on my behalf with my insurers and specialty pharmacies regarding my use and receipt of STELARA®; (iv) assist in understanding adherence to STELARA®, and; (v) to manage and improve the STELARA® Nurse Navigator Program. I also understand that information regarding my participation in Nurse Navigators from Janssen CarePath will be shared with my prescribing physician. Furthermore, I understand that my protected health information will not be used or disclosed by Janssen Biotech for any other purpose unless permitted by law or unless information that specifically identifies me is removed. I understand that Janssen Biotech will make every effort to keep my information private. If my information is accidentally shared, federal privacy laws do not require that the person/party receiving it not disclose the information further. Information disclosed under these circumstances and provided to a third party may no longer be protected by federal privacy laws. For additional information on how Janssen Biotech collects, uses, and discloses personal information visit **JanssenCarePath.com/Privacy-Policy**.

I understand that I am not required to sign the Nurse Navigator Enrollment Form. My choice about whether to sign will not change the way my healthcare providers treat me. If I do not sign the Nurse Navigator Enrollment Form, or revoke my authorization later, I understand that this means I will not be able to participate in Nurse Navigators from Janssen CarePath.

This authorization will last until I am no longer participating in Nurse Navigators from Janssen CarePath. I understand that I may cancel this authorization at any time by mailing a letter requesting such cancellation to:

Nurse Navigators from Janssen CarePath
500 Atrium Drive, 3rd Floor, Somerset, NJ 08873

I can also revoke my authorization by informing my healthcare providers in writing that I do not want them to share any information with Janssen Biotech, but this will not affect Janssen Biotech's ability to use and disclose protected health information that it has received prior to its receipt of notification that I wish to discontinue my participation in the program. My authorization will also end if Nurse Navigators from Janssen CarePath is discontinued. Furthermore, I understand that I have the right to see or copy the protected health information my healthcare providers have given to Janssen Biotech.

PATIENT AUTHORIZATION SIGNATURE _____

DATE _____

The nurse program is limited to education for patients about their Janssen therapy, its administration, and/or their disease. It is intended to supplement a patient's understanding of their therapy, and is not intended to provide medical advice, replace a treatment plan from the patient's doctor or nurse, provide case management services, or serve as a reason to prescribe.

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

Janssen

Janssen CarePath Patient Authorization

- **Patients should read the Patient Authorization and sign electronically or download, print, and sign.**
  - **Completed form may be uploaded to Patient Account or Provider Portal, faxed to Janssen CarePath at 866-769-3903, or mailed to address below.**
- **Patients can access a copy of completed form in their Janssen CarePath Account – My Profile.**

My signature on this Patient Authorization Form confirms that I authorize each of my physicians, pharmacists, including any specialty pharmacy that receives my prescription for a Janssen medication and other healthcare providers (together, "Healthcare Providers") and each of my health insurers (together, "Insurers") to disclose my protected health information, including but not limited to information related to my medical condition and treatment, my health insurance coverage, my name, address, telephone number, insurance plan and/or group numbers (together, "Protected Health Information") to Johnson & Johnson Health Care Systems Inc., its affiliated companies, agents and representatives (together, "Janssen"), including providers of alternate sources of funding for prescription drug costs, and other approved service providers authorized to manage, administer, and/or support Janssen CarePath programs, Janssen CarePath Account for Patients, and Provider Portal for their Healthcare Providers for the purposes described below.

Specifically, I authorize Janssen to receive, use, and disclose my Protected Health Information in order to (i) enroll me in, determine my eligibility for, and contact me about, Janssen medication support programs; (ii) provide me with educational materials, information, and services related to my Janssen medication; (iii) verify, investigate, assist with, and coordinate my coverage for my Janssen medication with my Insurers; (iv) coordinate prescription fulfillment; (v) assist with analyses related to the quality, efficacy, and safety of my Janssen medication, and patient access to and adherence to my Janssen medication; (vi) to share and provide access to, information generated by Janssen CarePath that may be useful for my care, and; (vii) to improve, develop, and evaluate Janssen CarePath, its offerings, and materials. I also understand that pharmacies that ship my medication may be paid to share this information with Janssen CarePath to help provide the offerings requested for me. Furthermore, I understand that my Protected Health Information will not be used or disclosed by Janssen for any other purpose without my prior authorization unless permitted by law or unless information that specifically identifies me is removed. I understand that Janssen will make every effort to keep my information private. Further, I understand that if my information is accidentally shared, federal privacy laws do not require that the person/party receiving it not disclose the information further and that such information provided to a third party may no longer be protected by federal privacy laws.

I understand that I am not required to sign this Patient Authorization Form. My choice about whether to sign will not change the way my Healthcare Providers or Insurers treat me. If I refuse to sign the Patient Authorization Form, or revoke my authorization later, I understand that this means I will not be able to participate or receive assistance from Janssen CarePath.

This authorization will last until I am no longer participating in Janssen CarePath, or accessing my Janssen CarePath Account. I understand that I may cancel or revoke this Authorization at any time by mailing a letter requesting such cancellation to Janssen CarePath, 2250 Perimeter Park Drive, Suite 300, Morrisville, NC 27560 or by informing my Healthcare Providers and Insurers in writing that I do not want them to share any information with Janssen. I further understand that cancellation or revocation will not affect Janssen's ability to use and disclose Protected Health Information that it has received prior to its receipt of my cancellation and revocation of participation in the program. My authorization will also end if Janssen CarePath support programs or the Janssen CarePath Account is discontinued. Furthermore, I understand that I have the right to see or copy the Protected Health Information my Healthcare Providers or Insurers have given to Janssen.

Patient name: _____ Date of birth (mm/dd/yyyy): _____

Patient address: _____

City: _____ State: _____ ZIP Code: _____

Patient sign here: _____ Date: _____

If 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: _____

Janssen CarePath
2250 Perimeter Park Drive, Suite 300
Morrisville, NC 27560
Fax 866-769-3903