ILARIS companion

Dedicated and dependable support

ILARIS START FORM

Now that the decision to prescribe ILARIS has been made, use this 2-page form to initiate treatment and patient support*

INDICATIONS

ILARIS® (canakinumab) is an interleukin-1β blocker indicated for the treatment of the following autoinflammatory Periodic Fever Syndromes:

- Cryopyrin-Associated Periodic Syndromes (CAPS), in adults and pediatric patients 4 years of age and older, including:
  - Familial Cold Autoinflammatory Syndrome (FCAS)
  - Muckle-Wells Syndrome (MWS)
- Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS) in adult and pediatric patients
- Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD) in adult and pediatric patients
- Familial Mediterranean Fever (FMF) in adult and pediatric patients

ILARIS is indicated for the treatment of active Still's disease, including Adult-Onset Still's Disease (AOSD) and Systemic Juvenile Idiopathic Arthritis (SJIA) in patients 2 years of age and older.

ILARIS is indicated for the symptomatic treatment of adult patients with gout flares in whom nonsteroidal anti-inflammatory drugs (NSAIDs) and colchicine are contraindicated, are not tolerated, or do not provide an adequate response, and in whom repeated courses of corticosteroids are not appropriate.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

ILARIS is contraindicated in patients with confirmed hypersensitivity to canakinumab or to any of the excipients.

***All sections of this form must be completed by the physician, patient, and/or appropriate office staff member only.**

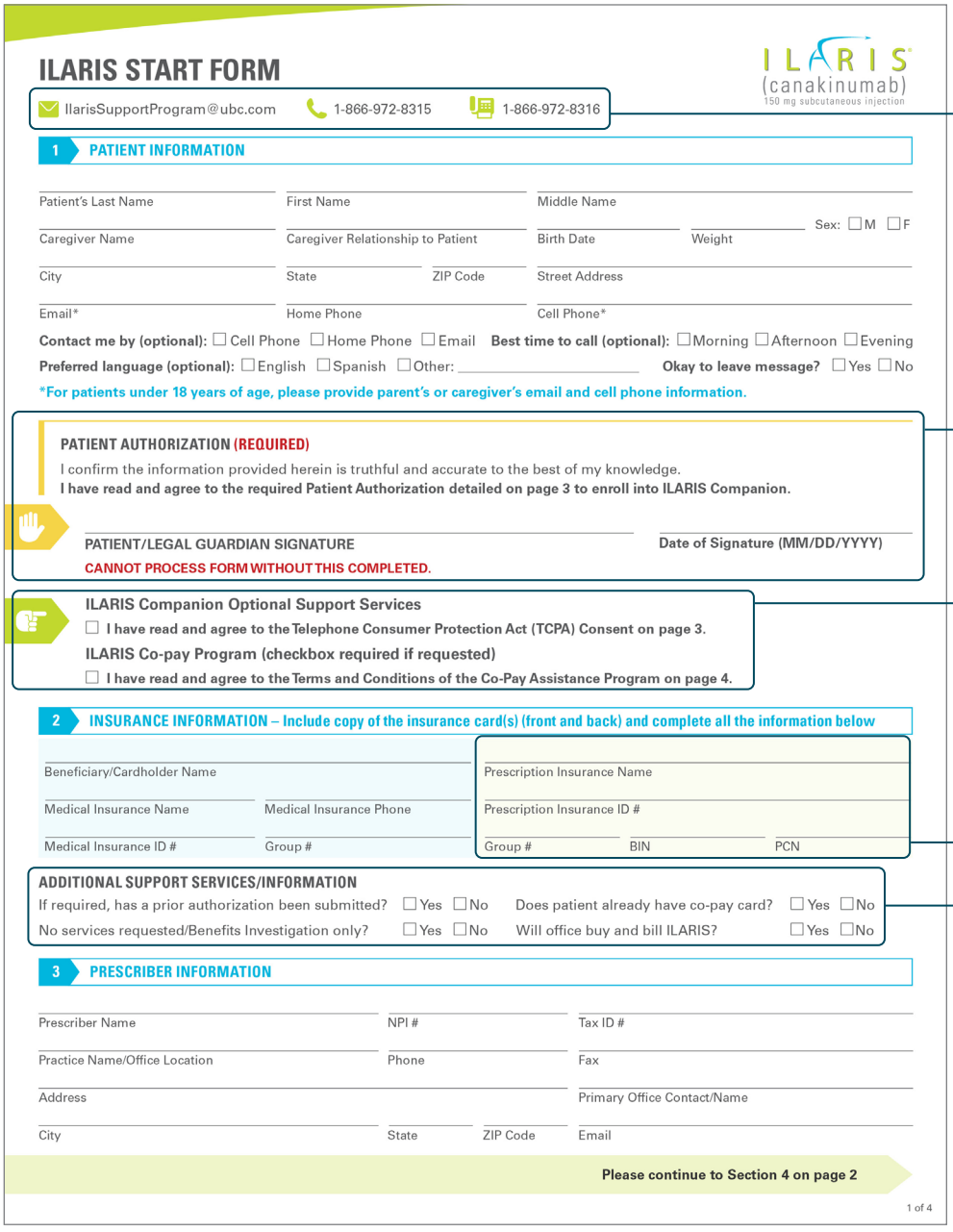
ILARIS® (canakinumab) 150 mg subcutaneous injection

Please see additional Important Safety Information on the last page and full Prescribing Information, including Medication Guide.

