ILARIS companion

Dedicated and dependable support

ILARIS® (canakinumab)
Acquisition and Reimbursement Guide

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 children aged 4 years and older, including:
  - Familial Cold Autoinflammatory Syndrome (FCAS)
  - Muckle-Wells Syndrome (MWS)
- Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS) in adults and pediatric patients
- Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD) in adults and pediatric patients
- Familial Mediterranean Fever (FMF) in adults 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 aged 2 years 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.

ILARIS® (canakinumab) 150 mg subcutaneous injection

Please see additional Important Safety Information on pages 40 and 41 and full Prescribing Information, including Medication Guide.

WELCOME TO THE ILARIS ACQUISITION AND REIMBURSEMENT GUIDE

At Novartis, we know you may not often see the rare disease patients requiring treatment with ILARIS. Now that you have made the clinical decision to prescribe ILARIS, the following information will be helpful to you while treating your patients.

These patients may experience a long journey to get to their rare disease diagnosis, and we know you want to get them started on treatment without delay. The process of acquisition and reimbursement for ILARIS may not be as familiar to your office. We developed this guide to provide information to help practices get their patients started on ILARIS.

TABLE OF CONTENTS

How to navigate this guide

This guide contains information to help you navigate the coverage process for your patients who have been prescribed ILARIS. Use this information for support from clinical decision through administration and reimbursement.

This resource is interactive—use the navigation tabs at the top to jump to a specific section.

Click on any section below to jump to that page.

Please see Important Safety Information on pages 1, 40, and 41 and full Prescribing Information, including Medication Guide.

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INTRODUCTION TO ILARIS COMPANION

Prescribe ILARIS with confidence. ILARIS Companion provides access to a wide range of services—all in one place—that can help patients get their prescribed treatment.

Program services are available after the clinical decision to prescribe ILARIS has been made.

*Allows patients to learn about the coverage and cost of ILARIS.

†Information provided in support of a prior authorization must be based on the physician's clinical judgment and forms must be completed by the physician/office staff.

‡Limitations apply. See Program Terms and Conditions on the ILARIS Start Form available at www.ilarishcp.com/access. **This offer is not valid under Medicare, Medicaid, or any other federal or state program.** Novartis reserves the right to rescind, revoke, or amend this Program without notice.

ILARIS Companion can help make treatment access simple

HIGH PRIOR AUTHORIZATION (PA) APPROVAL RATE

≈90% of PA requests are approved[1]

ILARIS SHIPMENT TIME

12 days is the median time to ship ILARIS to patients[1]

Reference: 1. Data on file. ILARIS Companion CRM Statistics Updates 2023. Novartis Pharmaceuticals Corp; 2023.

Please see Important Safety Information on pages 1, 40, and 41 and full Prescribing Information, including Medication Guide.

ILARIS® (canakinumab) 150 mg subcutaneous injection

ILARIS COMPANION PROVIDES ONGOING, DEDICATED SUPPORT FOR YOU AND YOUR PATIENTS—FROM RX TO DISPENSE

ILARIS Access & Reimbursement Managers

ILARIS Access & Reimbursement Managers (ARMs) serve as a resource for physicians and office staff by providing support to help streamline access and reimbursement for ILARIS.

Your ARM can provide:

- Resources to educate patients and office staff on program offerings
- Information about plan coverage
- Guidance along the access process, from clinical decision through product administration
- Correct forms and other considerations for claims submissions

ILARIS Companion Case Managers help support patients and practices

Your dedicated case manager will work in tandem with your ARM to provide support for your practice.

Case managers can:

- Conduct a benefits investigation
- Enroll eligible commercial patients for co-pay support
- Work with the specialty pharmacy (SP) for dispensing
- Communicate with patients and office staff to relay important information
- Facilitate prior authorization/appeals support

Once enrolled in ILARIS Companion, a case manager will call the patient to introduce the ILARIS Companion patient support team, provide details on program offerings, and answer any questions. **Case managers can help support patient adherence by:**

- Laying out next steps and follow-up points
- Providing home health injection administration coordination
- Verifying scheduled refills prior to each fill, including plan information, SP, and Home Health Agency communications

NOTE: Patients must be enrolled in ILARIS Companion with completed HIPAA authorization before they are contacted by a case manager.

Eligibility Requirement

For eligibility to participate in these services, the patient must meet the following criterion:

- Prescribed to be treated for an FDA-approved indication for ILARIS (both diagnosis and age restrictions apply)

FDA, US Food and Drug Administration; HIPAA, Health Insurance Portability and Accountability Act of 1996.

Please see Important Safety Information on pages 1, 40, and 41 and full Prescribing Information, including Medication Guide.

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GETTING PATIENTS STARTED WITH ILARIS COMPANION

Submitting a completed ILARIS Start Form is the first step to getting your patients started with ILARIS Companion. **This form serves as the prescription for ILARIS** and as a way for patients to enroll in select ILARIS Companion services.

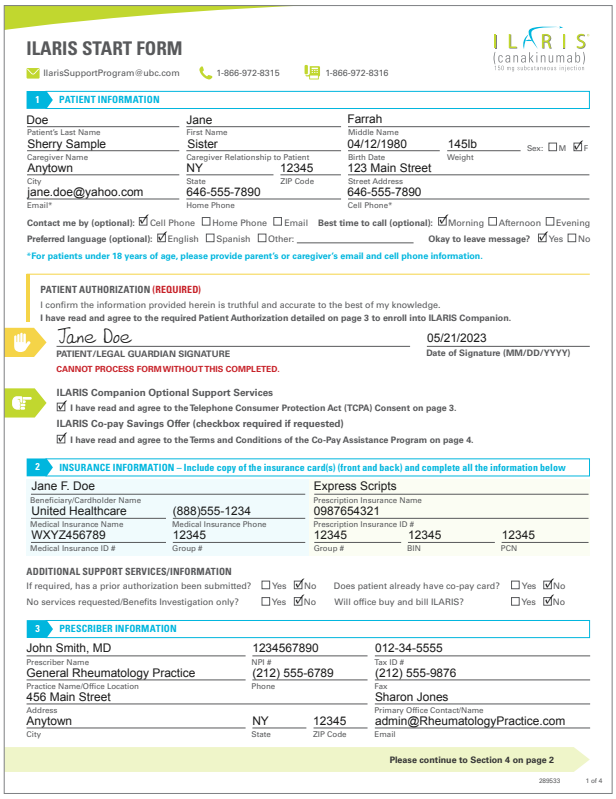
ILARIS Companion determines eligibility for patient assistance programs to help reduce patients' out-of-pocket costs. The physician and patient are each responsible for completing their designated sections of the form.