HOW TO FILL OUT THE ILARIS START FORM

ILARIS companion
Dedicated and dependable support

A complete and accurate Start Form is essential to getting patients started on ILARIS without delay. The following pages review the form, and highlighted sections point to the most critical information that must be included to process the form for your patients.



ILARIS START FORM

ILARIS (canakinumab) 150 mg subcutaneous injection

IlarisSupportProgram@ubc.com | 1-866-972-8315 | 1-866-972-8316

1 PATIENT INFORMATION

Patient's Last Name | First Name | Middle Name

Caregiver Name | Caregiver Relationship to Patient | Birth Date | Weight | Sex: M F

City | State | ZIP Code | Street Address

Email* | Home Phone | Cell Phone*

Contact me by (optional): Cell Phone Home Phone Email Best time to call (optional): Morning Afternoon Evening

Preferred language (optional): English Spanish Other: Okay to leave message? Yes No

*For patients under 18 years of age, please provide parent's or caregiver's email and cell phone information.

PATIENT AUTHORIZATION (REQUIRED)

I confirm the information provided herein is truthful and accurate to the best of my knowledge.
I have read and agree to the required Patient Authorization detailed on page 3 to enroll into ILARIS Companion.

PATIENT/LEGAL GUARDIAN SIGNATURE | Date of Signature (MM/DD/YYYY)

CANNOT PROCESS FORM WITHOUT THIS COMPLETED.

ILARIS Companion Optional Support Services

I have read and agree to the Telephone Consumer Protection Act (TCPA) Consent on page 3.

ILARIS Co-pay Program (checkbox required if requested)

I have read and agree to the Terms and Conditions of the Co-Pay Assistance Program on page 4.

2 INSURANCE INFORMATION – Include copy of the insurance card(s) (front and back) and complete all the information below

Beneficiary/Cardholder Name

Medical Insurance Name | Medical Insurance Phone

Medical Insurance ID # | Group #

Prescription Insurance Name

Prescription Insurance ID #

Group # | BIN | PCN

ADDITIONAL SUPPORT SERVICES/INFORMATION

If required, has a prior authorization been submitted? Yes No Does patient already have co-pay card? Yes No

No services requested/Benefits Investigation only? Yes No Will office buy and bill ILARIS? Yes No

3 PRESCRIBER INFORMATION

Prescriber Name | NPI # | Tax ID #

Practice Name/Office Location | Phone | Fax

Address | Primary Office Contact/Name

City | State | ZIP Code | Email

Please continue to Section 4 on page 2

1 of 4

Fax the completed Start Form to 1-866-972-8316.

PATIENT AUTHORIZATION/ SIGNATURE

Print and sign the Start Form and have it signed by your patient. If patients are unavailable to sign the Start Form, they can provide consent at **www.hipaaconsent.com**

ILARIS COMPANION SERVICES (optional)

This section should be completed if your patient would like to be enrolled in selected ILARIS Companion support services.

INSURANCE INFORMATION

Be sure to include information from the patient's pharmacy card, in addition to the medical coverage.

ADDITIONAL INFORMATION

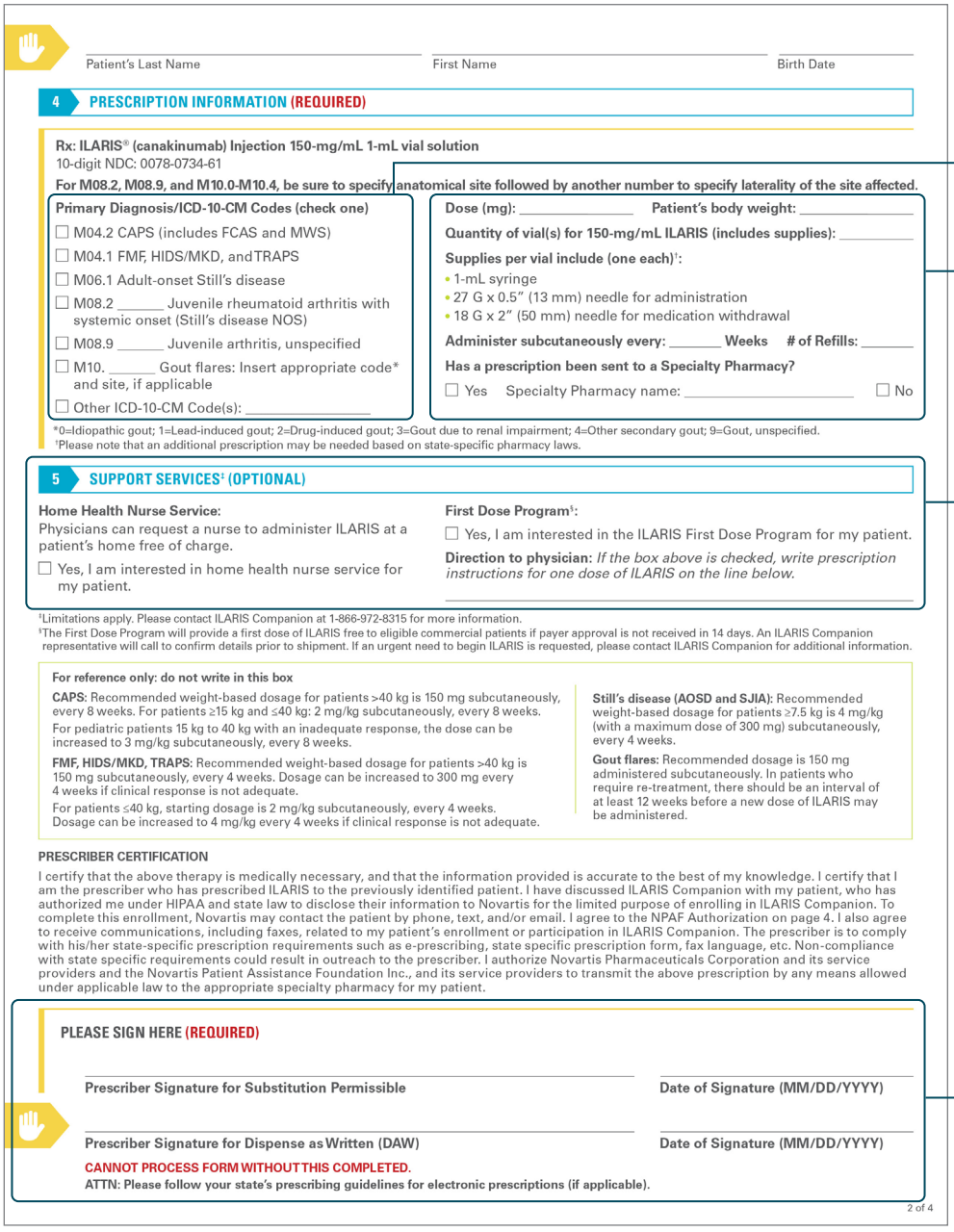
Please select any relevant information to help with processing your form efficiently.

DOWNLOAD THE ILARIS START FORM ONLINE AT
www.ilarishcp.com/access-and-support/getting-patients-started

ILARIS (canakinumab) 150 mg subcutaneous injection

HOW TO FILL OUT THE ILARIS START FORM (cont)

ILARIS companion
Dedicated and dependable support



Patient's Last Name | First Name | Birth Date

4 PRESCRIPTION INFORMATION (REQUIRED)

Rx: ILARIS® (canakinumab) Injection 150-mg/mL 1-mL vial solution
10-digit NDC: 0078-0734-61

For M08.2, M08.9, and M10.0-M10.4, be sure to specify anatomical site followed by another number to specify laterality of the site affected.

Primary Diagnosis/ICD-10-CM Codes (check one)

- ☐ M04.2 CAPS (includes FCAS and MWS)
- ☐ M04.1 FMF, HIDS/MKD, and TRAPS
- ☐ M06.1 Adult-onset Still's disease
- ☐ M08.2 _____ Juvenile rheumatoid arthritis with systemic onset (Still's disease NOS)
- ☐ M08.9 _____ Juvenile arthritis, unspecified
- ☐ M10. _____ Gout flares: Insert appropriate code* and site, if applicable
- ☐ Other ICD-10-CM Code(s): _____

Dose (mg): _____ **Patient's body weight:** _____

Quantity of vial(s) for 150-mg/mL ILARIS (includes supplies): _____

Supplies per vial include (one each)†:

- 1-mL syringe
- 27 G x 0.5" (13 mm) needle for administration
- 18 G x 2" (50 mm) needle for medication withdrawal

Administer subcutaneously every: _____ **Weeks** **# of Refills:** _____

Has a prescription been sent to a Specialty Pharmacy?

☐ Yes Specialty Pharmacy name: _____ ☐ No

*0=Idiopathic gout; 1=Lead-induced gout; 2=Drug-induced gout; 3=Gout due to renal impairment; 4=Other secondary gout; 9=Gout, unspecified.
†Please note that an additional prescription may be needed based on state-specific pharmacy laws.

5 SUPPORT SERVICES‡ (OPTIONAL)

Home Health Nurse Service:
Physicians can request a nurse to administer ILARIS at a patient's home free of charge.