1. **Download the Start Form online at www.ilarishcp.com/access-and-support/getting-patients-started**

2. **Fill out necessary information on the Start Form, including:**
   - Physician AND patient signatures
   - ICD-10-CM code
   - Number of ILARIS vials
   - Number of refills
   - Patient's insurance information
   - Dosage and administration instructions
   - Place of administration (at home or at a physician's office)

3. **Print and sign the Start Form and have it signed by your patient.**

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



ILARIS START FORM

ILARIS (canakinumab) 150 mg subcutaneous injection

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

1 PATIENT INFORMATION

Doe (Patient's Last Name) | Jane (First Name) | Farrah (Middle Name)
Sherry Sample (Caregiver Name) | Sister (Caregiver Relationship to Patient) | 04/12/1980 (Birth Date) | 145lb (Weight) | Sex: ☐M ☑F
Anytown (City) | NY (State) | 12345 (ZIP Code) | 123 Main Street (Street Address)
jane.doe@yahoo.com (Email*) | 646-555-7890 (Home Phone) | 646-555-7890 (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.
Jane Doe — PATIENT/LEGAL GUARDIAN SIGNATURE — 05/21/2023 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 Savings Offer (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

Jane F. Doe (Beneficiary/Cardholder Name) | Express Scripts (Prescription Insurance Name)
United Healthcare (Medical Insurance Name) | (888)555-1234 (Medical Insurance Phone) | 0987654321 (Prescription Insurance ID #)
WXYZ456789 (Medical Insurance ID #) | 12345 (Group #) | 12345 (Group #) | 12345 (BIN) | 12345 (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

John Smith, MD (Prescriber Name) | 1234567890 (NPI #) | 012-34-5555 (Tax ID #)
General Rheumatology Practice (Practice Name/Office Location) | (212) 555-6789 (Phone) | (212) 555-9876 (Fax)
456 Main Street (Address) | Sharon Jones (Primary Office Contact/Name)
Anytown (City) | NY (State) | 12345 (ZIP Code) | admin@RheumatologyPractice.com (Email)

Please continue to Section 4 on page 2

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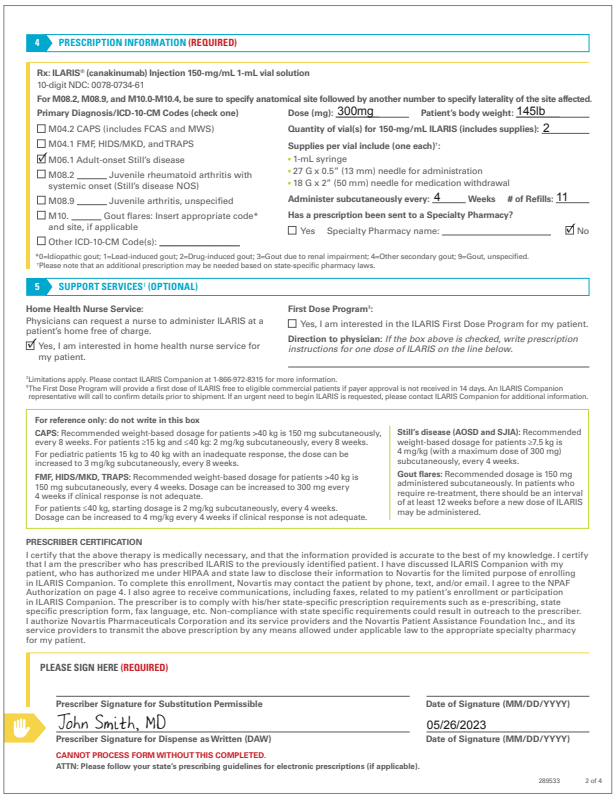

4 PRESCRIPTION INFORMATION (REQUIRED)

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) Dose (mg): 300mg Patient's body weight: 145lb
☐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): _____
Quantity of vial(s) for 150-mg/mL ILARIS (includes supplies): 2
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: 4 Weeks # of Refills: 11
Has a prescription been sent to a Specialty Pharmacy?
☐Yes Specialty Pharmacy name: _____ ☑No
*O=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)
John Smith, MD — Prescriber Signature for Dispense as Written (DAW) — 05/26/2023 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).

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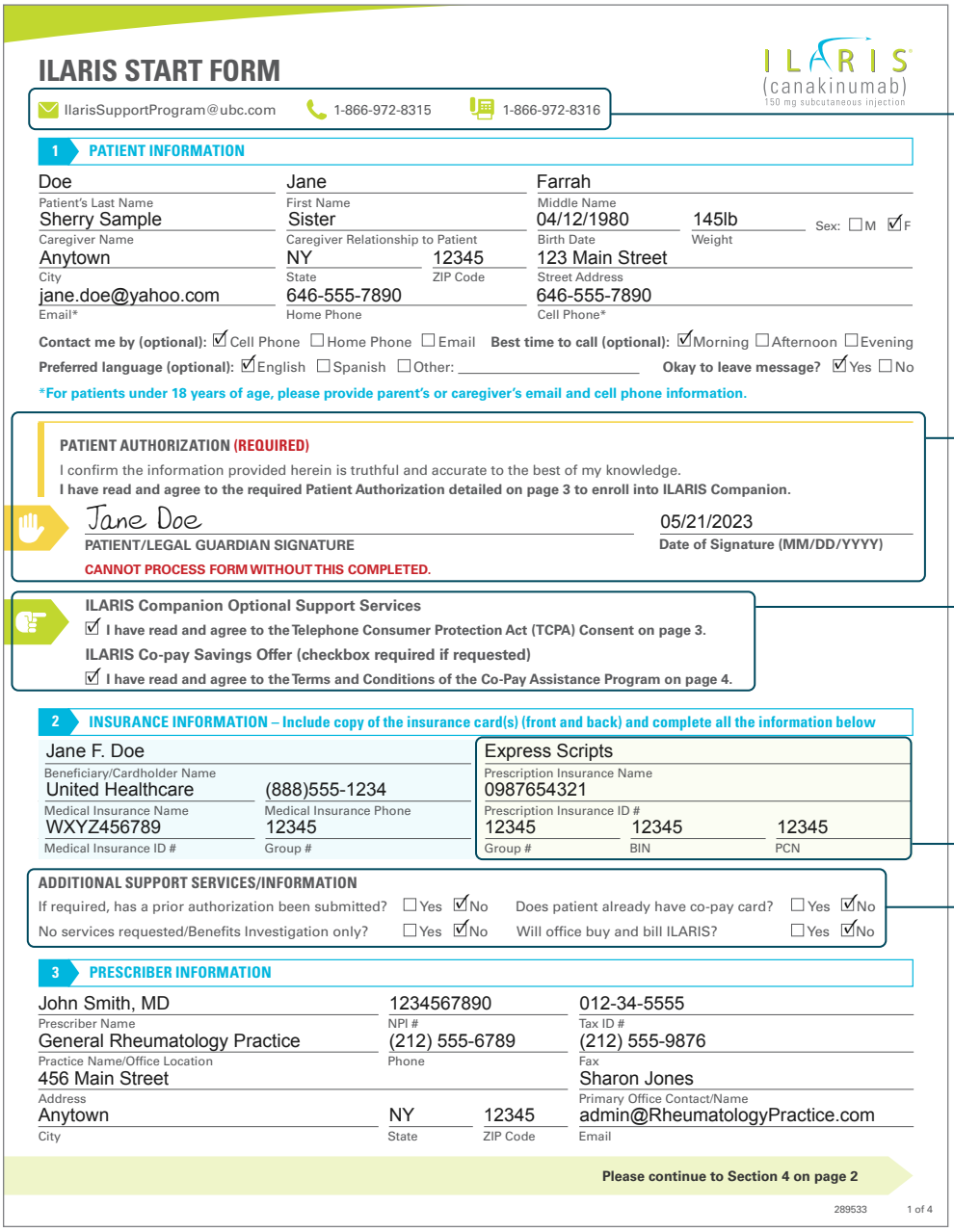
ICD-10-CM, International Classification of Diseases, 10th Revision, Clinical Modification.

Please see Important Safety Information on pages 1, 40, and 41 and full Prescribing Information, including Medication Guide.

ILARIS® (canakinumab) 150 mg subcutaneous injection

GUIDE TO FILLING OUT THE ILARIS START FORM



ILARIS START FORM

ILARIS (canakinumab) 150 mg subcutaneous injection

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

1 PATIENT INFORMATION

Doe (Patient's Last Name)	Jane (First Name)	Farrah (Middle Name)		
Sherry Sample (Caregiver Name)	Sister (Caregiver Relationship to Patient)	04/12/1980 (Birth Date)	145lb (Weight)	Sex: ☐M ☑F
Anytown (City)	NY (State)	12345 (ZIP Code)	123 Main Street (Street Address)	
jane.doe@yahoo.com (Email*)	646-555-7890 (Home Phone)	646-555-7890 (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.

Jane Doe — PATIENT/LEGAL GUARDIAN SIGNATURE
05/21/2023 — 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 Savings Offer (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

Jane F. Doe (Beneficiary/Cardholder Name)		Express Scripts (Prescription Insurance Name)		
United Healthcare (Medical Insurance Name)	(888)555-1234 (Medical Insurance Phone)	0987654321 (Prescription Insurance ID #)		
WXYZ456789 (Medical Insurance ID #)	12345 (Group #)	12345 (Group #)	12345 (BIN)	12345 (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

John Smith, MD (Prescriber Name)	1234567890 (NPI #)	012-34-5555 (Tax ID #)	
General Rheumatology Practice (Practice Name/Office Location)	(212) 555-6789 (Phone)	(212) 555-9876 (Fax)	
456 Main Street (Address)		Sharon Jones (Primary Office Contact/Name)	
Anytown (City)	NY (State)	12345 (ZIP Code)	admin@RheumatologyPractice.com (Email)

Please continue to Section 4 on page 2

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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.

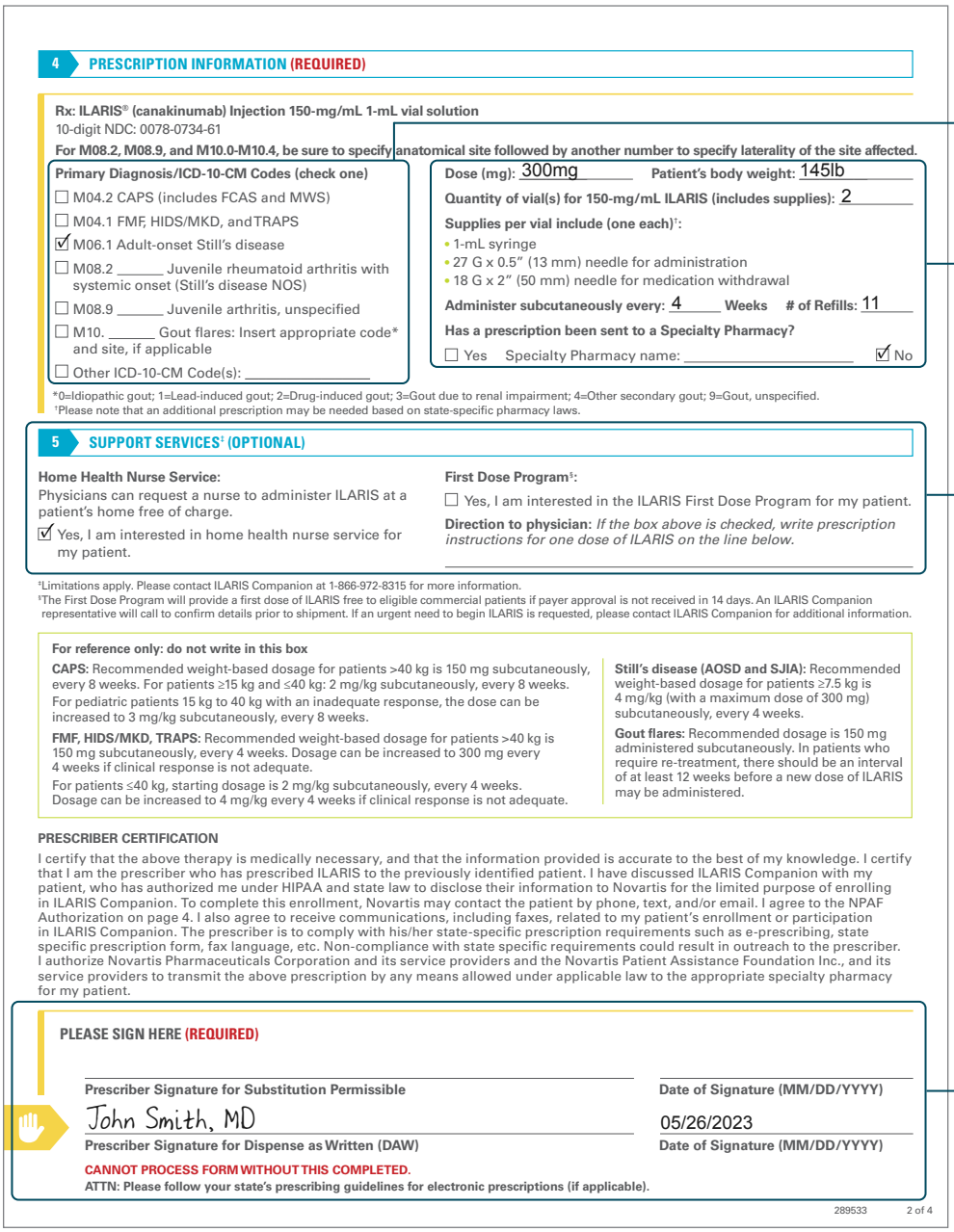
INSURANCE INFORMATION

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.

GUIDE TO FILLING OUT THE ILARIS START FORM (cont)



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): 300mg **Patient's body weight:** 145lb
Quantity of vial(s) for 150-mg/mL ILARIS (includes supplies): 2
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: 4 **Weeks** **# of Refills:** 11
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)**
John Smith, MD 05/26/2023
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).

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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 you would like your patient 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.

PATIENT SUPPORT AND AFFORDABILITY OPTIONS

ILARIS Companion can provide financial support information about:

- Commercially insured co-pay support and eligibility determinations
- Independent Charitable Co-pay Foundation (ICCF) information
- Novartis Patient Assistance Foundation (NPAF)

ILARIS Co-pay Savings Offer*

The ILARIS Co-pay Savings Offer was designed to make ILARIS more affordable. Eligible commercially insured patients pay no more than $30 per month (subject to an annual cap of $36,000).

There are 2 ways for eligible patients to sign up:

- **Enroll through the ILARIS Start Form:** Consent to the terms and conditions of the ILARIS Co-pay Savings Offer on the Start Form, and sign/date and check the applicable boxes
- **Enroll online** at www.copay.novartispharma.com/nvscopay and select "ILARIS"

Patients with insurance through federal or state programs are not eligible.

Online rebate for eligible commercially insured patients

Patients may submit a rebate request online for reimbursement on a claim paid at the physician's office or through an SP for ILARIS.

Patients who receive ILARIS through buy and bill at their physician's office

Eligible patients covered under the medical benefit with an office that acquires ILARIS through buy and bill may request reimbursement for their remaining out-of-pocket (OOP) costs above the $30 co-pay offer after administration.