☐ Yes, I am interested in home health nurse service for my patient.

First Dose Program§:

☐ Yes, I am interested in the ILARIS First Dose Program for my patient.

Direction to physician: *If the box above is checked, write prescription instructions for one dose of ILARIS on the line below.*

‡Limitations apply. Please contact ILARIS Companion at 1-866-972-8315 for more information.
§The First Dose Program will provide a first dose of ILARIS free to eligible commercial patients if payer approval is not received in 14 days. An ILARIS Companion representative will call to confirm details prior to shipment. If an urgent need to begin ILARIS is requested, please contact ILARIS Companion for additional information.

For reference only: do not write in this box

CAPS: Recommended weight-based dosage for patients >40 kg is 150 mg subcutaneously, every 8 weeks. For patients ≥15 kg and ≤40 kg: 2 mg/kg subcutaneously, every 8 weeks.
For pediatric patients 15 kg to 40 kg with an inadequate response, the dose can be increased to 3 mg/kg subcutaneously, every 8 weeks.

FMF, HIDS/MKD, TRAPS: Recommended weight-based dosage for patients >40 kg is 150 mg subcutaneously, every 4 weeks. Dosage can be increased to 300 mg every 4 weeks if clinical response is not adequate.
For patients ≤40 kg, starting dosage is 2 mg/kg subcutaneously, every 4 weeks. Dosage can be increased to 4 mg/kg every 4 weeks if clinical response is not adequate.

Still's disease (AOSD and SJIA): Recommended weight-based dosage for patients ≥7.5 kg is 4 mg/kg (with a maximum dose of 300 mg) subcutaneously, every 4 weeks.

Gout flares: Recommended dosage is 150 mg administered subcutaneously. In patients who require re-treatment, there should be an interval of at least 12 weeks before a new dose of ILARIS may be administered.

PRESCRIBER CERTIFICATION

I certify that the above therapy is medically necessary, and that the information provided is accurate to the best of my knowledge. I certify that I am the prescriber who has prescribed ILARIS to the previously identified patient. I have discussed ILARIS Companion with my patient, who has authorized me under HIPAA and state law to disclose their information to Novartis for the limited purpose of enrolling in ILARIS Companion. To complete this enrollment, Novartis may contact the patient by phone, text, and/or email. I agree to the NPAF Authorization on page 4. I also agree to receive communications, including faxes, related to my patient's enrollment or participation in ILARIS Companion. The prescriber is to comply with his/her state-specific prescription requirements such as e-prescribing, state specific prescription form, fax language, etc. Non-compliance with state specific requirements could result in outreach to the prescriber. I authorize Novartis Pharmaceuticals Corporation and its service providers and the Novartis Patient Assistance Foundation Inc., and its service providers to transmit the above prescription by any means allowed under applicable law to the appropriate specialty pharmacy for my patient.

PLEASE SIGN HERE (REQUIRED)

Prescriber Signature for Substitution Permissible | Date of Signature (MM/DD/YYYY)

Prescriber Signature for Dispense as Written (DAW) | Date of Signature (MM/DD/YYYY)

CANNOT PROCESS FORM WITHOUT THIS COMPLETED.
ATTN: Please follow your state's prescribing guidelines for electronic prescriptions (if applicable).

2 of 4

PRIMARY DIAGNOSIS

Be sure to select or enter appropriate ICD-10-CM code for your patient. For patients with juvenile arthritis, be sure to also specify anatomical site and laterality of the site.

DOSE INFORMATION

Enter dose and body weight separately (do not input dose by weight).

Be sure to include the quantity of vials, including dosing directions and number of refills.

ILARIS COMPANION SERVICES (optional)

This section should be completed if your patient would like to be enrolled in these ILARIS Companion support services.

PRESCRIBER SIGNATURE

This section is required to process the form and complete the initial benefits investigation.

AN INCOMPLETE START FORM MAY DELAY THE START OF TREATMENT.

ILARIS® (canakinumab)
150 mg subcutaneous injection

ILARIS START FORM

ILARIS (canakinumab) 150 mg subcutaneous injection

IlarisSupportProgram@ubc.com | 1-866-972-8315 | 1-866-972-8316

1 PATIENT INFORMATION

Patient's Last Name | First Name | Middle Name

Caregiver Name | Caregiver Relationship to Patient | Birth Date | Weight | Sex: ☐ M ☐ F

City | State | ZIP Code | Street Address

Email* | Home Phone | Cell Phone*

Contact me by (optional): ☐ Cell Phone ☐ Home Phone ☐ Email **Best time to call (optional):** ☐ Morning ☐ Afternoon ☐ Evening

Preferred language (optional): ☐ English ☐ Spanish ☐ Other: _____ **Okay to leave message?** ☐ Yes ☐ No

***For patients under 18 years of age, please provide parent's or caregiver's email and cell phone information.**

PATIENT AUTHORIZATION (REQUIRED)

I confirm the information provided herein is truthful and accurate to the best of my knowledge.
I have read and agree to the required Patient Authorization detailed on page 3 to enroll into ILARIS Companion.