Patients who receive ILARIS through an SP

Eligible commercially insured patients covered under the pharmacy benefit should already have the co-pay offer applied. If the SP does not leverage the co-pay card, the patient may request reimbursement.

Steps for eligible patients to request online reimbursement

1. Patient submits a claim through the rebate portal at www.patientrebateonline.com
   - **NOTE: The patient must be enrolled in the ILARIS Co-pay Savings Offer and have their information available to access the rebate portal**
2. After entering all applicable information, patients must include and/or upload the following information:
   - Front and back of commercial insurance card information
   - Explanation of Benefits from their health care plan
   - OOP costs associated with the claim and proof of payment
3. The submission is processed as a submitted claim and may be reimbursed up to the $36,000 annual cap.
4. Patients are notified if their submission is missing information.

*Limitations apply. Valid only for those with private insurance. The Program includes the Co-pay Card, Payment Card (if applicable), and Rebate, subject to a combined annual limit. 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, or (iii) where the patient's insurance plan reimburses for the entire cost of the drug. Additional limitations may apply in CA and MA, or where product is not covered by the patient's insurance. Program is not valid where prohibited by law. Valid only in the United States and Puerto Rico. 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, co-insurance, and deductibles. 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. 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.

Please see Important Safety Information on pages 1, 40, and 41 and full Prescribing Information, including Medication Guide.

PATIENT SUPPORT AND AFFORDABILITY OPTIONS (cont)

Other support resources

*First Dose Program**

If an approval decision is delayed, the physician will be contacted to discuss program enrollment for the patient. The First Dose Program will ship the initial dose of ILARIS to eligible patients free of charge if a plan approval is not received within 2 weeks.

Home Health Nurse Service

Patients can have their injections administered in their homes or at another location outside of the physician's office. Injections will be administered per the patient's dosing schedule.

- Available in all 50 US states and Puerto Rico
- Requesting physician will receive a visit confirmation

*Limitations apply. Valid only for those with private insurance. The Program includes the Co-pay Card, Payment Card (if applicable), and Rebate, subject to a combined annual limit. 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, or (iii) where the patient's insurance plan reimburses for the entire cost of the drug. Additional limitations may apply in CA and MA, or where product is not covered by the patient's insurance. Program is not valid where prohibited by law. Valid only in the United States and Puerto Rico. 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, co-insurance, and deductibles. 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. 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.

Please see Important Safety Information on pages 1, 40, and 41 and full Prescribing Information, including Medication Guide.

PRODUCT ACQUISITION FOR ILARIS

ILARIS is covered for patients on either the **pharmacy benefit** or **medical benefit**, with flexible acquisition methods determined by their health care coverage.

- For patients covered under the pharmacy benefit, ILARIS is acquired through a specialty pharmacy (SP)
- For patients covered under the medical benefit, ILARIS may be acquired through the buy and bill process **OR** commercial plans may require ILARIS to be acquired through an SP (through assignment of benefits)

Coverage and availability of ILARIS by plan type

Commercial plans

Policies vary by plan. Acquisition method for ILARIS may be determined by your patient's health care plan. Always verify benefit coverage early.

Medicare

ILARIS is typically covered under Medicare Part B. Some plans might choose to extend coverage under the Medicare Part D benefit.

Check the individual plan for coverage information.

Medicaid

Requirements for Medicaid coverage and reimbursement for ILARIS vary by state.

Once ILARIS is ordered for a clinically appropriate patient, there are 2 options through which ILARIS can be acquired:

Specialty pharmacy

Buy and bill

See the following page for an overview of the acquisition processes for ILARIS.

FLEXIBLE ACQUISITION METHODS FOR ILARIS

Selection may be determined by your patient's health care plan. Always verify benefit coverage.

Step 1: CONDUCT BENEFITS INVESTIGATION
Verify the patient's coverage type (pharmacy or medical benefit) with their health care plan and complete the ILARIS Start Form and a prior authorization (PA), if required.

Step 2: ORDER ILARIS
Order ILARIS through the selected acquisition process (SP or buy and bill).

Step 3: ADMINISTER ILARIS
Review out-of-pocket (OOP) costs and co-pay with the patient. Confirm administration and treatment follow-up. Regardless of the acquisition method, work with the SP to get the co-pay applied for eligible commercially insured patients.

Step 4: SUBMIT CLAIM
Fill out a reimbursement claim form based on administration setting. Submit claim to plan.

Step 5: RECEIVE REIMBURSEMENT
Track the reimbursement claim and audit claims for expedited product reimbursement.

Confirm health care plan coverage and select an acquisition method.

Coverage under the pharmacy benefit	Coverage under the medical benefit	
The SP handles the acquisition process. The SP delivers the product for the injection.	The physician acquires ILARIS through an SP and sends the prescription to the SP. The SP delivers the product for injection.	The physician acquires ILARIS through buy and bill for direct product ordering through a specialty distributor.
ILARIS is administered to the patient.	ILARIS is administered to the patient.	ILARIS is administered to the patient.
No action for the physician.	No action for the physician.	The physician submits claim to health care plan for product reimbursement.
The SP handles product reimbursement.	The SP handles product reimbursement.	The physician receives reimbursement for buy and bill acquisition.

For more information on how physicians can get reimbursed for the administration of ILARIS, visit **Step 4 in the Buy and Bill** section.

SPECIALTY PHARMACY ACQUISITION PROCESS FOR ILARIS

SP acquisition is the more familiar acquisition process for most physicians. This typically applies to patients whose insurance coverage for a product is under the **pharmacy benefit**.

For patients covered under the **medical benefit**, some plans may require ILARIS to be acquired through an SP. Physicians then bill the plans only for administering the injection.

Review the patient's coverage to determine the appropriate acquisition method for ILARIS.

ILARIS Companion helps with SP outreach

ILARIS Companion can help support your practice throughout the ILARIS acquisition process and works with the patient's SP for delivery and follow-up. Once ILARIS Companion receives the completed ILARIS Start Form and patient authorization, the prescription is triaged to the appropriate SP selected by the physician (or mandated by the plan) for delivery to the patient's home or physician's office.

Contact ILARIS Companion to learn more about the comprehensive support available along each step of the patient access journey.

BUY AND BILL PROCESS FOR ILARIS

Buy and bill is the process for acquiring specialty drugs administered by the physician at the practice. This typically applies to patients whose insurance coverage for a product is under the **medical benefit**.

Through the buy and bill model, physicians manage interactions with the drug from beginning to end.[1]

The physician purchases, stores, and administers the product to the patient, assuming full financial responsibility, rather than using an SP or other option to acquire the product. Practices are responsible for:

- Ordering and paying for the product up front
- Managing in-house inventory of the product
- Storing the drug appropriately
- Prescribing and administering the drug to a patient
- Billing the third-party payer for the drug, its administration, and any related professional services

Your detailed guide to the buy and bill process

This section details each step of the buy and bill process. Each step includes tips, recommendations, and FAQs to ensure your buy and bill experience with ILARIS goes smoothly.