PATIENT/LEGAL GUARDIAN SIGNATURE | Date of Signature (MM/DD/YYYY)

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ILARIS Companion Optional Support Services

☐ **I have read and agree to the Telephone Consumer Protection Act (TCPA) Consent on page 3.**

ILARIS Co-pay Program (checkbox required if requested)

☐ **I have read and agree to the Terms and Conditions of the Co-Pay Assistance Program on page 4.**

2 INSURANCE INFORMATION – Include copy of the insurance card(s) (front and back) and complete all the information below

Beneficiary/Cardholder Name | Prescription Insurance Name

Medical Insurance Name | Medical Insurance Phone | Prescription Insurance ID #

Medical Insurance ID # | Group # | Group # | BIN | PCN

ADDITIONAL SUPPORT SERVICES/INFORMATION

If required, has a prior authorization been submitted? ☐ Yes ☐ No

Does patient already have co-pay card? ☐ Yes ☐ No

No services requested/Benefits Investigation only? ☐ Yes ☐ No

Will office buy and bill ILARIS? ☐ Yes ☐ No

3 PRESCRIBER INFORMATION

Prescriber Name | NPI # | Tax ID #

Practice Name/Office Location | Phone | Fax

Address | Primary Office Contact/Name

City | State | ZIP Code | Email

Please continue to Section 4 on page 2

Patient's Last Name | First Name | Birth Date

4 PRESCRIPTION INFORMATION (REQUIRED)

Rx: ILARIS® (canakinumab) Injection 150-mg/mL 1-mL vial solution
10-digit NDC: 0078-0734-61

For M08.2, M08.9, and M10.0-M10.4, be sure to specify anatomical site followed by another number to specify laterality of the site affected.

Primary Diagnosis/ICD-10-CM Codes (check one)

- ☐ M04.2 CAPS (includes FCAS and MWS)
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- ☐ M06.1 Adult-onset Still's disease
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- ☐ M08.9 _____ Juvenile arthritis, unspecified
- ☐ M10. _____ Gout flares: Insert appropriate code* and site, if applicable
- ☐ Other ICD-10-CM Code(s): _____

Dose (mg): _____ **Patient's body weight:** _____

Quantity of vial(s) for 150-mg/mL ILARIS (includes supplies): _____

Supplies per vial include (one each)†:

- 1-mL syringe
- 27 G x 0.5" (13 mm) needle for administration
- 18 G x 2" (50 mm) needle for medication withdrawal

Administer subcutaneously every: _____ **Weeks** **# of Refills:** _____

Has a prescription been sent to a Specialty Pharmacy?

☐ Yes Specialty Pharmacy name: _____ ☐ No

*0=Idiopathic gout; 1=Lead-induced gout; 2=Drug-induced gout; 3=Gout due to renal impairment; 4=Other secondary gout; 9=Gout, unspecified.
†Please note that an additional prescription may be needed based on state-specific pharmacy laws.

5 SUPPORT SERVICES‡ (OPTIONAL)

Home Health Nurse Service:
Physicians can request a nurse to administer ILARIS at a patient's home free of charge.

☐ Yes, I am interested in home health nurse service for my patient.

First Dose Program§:

☐ Yes, I am interested in the ILARIS First Dose Program for my patient.

Direction to physician: *If the box above is checked, write prescription instructions for one dose of ILARIS on the line below.*

_____

‡Limitations apply. Please contact ILARIS Companion at 1-866-972-8315 for more information.
§The First Dose Program will provide a first dose of ILARIS free to eligible commercial patients if payer approval is not received in 14 days. An ILARIS Companion representative will call to confirm details prior to shipment. If an urgent need to begin ILARIS is requested, please contact ILARIS Companion for additional information.

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CAPS: Recommended weight-based dosage for patients >40 kg is 150 mg subcutaneously, every 8 weeks. For patients ≥15 kg and ≤40 kg: 2 mg/kg subcutaneously, every 8 weeks.

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For patients ≤40 kg, starting dosage is 2 mg/kg subcutaneously, every 4 weeks. Dosage can be increased to 4 mg/kg every 4 weeks if clinical response is not adequate.

Still's disease (AOSD and SJIA): Recommended weight-based dosage for patients ≥7.5 kg is 4 mg/kg (with a maximum dose of 300 mg) subcutaneously, every 4 weeks.

Gout flares: Recommended dosage is 150 mg administered subcutaneously. In patients who require re-treatment, there should be an interval of at least 12 weeks before a new dose of ILARIS may be administered.