1. VERIFY BENEFITS
2. ORDER ILARIS
3. ADMINISTER ILARIS
4. SUBMIT CLAIM
5. MANAGE REIMBURSEMENT

Reference: 1. Fein AJ. Follow the vial: the buy-and-bill system for distributing and reimbursing provider-administered outpatient drugs. Drug Channels. October 26, 2021. Accessed June 26, 2023. https://www.drugchannels.net/2021/10/follow-vial-buy-and-bill-system-for.html

Please see Important Safety Information on pages 1, 40, and 41 and full Prescribing Information, including Medication Guide.

1 VERIFY BENEFITS

Conduct a benefits investigation.

- Confirm the patient's benefits with their health care plan
- ILARIS Companion can help verify your patient's benefits. To get started, complete the ILARIS Start Form*
  - For more information about the Start Form, visit the **Getting Patients Started With ILARIS Companion** section
  - If you submit the Start Form, a statement of benefits (SOB) will be sent to your office within approximately 3 to 5 business days
- Once the SOB is received (via fax), you will learn:
  - If a PA is required, as well as any plan-specific PA criteria
  - The patient's OOP costs
  - Methods of acquisition allowed by the plan
  - Plan site-of-care requirements
  - Billing and coding information

*ILARIS Companion does not guarantee reimbursement. Your office must always confirm information with the plan.

Key considerations for a PA (if required)

- A PA submission may be required for ILARIS. Before submitting a PA, ensure the patient has met their plan's PA criteria. PA criteria may vary by plan

FAQs

Q ***My patient's health care plan has a PA in place for ILARIS. What criteria do plans commonly have in place to approve a PA?***

A PA criteria may vary by plan, but some examples of criteria may include the following: a tuberculosis test, diagnosis by a rheumatologist or immunologist, the prescribed dosing amount per the Prescribing Information, and confirmation that the patient is not receiving ILARIS in combination with another biologic. Always review and confirm the PA criteria specified by the plan.

Q ***My patient's health care plan does not cover ILARIS. What should I do next?***

A If your patient's plan does not cover ILARIS, you may be able to submit a Letter of Medical Exception to the plan. If it is still not approved after that, you may be able to submit a Letter of Appeal.

Your ILARIS Access & Reimbursement Manager (ARM) and ILARIS Companion can provide information and resources regarding the PA submission process.

2 ORDER ILARIS

After prescribing ILARIS, the physician orders it from an authorized specialty distributor.

Product supply and NDC

ILARIS is a sterile, preservative-free, clear to slightly opalescent, and colorless to a slight brownish to yellow solution for subcutaneous injection. ILARIS is available in cartons containing 1 single-dose, unopened vial. For more information, visit the **Coding and Reimbursement** section of this guide.

Product ordering

If your office is acquiring ILARIS through buy and bill, visit the **Product Distribution and Delivery** section of this guide for a list of the authorized distributors through which you can order.

Key considerations for ordering ILARIS:

- Develop methods for separating ILARIS by acquisition method: buy and bill, First Dose Program, and SP inventory
- Finalize storage logistics for ILARIS. Remember unopened vials of ILARIS must be stored refrigerated at 2 °C to 8 °C (36 °F to 46 °F) and should not be frozen. Make sure to protect from light
- If acquiring ILARIS through buy and bill, prepare to assume financial responsibility for inventory

FAQ

Q ***How long does it take to receive ILARIS after it is ordered?***

A Most orders may arrive in 1 to 3 business days. For a more accurate estimate, confirm with the distributor.

NDC, National Drug Code.

3 ADMINISTER ILARIS

The administration process for ILARIS includes the important steps outlined below.

1. Review the patient's OOP costs.

After you verify your patient's health care plan benefits, you will learn what their OOP costs will be for ILARIS. It is important to review this information with the patient before ILARIS is administered.

2. Collect the co-pay.

Collect the patient's co-pay or co-insurance according to your practice's billing protocols.

3. Administer ILARIS.

Patient arrives at your practice, and ILARIS is administered by a physician per the Prescribing Information.

4. Schedule a follow-up.

If the patient is receiving their initial dose of ILARIS, schedule them to come back for another dose every 8 weeks for CAPS and every 4 weeks for TRAPS, HIDS/MKD, FMF, AOSD, and SJIA.[1]

Key considerations for administering ILARIS

- Establish a routine for collecting co-pays and scheduling follow-ups with the patient
- Communicate with ILARIS Companion to help ensure the patient's plan information is up to date. **If their plan has changed, you will have to reverify their benefits**

FAQs

Q ***Can patients self-administer ILARIS?***

A No. ILARIS must be administered by a physician.

Q ***Where can I find co-pay support for my patient?***

A
- Your eligible patients with commercial insurance may pay as little as $30 for each ILARIS treatment. No financial information is required. Subject to terms and conditions. Limitations apply*
- Enroll your patients in the co-pay program and manage claims for reimbursement on behalf of your patients via fax at **1-866-972-8316**

AOSD, adult-onset Still's disease; CAPS, cryopyrin-associated periodic syndromes; FMF, familial Mediterranean fever; HIDS, hyperimmunoglobulin D syndrome; MKD, mevalonate kinase deficiency; SJIA, systemic juvenile idiopathic arthritis; TRAPS, tumor necrosis factor receptor-associated periodic syndrome.

*Limitations apply. See Program Terms and Conditions on the ILARIS Start Form available at www.ilarishcp.com/access. **This offer is not valid under Medicare, Medicaid, or any other federal or state program.** Novartis reserves the right to rescind, revoke, or amend this Program without notice.

Reference: 1. Ilaris. Prescribing information. Novartis Pharmaceuticals Corp.

Please see Important Safety Information on pages 1, 40, and 41 and full Prescribing Information, including Medication Guide.

ILARIS® (canakinumab) 150 mg subcutaneous injection

4 SUBMIT CLAIM

The physician submits a claim to the plan to receive reimbursement for ILARIS and its administration.

To submit a claim to get reimbursed for ILARIS and related services, you may have to fill out either a CMS-1500 or CMS-1450 (UB-04) claim form. The CMS-1500 form is used when billing prescribed medications administered in physician offices. The UB-04 form is used when billing prescribed medications administered in hospital outpatient settings. Visit the **Sample Claims Forms** section for more information.

Codes that may be used for ILARIS

For more information on relevant codes for filing a claim for ILARIS, visit the **Coding and Reimbursement** section.

Key considerations for filing a claim

- Understand current health care plan contracts for reimbursement of product and administration
- Ensure the appropriate number of units for ILARIS are captured, as ILARIS is dosed by weight (1 unit=1 mg)
- Plans may reimburse for the contents of the vial that were not utilized. Verify with the specific plan, as policies may vary
- Contact the plan directly to check the status of the claim

FAQs

Q ***Can my ILARIS Access & Reimbursement Manager help me fill out a claim form if I need help?***

A No, an ILARIS ARM or other Novartis representative may not fill out a claim form on your behalf, but they can answer any questions you have throughout the process.

Q ***Are the codes provided in the Coding and Reimbursement section the only codes I should be aware of for ILARIS?***

A Information specific to billing and coding is subject to change without notice and should be verified by the physician for each patient prior to treatment. A physician should contact the patient's health care plan directly for any revised or new requirements, information, or guidance.

Q ***How soon after service do I need to submit a claim?***

A The suggested timeline for submitting a claim is 24 to 48 hours between the service being provided and billing for it.

Have more questions about submitting a claim?

Reach out to your ARM or case manager through ILARIS Companion.

5 MANAGE REIMBURSEMENT

There are different types of reimbursement for drugs under the medical benefit.

Reimbursement under commercial insurance, Medicare, and Medicaid will vary by health care plan, contract, and fee schedule. It is the physician's responsibility to research plan contract status and agreements.

Key considerations for managing reimbursement

- Understand your reimbursement rate based on the plan contract in place and published fee schedules. Review these rates and fee schedules on a quarterly basis in case of an update
- Allocate an experienced staff member to submit and track reimbursement claims
- Establish a reconciliation process to ensure the consumed inventory is captured in the billing process
- Review the remittance advice—also called an explanation of benefits (EOB)—to ensure the appropriate payment is received
- Audit claims on a regular basis
- Ensure that accounts receivable match the accounts payable
- If your claim is denied, there is an appeals process you can follow to help get the claim approved. Contact ILARIS Companion for more information

Patient reimbursement support for ILARIS

Eligible patients may be able to receive reimbursement for their OOP costs after the claim has been filed and approved. Refer to the **Patient Support and Affordability Options** section for more information.

For information about billing for wastage, visit the **Coding and Reimbursement** section of this guide.

FAQ

Q ***What happens if my claim is denied?***

A If the health care plan does not cover ILARIS, the physician can file a first-level appeal.

Have more questions?

Contact your ILARIS ARM if you have any questions throughout the reimbursement process.

PRODUCT DISTRIBUTION AND DELIVERY

ILARIS is available through a select system of SPs, specialty distributors, and group purchasing organizations (GPOs). Novartis does not recommend the use of any particular distributor.

Specialty pharmacies

Novartis has an open network of participating SPs limited to those with URAC and/or ACHC accreditation, but health care plans may dictate a specific SP. ILARIS Companion can conduct a benefits investigation to determine the SPs available to your patients. This option provides access to ILARIS without a physician having to directly buy and bill.

ILARIS Companion provides product delivery support by working with a plan's preferred SP to support coordination and delivery of ILARIS to the patient's home or physician's office.

Specialty distributors

These companies provide priority health care distribution of ILARIS for office or clinic administration. Integrated delivery services include customer service and support, payment terms, and ordering and shipping options.

DISTRIBUTOR	CONTACT INFO	WEBSITE
ASD Healthcare*	**Phone:** 1-800-746-6273 **Fax:** 1-800-547-9413	www.asdhealthcare.com
Besse Medical*	**Phone:** 1-800-543-2111 **Fax:** 1-800-543-8695	www.besse.com
Cardinal Health Specialty Distribution	**Phone:** 1-855-855-0708	specialtyonline.cardinalhealth.com
CuraScript SD	**Phone:** 1-877-599-7748 **Fax:** 1-800-862-6208	curascriptsd.com
McKesson Plasma and Biologics (MPB)	**Phone:** 1-877-625-2566	connect.mckesson.com
McKesson Specialty Care Distribution	**Phone:** 1-855-477-9800	mscs.mckesson.com
Metro Medical (A Cardinal Health Company)	**Phone:** 1-800-768-2002 **Fax:** 1-615-256-4194	www.metromedicalorder.com
Oncology Supply*	**Phone:** 1-800-633-7555 **Fax:** 1-800-248-8205	www.oncologysupply.com

ACHC, Accreditation Commission for Health Care; URAC, Utilization Review Accreditation Commission.
*ASD Healthcare, Besse Medical, and Oncology Supply are now part of Cencora.

Please see Important Safety Information on pages 1, 40, and 41 and full Prescribing Information, including Medication Guide.

PRODUCT DISTRIBUTION AND DELIVERY (cont)

GPOs for independent outpatient and infusion sites

GPOs provide additional discounts and services for office or clinic administration of ILARIS. Other services offered may include operational, administrative, financial, and analytics support. Below are the GPOs that carry ILARIS.

GPO	CONTACT INFO	WEBSITE	NOTES
Cornerstone Rheumatology GPO/Mosaic GPO Solutions	1-800-768-2002	www.cardinalhealth.com/cornerstonerheumatology www.cardinalhealth.com/mosaicgpo	For Cardinal Health SD/Metro Medical customers
Matrix GPO	1-888-263-9982	www.matrixgpo.com	For CuraScript SD customers
Onmark GPO	1-800-482-6700	www.mckesson.com/Specialty/Group-Purchasing	For McKesson Specialty Care and Plasma and Biologics customers
IPN	1-610-727-7000	www.specialtypracticenetwork.com	For ASD Healthcare and Besse Medical Customers

EXAMPLES OF FORMULARY CRITERIA FOR ILARIS ACCESS

While not exhaustive, the criteria in the following tables can help you anticipate the types of restrictions that health care plans establish. These criteria are only examples of those you may encounter. Criteria will vary from plan to plan, and these examples are not intended to represent complete descriptions of the criteria, which may be more detailed than those shown here.

Formulary criteria for ILARIS access for patients diagnosed with AOSD and SJIA*

EXAMPLE CRITERIA	MORE RESTRICTIVE CRITERIA
CLINICAL	
TB test[1]	Documentation of results[2]
Age ≥2 years (for SJIA)[3]	X
Diagnosed by, or in consultation with, a rheumatologist or immunologist with expertise in the condition[4]	• Prescribed by a rheumatologist[5] • Consultation notes, if applicable[6]
Dosing per the Prescribing Information[4]	X
• Patient is not receiving ILARIS in combination with another biologic[4] • Clinical documentation supporting the diagnosis[1]	• Letter of Medical Necessity with supporting evidence[6] • Documented active systemic features[7] • Features of poor prognosis, such as[8]: – Arthritis of the hip – Radiographic damage – 6-month duration of active systemic disease
STEP EDIT	
Inadequate response at optimal doses or an inability to tolerate with documentation of dates and duration of therapy (required time frame for trial can vary by plan)[1,3]: • Methotrexate or leflunomide **OR** • Both nonsteroidal anti-inflammatory drugs (NSAIDs) and corticosteroids Some plans may also require trial of anakinra.[9]	In addition to drugs listed on the left, some plans may require trial of two or more indicated biologics.[8] Plans may also require longer duration of trial of each step.[2,6]

*Based primarily on plan criteria for SJIA.

AOSD, adult-onset Still's disease; SJIA, systemic juvenile idiopathic arthritis; TB, tuberculosis.