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PLEASE SIGN HERE (REQUIRED)

Prescriber Signature for Substitution Permissible | **Date of Signature (MM/DD/YYYY)**

Prescriber Signature for Dispense as Written (DAW) | **Date of Signature (MM/DD/YYYY)**

CANNOT PROCESS FORM WITHOUT THIS COMPLETED.
ATTN: Please follow your state's prescribing guidelines for electronic prescriptions (if applicable).

ILARIS START FORM

IlarisSupportProgram@ubc.com 1-866-972-8315 1-866-972-8316

ILARIS® (canakinumab) 150 mg subcutaneous injection

Please read the following carefully, then sign and date where indicated on page 1.

PATIENT AUTHORIZATION

I give permission for my health care providers (HCPs), pharmacies, service providers, and their contractors ("Health Care Providers"), health insurer(s) and their contractors ("Insurers"), and third-party contractors, to disclose my personal information, including information about my insurance benefits, prescriptions, my medical condition and history, adherence to my treatment, and my general health ("Personal Information") to Novartis Pharmaceuticals Corporation, its affiliates, business partners, and agents, ("Novartis") and the Novartis Patient Assistance Foundation, Inc. ("NPAF") (collectively, "the Companies") so that the Companies may: (i) help to verify or coordinate insurance coverage or otherwise obtain payment for my treatment with ILARIS® (canakinumab), (ii) coordinate my receipt of and payment for ILARIS, (iii) facilitate my access to ILARIS, (iv) provide me with information about Novartis products, disease education and management programs, and promotional materials, (v) if I am eligible, coordinate the ILARIS Co-pay Program, including managing and communicating with me about the co-pay support options available to me, (vi) provide me with medication reminders and support, (vii) conduct quality assurance, surveys, and other internal business activities in connection with ILARIS Companion and other related programs, and (viii) if I am eligible to apply to programs offered by NPAF, administer those programs, send me information about programs that might help me pay for medicines, and coordinate or share my Personal Information with my Health Care Providers, other programs that might help me pay for medicines, government agencies, and insurance companies for purposes of providing or facilitating this assistance.

I give permission to the Companies to disclose my Personal Information to my Health Care Providers, insurer(s), caregivers, and other third-party contractors or service providers for the purposes described above. I also give permission to the Companies to combine or aggregate any information collected from me with information the Companies may collect about me from other sources for the purpose of providing or administering Program services.

I understand that some of my pharmacies or other Health Care Providers may receive payment from the Companies depending on my enrollment or participation in therapy support services such as prescription refill reminders. I understand that once my Personal Information is disclosed, it may no longer be protected by federal privacy law and applicable state laws. Even though HIPAA may no longer apply, the Companies safeguard patient data through reasonable security measures and will use and share it only for the purposes specified in this Authorization.

I understand that I may refuse to sign this Authorization. I also may revoke (cancel) or get a copy of this Authorization at any time by calling 1-866-972-8315 or by writing to the Customer Interaction Center, Novartis Pharmaceuticals Corporation, One Health Plaza, East Hanover, NJ 07936-1080. If I cancel my consent, I will no longer qualify for the services described. I also understand that some of my pharmacies or other Health Care Providers may receive payment from the Companies for disclosing my Personal Information as outlined in this Authorization and for therapy support services depending on my enrollment or participation in therapy support services such as prescription refill reminders.

My refusal or future revocation will not affect my medical treatment or insurance benefits; however, if I revoke this authorization, I may no longer be able to participate in ILARIS Companion and related programs. If I revoke this Authorization, the Companies will stop using or sharing my information (except as necessary to end my participation in the program), but my revocation will not affect uses and disclosures of Personal Information previously disclosed in reliance upon this Authorization. I understand that this authorization will remain valid for 5 years after the date of my signature, unless a shorter period is required by applicable state law or I revoke it earlier. I also understand that ILARIS Companion may change or end at any time without prior notification. I understand that I am entitled to receive a copy of this Patient Authorization.

I agree to be contacted by mail, email, telephone calls, and text messages at the numbers and addresses provided on this Form for all purposes described in this Patient Authorization. I also agree to be contacted by the Companies and others on its behalf by telephone calls and text messages made by or using automatic telephone dialing machines or artificial or prerecorded voice, at the number(s) provided on this form, for all non-marketing purposes, including but not limited to sending me materials and asking for my participation in surveys.

I confirm that I am the subscriber for the telephone number(s) provided and the authorized user for the email address(es) provided, and I agree to notify the Companies promptly if any of my number(s) or address(es) change in the future. I understand that my wireless service provider's message and data rates may apply.

I understand that the Companies do not permit my Personal Information to be used by their business partners for their own separate marketing purposes. I understand and agree that Personal Information transmitted by email and cell phone cannot be secured against unauthorized access.

TELEPHONE CONSUMER PROTECTION ACT (TCPA) CONSENT (OPTIONAL)

Telephone Consumer Protection Act (TCPA) Consent (Optional): I consent to receive marketing calls and texts from and on behalf of Novartis Pharmaceuticals Corporation, made with an auto dialer or prerecorded voice, at the phone number(s) provided. I understand that my consent is not required as a condition of purchase. I agree to the TCPA Terms & Conditions. Number of messages will vary based on my program selections. Message and data rates may apply. I understand that I can read the full Novartis Pharmaceuticals Corporation Privacy Policy at www.usprivacy.novartis.com. Text STOP to opt out and HELP for help.

ILARIS START FORM

IlarisSupportProgram@ubc.com 1-866-972-8315 1-866-972-8316

ILARIS® (canakinumab) 150 mg subcutaneous injection

TELEPHONE CONSUMER PROTECTION ACT (TCPA) TERMS AND CONDITIONS

By signing up to receive marketing texts and calls, or by requesting information by telephone, text message, fax, email, direct mail, or other means, you accept, without limitation or qualification, that:

- You and Novartis agree that any legal disputes or claims arising out of or related to these TCPA Terms and Conditions, or the use of the Novartis products and/or the Services (including but not limited to telephone calls or text messages sent by Novartis), or the interpretation, enforceability, revocability, or validity of these TCPA Terms and Conditions, or the arbitrability of any dispute that cannot be resolved informally shall be submitted to binding arbitration in the State of New York. The arbitration shall be conducted by the American Arbitration Association under its Commercial Arbitration Rules.
- This arbitration clause is an independent agreement and shall survive the termination and/or transfer of these TCPA Terms and Conditions or any other agreement between you and Novartis. If any provision of the agreement to arbitrate in this Section is found unenforceable, the unenforceable provision will be severed and the remaining arbitration terms will be enforced (but in no case will there be a class, representative, or private attorney general arbitration). Any judgment on the award rendered by the arbitrator may be entered in any court having jurisdiction thereof. Claims shall be brought within the time required by applicable law. The laws of the State of New York will govern these TCPA Terms and Conditions, and the Federal Arbitration Act, 9 U.S.C. §§ 1-16, will govern this Section, without giving effect to any principles of conflicts of laws. Each party shall bear its own costs relating to the arbitration consistent with the Commercial Arbitration Rules of the American Arbitration Association.
- You and Novartis agree that any claim, action, or proceeding arising out of or related to these TCPA Terms and Conditions, or the use of the Novartis products and/or the Services (including but not limited to telephone calls or text messages sent by Novartis) must be brought in your individual capacity, and not as a plaintiff or class member in any purported class, collective, or representative proceeding. The arbitrator may not consolidate more than one person's claims, and the arbitrator may not otherwise preside over any form of a representative, collective, or class proceeding.

YOU ACKNOWLEDGE AND AGREE THAT YOU AND NOVARTIS ARE EACH WAIVING THE RIGHT TO A TRIAL BY JURY OR TO PARTICIPATE AS A PLAINTIFF OR CLASS MEMBER IN ANY PURPORTED CLASS ACTION OR REPRESENTATIVE PROCEEDING.

CO-PAY ASSISTANCE PROGRAM TERMS AND CONDITIONS

Program Terms & Conditions

Limitations apply. Valid only for those with private insurance. The Program includes the Co-pay Card, Payment Card (if applicable), and Rebate, with a combined annual limit of $36,000. Patient is responsible for any costs once limit is reached in a calendar year. Program not valid: (i) under Medicare, Medicaid, TRICARE, VA, DoD, or any other federal or state health care program, (ii) where patient is not using insurance coverage at all, (iii) where the patient's insurance plan reimburses for the entire cost of the drug, or (iv) where product is not covered by patient's insurance. The value of this program is exclusively for the benefit of patients and is intended to be credited towards patient out-of-pocket obligations and maximums, including applicable co-payments, coinsurance, and deductibles. Program is not valid where prohibited by law. Patient may not seek reimbursement for the value received from this program from other parties, including any health insurance program or plan, flexible spending account, or health care savings account. Patient is responsible for complying with any applicable limitations and requirements of their health plan related to the use of the Program. Valid only in the United States and Puerto Rico. This Program is not health insurance. Program may not be combined with any third-party rebate, coupon, or offer. Proof of purchase may be required. Novartis reserves the right to rescind, revoke, or amend the Program and discontinue support at any time without notice.

PRESCRIBER AUTHORIZATION FOR THE NOVARTIS PATIENT ASSISTANCE FOUNDATION, INC. (NPAF)

I certify that any medication received will be used only for the patient named on this form and will not be offered for sale, trade, or barter. Further, no claim for reimbursement will be submitted concerning this medication, nor will any medication be returned for credit. I acknowledge that NPAF is exclusively for purposes of patient care and not for remuneration of any sort. I understand that NPAF may revise, change, or terminate programs at any time.

All sections of this form must be completed by the physician, patient, and/or appropriate office staff member only.