References: 1. CVS/caremark. Ilaris prior authorization request. Effective August 2020. Accessed July 31, 2023. https://member.carefirst.com/carefirst-resources/provider/pdf/drug/Ilaris-SGM.pdf **2.** Humana CareSource. Pharmacy Policy Statement: Kentucky Medicaid. Effective July 1, 2019. Accessed July 31, 2023. https://www.caresource.com/documents/medicaid-ky-policy-pharmacy-ilaris-20190624/ **3.** Aetna. Canakinumab (Ilaris) clinical policy bulletins: medical policy bulletins. Effective May 12, 2014. Reviewed March 27, 2023. Accessed July 31, 2023. http://www.aetna.com/cpb/medical/data/800_899/0881.html **4.** Harvard Pilgrim Health Care, Tufts Health Plan. Medical necessity guidelines: Ilaris (canakinumab). Effective January 1, 2023. Accessed July 31, 2023. https://tuftshealthplan.com/documents/providers/guidelines/md-mngs/ilaris-comm-dmng **5.** UnitedHealthcare. Commercial medical benefit policy – Ilaris (canakinumab). Effective October 10, 2022. Accessed July 31, 2023. https://www.uhcprovider.com/content/dam/provider/docs/public/policies/comm-medical-drug/ilaris-canakinumab.pdf **6.** Molina Healthcare. Drug and biologic coverage criteria: Ilaris (canakinumab). Effective December 28, 2022. Accessed July 31, 2023. https://www.molinahealthcare.com/-/media/Molina/PublicWebsite/PDF/Providers/common/pa-criteria/Ilaris-canakinumab-C2435-A.pdf **7.** Prime Therapeutics. Medicare 2019 prior authorization criteria. MyPrime website. Effective November 2019. Accessed July 31, 2023. https://www.myprime.com/content/dam/prime/memberportal/forms/2019/FullyQualified/Other/ALL/HBCBSNJ/MEDICARE_D/NJSNPHMO/Prior_Authorization_Criteria.pdf **8.** Express Scripts. Medicare (PDP) Choice: drugs that require prior authorization (PA) before being approved for coverage. Reviewed November 2016. Accessed July 31, 2023. https://www.expressscripts.com/art/medicare16/pdf/prior_authorization_choice.pdf **9.** BlueCross BlueShield of Michigan. Ilaris (Canakinumab) Medical Policy. Accessed July 31, 2023. http://www.bcbsm.com/amslibs/content/dam/public/providers/documents/ilaris-canakinumab-medical-policy.pdf

Please see Important Safety Information on pages 1, 40, and 41 and full Prescribing Information, including Medication Guide.

EXAMPLES OF FORMULARY CRITERIA FOR ILARIS ACCESS (cont)

Formulary criteria for ILARIS access for patients diagnosed with PFS conditions

CAPS	TRAPS	HIDS/ MKD	FMF	EXAMPLE CRITERIA	MORE RESTRICTIVE CRITERIA
●	●	●	●	TB test within previous 12 months[1]	X
●	●	●	●	Diagnosed by, or in consultation with, a rheumatologist or immunologist with expertise in the condition[2]	X
●	●	●	●	Age and dosing per the Prescribing Information[2,3]	Weight[4]
●	●	●	●	Patient is not receiving ILARIS in combination with another biologic[5]	X
●				• Classic signs and symptoms[6] • Functional impairment limiting activities of daily living[1,6]	• Genetic testing[5,7] • Elevated inflammatory markers (CRP and SAA) and at least 2 typical CAPS manifestations[5] • Significant functional impairment resulting in limitations of ADLs[4]
	●			Chronic or recurrent disease activity with active flares within the past 6 months **and** PGA ≥2 or CRP >10 mg/L[6]	Documentation in chart notes of PGA ≥2, key signs and symptoms, CRP >10 mg/L, and at least 6 flares per year[8]
		●		Active flares within the past 6 months **and** PGA ≥2 **or** CRP >10 mg/L[6]	• Documentation in chart notes of PGA ≥2, key signs and symptoms, CRP >10 mg/L[8] • 3 or more febrile acute flares within a 6-month period[3] • Documented diagnosis of HIDS plus an elevated immunoglobulin D level or MVK gene mutation[4]
			●	Active disease with flares within the past 6 months **and** CRP >10 mg/L **and** inadequate response, intolerance to, or contraindication to colchicine[6]	• Documentation in chart notes of PGA ≥2, key signs and symptoms, and CRP >10 mg/L[8] • At least 1 flare per month despite colchicine therapy or documented intolerance to effective doses of colchicine[3] • Prescriber documents patient baseline disease activity and treatment goals to evaluate efficacy (eg, recurrent fever, abdominal pain, joint point, etc)[4]

ADLs, activities of daily living; CAPS, cryopyrin-associated periodic syndromes; CRP, C-reactive protein; FMF, familial Mediterranean fever; HIDS, hyperimmunoglobulin D syndrome; MKD, mevalonate kinase deficiency; PFS, periodic fever syndrome; PGA, Physician's Global Assessment; SAA, serum amyloid A; TRAPS, tumor necrosis factor receptor-associated periodic syndrome.

References: 1. CVS/caremark. Ilaris prior authorization request. Effective August 2020. Accessed July 31, 2023. https://member.carefirst.com/carefirst-resources/provider/pdf/drug/Ilaris-SGM.pdf **2.** UnitedHealthcare. Commercial medical benefit policy – Ilaris (canakinumab). Effective October 10, 2022. Accessed July 31, 2023. https://www.uhcprovider.com/content/dam/provider/docs/public/policies/comm-medical-drug/ilaris-canakinumab.pdf **3.** Cigna. Drug and biologic coverage policy: canakinumab. Effective June 1, 2022. Accessed July 31, 2023. https://static.cigna.com/assets/chcp/pdf/coveragePolicies/pharmacy/ip_0235_coveragepositioncriteria_canakinumab.pdf **4.** Molina Healthcare. Drug and biologic coverage criteria: Ilaris (canakinumab). Effective December 28, 2022. Accessed July 31, 2023. https://www.molinahealthcare.com/-/media/Molina/PublicWebsite/PDF/Providers/common/pa-criteria/Ilaris-canakinumab-C2435-A.pdf **5.** BlueCross BlueShield of Michigan. Ilaris (canakinumab). Effective December 1, 2022. Accessed July 31, 2023. https://www.bcbsm.com/amslibs/content/dam/public/providers/documents/ilaris-canakinumab-medical-policy.pdf **6.** Aetna. Canakinumab (Ilaris) clinical policy bulletins: medical policy bulletins. Effective May 12, 2014. Reviewed March 27, 2023. Accessed July 31, 2023. http://www.aetna.com/cpb/medical/data/800_899/0881.html **7.** CVS/caremark. Ilaris HMSA prior authorization request. Effective January 2023. Accessed July 31, 2023. https://www.caremark.com/portal/asset/HMSAFaxForm_Ilaris.pdf **8.** Humana CareSource. Pharmacy Policy Statement: Kentucky Medicaid. Effective July 1, 2019. Accessed July 31, 2023. https://www.caresource.com/documents/medicaid-ky-policy-pharmacy-ilaris-20190624/

Please see Important Safety Information on pages 1, 40, and 41 and full Prescribing Information, including Medication Guide.

EXAMPLES OF FORMULARY CRITERIA FOR ILARIS ACCESS (cont)

Potential formulary criteria for ILARIS access for patients diagnosed with gout flares

Criteria shown below are based on clinical trial criteria and available Compendial Use criteria from plans. Plan policies may be updated approximately 6 months after FDA approval of the gout flares indication for ILARIS; however, timing will vary by payer. Medicare plans may take longer to update due to bid cycle timelines.