IMPORTANT SAFETY INFORMATION (cont)

ILARIS® (canakinumab) 150 mg subcutaneous injection

WARNINGS AND PRECAUTIONS

Serious Infections

ILARIS has been associated with an increased risk of serious infections. Exercise caution when administering ILARIS to patients with infections, a history of recurring infections or underlying conditions, which may predispose them to infections. Avoid administering ILARIS to patients during an active infection requiring medical intervention. Discontinue ILARIS if a patient develops a serious infection.

Infections, predominantly of the upper respiratory tract, in some instances serious, have been reported with ILARIS. Generally, the observed infections responded to standard therapy. Isolated cases of unusual or opportunistic infections (eg, aspergillosis, atypical mycobacterial infections, cytomegalovirus, herpes zoster) were reported during ILARIS treatment. A causal relationship of ILARIS to these events cannot be excluded. In clinical trials, ILARIS has not been administered concomitantly with tumor necrosis factor (TNF) inhibitors. An increased incidence of serious infections has been associated with administration of another interleukin-1 (IL-1) blocker in combination with TNF inhibitors. Coadministration of ILARIS with TNF inhibitors is not recommended because this may increase the risk of serious infections.

Drugs that affect the immune system by blocking TNF have been associated with an increased risk of new tuberculosis (TB) and reactivation of latent TB. It is possible that use of IL-1 inhibitors, such as ILARIS, increases the risk of reactivation of TB or of opportunistic infections.

Prior to initiating immunomodulatory therapies, including ILARIS, evaluate patients for active and latent TB infection. Appropriate screening tests should be performed in all patients. ILARIS has not been studied in patients with a positive TB screen, and the safety of ILARIS in individuals with latent TB infection is unknown. Treat patients testing positive in TB screening according to standard medical practice prior to therapy with ILARIS. Instruct patients to seek medical advice if signs, symptoms, or high risk exposure suggestive of TB (eg, persistent cough, weight loss, subfebrile temperature) appear during or after ILARIS therapy. Healthcare providers should follow current CDC guidelines both to evaluate for and to treat possible latent TB infections before initiating therapy with ILARIS.

Immunosuppression

The impact of treatment with anti-IL-1 therapy on the development of malignancies is not known. However, treatment with immunosuppressants, including ILARIS, may result in an increase in the risk of malignancies.

Hypersensitivity Reactions

Hypersensitivity reactions have been reported with ILARIS. During clinical trials, no anaphylactic reactions attributable to treatment with canakinumab have been reported. It should be recognized that symptoms of the underlying disease being treated may be similar to symptoms of hypersensitivity. Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS), characterized by serious skin eruptions, has been reported in patients with autoinflammatory conditions treated with ILARIS. If a severe hypersensitivity reaction occurs, immediately discontinue ILARIS; treat promptly and monitor until signs and symptoms resolve.

Immunizations

Avoid administration of live vaccines concurrently with ILARIS. Update all recommended vaccinations prior to initiation of therapy with ILARIS. In addition, because ILARIS may interfere with normal immune response to new antigens, vaccinations may not be effective in patients receiving ILARIS.

Canakinumab, like other monoclonal antibodies, is actively transported across the placenta mainly during the third trimester of pregnancy and may cause immunosuppression in the *in utero* exposed infant. The risks and benefits should be considered prior to administering live vaccines to infants who were exposed to ILARIS *in utero* for at least 4 to 12 months following the mother's last dose of ILARIS.

Macrophage Activation Syndrome

Macrophage Activation Syndrome (MAS) is a known, life-threatening disorder that may develop in patients with rheumatic conditions, in particular Still's disease, and should be aggressively treated. Physicians should be attentive to symptoms of infection or worsening of Still's disease as these are known triggers for MAS. Eleven cases of MAS were observed in 201 SJIA patients treated with canakinumab in clinical trials. Based on the clinical trial experience, ILARIS does not appear to increase the incidence of MAS in Still's disease patients, but no definitive conclusion can be made.

ADVERSE REACTIONS

Serious adverse reactions reported with ILARIS in the CAPS clinical trials included infections and vertigo. The most common adverse reactions greater than 10% associated with ILARIS treatment in CAPS patients were nasopharyngitis, diarrhea, influenza, rhinitis, headache, nausea, bronchitis, gastroenteritis, pharyngitis, weight increased, musculoskeletal pain, and vertigo.

The most common adverse reactions greater than or equal to 10% reported by patients with TRAPS, HIDS/MKD, and FMF treated with ILARIS were injection site reactions and nasopharyngitis.

The most common adverse drug reactions greater than 10% associated with ILARIS treatment in SJIA patients were infections (nasopharyngitis and upper respiratory tract infections), abdominal pain, and injection site reactions.

The most common adverse reactions greater than 2% reported by adult patients with gout flares treated with ILARIS in clinical trials were nasopharyngitis, upper respiratory tract infections, urinary tract infections, hypertriglyceridemia, and back pain.

Please see additional Important Safety Information on the first page and full Prescribing Information, including Medication Guide.

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