EXAMPLE CRITERIA	MORE RESTRICTIVE CRITERIA
Inadequate response or intolerance to maximum tolerated doses of NSAIDs, colchicine, and oral and injectable corticosteroid[1-3]	X
Contraindication to NSAIDs and colchicine[1-3]	X
Clinical reason to avoid repeated courses of corticosteroids[1,2]	X
Prescribed by, or in consultation with, a rheumatologist[4]	X

References: 1. ClinicalTrials.gov. Canakinumab in the treatment of acute gout flares and prevention of new flares in patients unable to use non-steroidal anti-inflammatory drugs (NSAIDs) and/or colchicines including a 12 week extension and a 1 year open-label extension study. (β-RELIEVED-II). Accessed June 30, 2023. https://www.clinicaltrials.gov/study/NCT01080131 **2.** Carefirst. CVS/caremark: Ilaris Prior Authorization Request. Accessed June 21, 2023. https://member.carefirst.com/carefirst-resources/provider/pdf/drug/Ilaris-SGM.pdf **3.** CVS/Caremark. Specialty guideline management: ILARIS (canakinumab). https://resources.massgeneralbrighamhealthplan.org/pharmacy/PharmacyPolicies/CVS/Ilaris_PA_ALL_MBRx.pdf Accessed June 30, 2023. **4.** Aetna. Canakinumab (Ilaris). Accessed June 21, 2023. http://www.aetna.com/cpb/medical/data/800_899/0881.html

Please see Important Safety Information on pages 1, 40, and 41 and full Prescribing Information, including Medication Guide.

ILARIS® (canakinumab) 150 mg subcutaneous injection

OVERVIEW OF PRIOR AUTHORIZATION (PA) AND APPEALS PROCESS

Your office can choose to submit the PA request directly to the health care plan

Many plans have a PA form for ILARIS or a general form they prefer you to use. You can locate the form on their website, or it can be provided by your specialty pharmacy (SP), ILARIS Companion, or your ILARIS Access & Reimbursement Manager (ARM).

What to know about submitting a PA directly:

- Submit the form according to the plan's instructions
  - The plan may also ask that you submit patient records, including lab tests and other information
- The form may include clinical and step edit criteria required for approval
- The plan will notify you and your patient of the approval or denial

ILARIS Companion can help support your office during the PA and appeals process

ILARIS Companion can help you obtain the correct forms and documentation needed to process the PA request. A case manager can also assist in identifying plan-specific PA criteria, if required. If the PA can be called in, the authorization phone number will be provided to your office. **Your office must still prepare and submit the PA form to the plan.**

ILARIS Companion Case Managers also monitor and check the PA status after submission and check the approval/denial status to provide an update before a letter arrives at your office.

PA denials

If a PA request is denied, then submit the appeal to the plan with a Letter of Appeal and Letter of Medical Necessity. Plans may request that appeals be submitted by fax or email.

› Faxing the denial letter to ILARIS Companion at **1-866-972-8316** can let your case manager provide additional appeals support, such as sending a sample Letter of Appeal to the office.

Reauthorizations

Reach out to ILARIS Companion 30 days prior to the expiration of the current authorization for assistance with the reauthorization process to help avoid gaps in therapy. ILARIS Companion can:

- Proactively contact the plan to determine renewal requirements
- Notify your office of expiring PAs and the need for renewals
- Identify required documentation, including PA forms
- Provide the authorization phone number if the PA can be called in

ILARIS Companion is committed to supporting your efforts to help patients access ILARIS.

TIPS FOR PA SUBMISSION

Many plans require a PA for biologics and will have their own PA forms available on their websites. If a patient's plan requires a PA for ILARIS, review the specific forms and information needed by the plan to ensure the PA request is as complete as possible.

All ILARIS PA forms must be completed and submitted to the plan by office staff—ILARIS ARMs are not permitted to fill out or submit the forms.

Additional tips:

- Refer to the plan's website to locate the PA form. Your ARM can also assist with finding the form
- Benefits investigations performed by ILARIS Companion and SPs can identify PA requirements, step edits, and form requirements
- Submit the PA request to the plan
- Fax the ILARIS Start Form to ILARIS Companion at **1-866-972-8316**
- Many SPs have the ability to submit a test claim to plans to confirm coverage of ILARIS
- If a proposed treatment in the step edit process will not be tolerated by the patient, an appeal to bypass that requirement may be submitted to the plan, accompanied by a Letter of Medical Necessity
- Many plans will allow up to 3 levels of appeal of PA denials
  - The third-level appeal may include review by an independent noninsurance-affiliated external review board or hearing

ILARIS Companion is here to help

- Your ILARIS ARM can help you find and understand your patient's health care coverage criteria and provide sample letter templates upon request
- For support throughout the coverage process and additional resources for your patient, you can submit the Start Form to enroll your patient in ILARIS Companion

See the following page for a helpful PA submission checklist.

PREPARING A PA SUBMISSION

PA submission checklist

Confirm you have completed the following when submitting a PA for your patient:

- ☐ Fill out the plan- and/or state-specific PA form
  - Conduct a benefits investigation to ensure you satisfy the plan's requirements for ILARIS
- ☐ Include the patient's name, policy number, and date of birth
- ☐ Specify a single diagnosis
- ☐ Include any relevant medical records and clinical notes supporting treatment with ILARIS
- ☐ Weights should be precise. Do not round
- ☐ Confirm and document that all PA requirements have been met, including any step edit requirements

NOTE: Some plans may require use of their own letter templates for PA requests.

The information herein is provided for educational purposes only. Novartis cannot guarantee insurance coverage or reimbursement. Coverage and reimbursement may vary significantly by payer, plan, patient, and setting of care. It is the sole responsibility of the health care provider to select the proper codes and ensure the accuracy of all statements used in seeking coverage and reimbursement for an individual patient.

SUBMITTING EXCEPTION REQUESTS

If the patient's plan has placed certain restrictions on ILARIS, such as formulary exclusion or tier assignment, you will need to submit an exception request.

Formulary Exception Request Letter

This type of letter can be used when ILARIS is not listed on a formulary or if it has an NDC block.

Tiering Exception Request Letter

This type of letter can be used when ILARIS is on formulary but on a tier with a high co-pay. Based on medical necessity, you can appeal to the plan to consider the drug as if it were a preferred branded agent to reduce the patient's out-of-pocket costs and help alleviate any financial burden.

Additional tips:

- A Formulary Exception Request Letter should be submitted along with a copy of your relevant medical records and Letter of Medical Necessity
  - Confirm whether the patient's plan has its own exception request form, which can be located on the plan's website or by contacting the plan's customer service
- Address the main reasons supporting your request for an exception for ILARIS
- Include a statement of financial hardship
  - This may be most useful for patients on plans requiring co-insurance
- You may also submit a tiering exception request or formulary exception request if your patient's plan previously approved ILARIS but has since changed its formulary to exclude or move ILARIS to a higher tier without grandfathering in current patients
- Consider asking your patient or their legal guardian to write their own exception request letter that is signed by the physician

ILARIS Companion is here to help

- Your ILARIS ARM can help you find and understand your patient's health care coverage criteria and provide sample letter templates upon request
  - If you or your patient need help writing to the plan, contact ILARIS Companion for support
- For support throughout the coverage process and to locate additional resources for your patient, you can submit the ILARIS Start Form to enroll your patient in ILARIS Companion

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See the following page for a helpful exception request checklist.

NDC, National Drug Code.

PREPARING AN EXCEPTION REQUEST

Exception request checklist

Confirm you have completed the following when requesting an exception:

- ☐ Complete the plan's exception request form, if required
  - – Conduct a benefits investigation to ensure you satisfy the plan's requirements
- ☐ Include the patient's name, policy number, date of birth, and, if appropriate, the denial reference number from a previous appeal and the date of denial
- ☐ Specify a single diagnosis
- ☐ List of previous therapies for this condition
- ☐ Relevant medical records
- ☐ **If this is a second-level or third-level formulary exception appeal,** include the letter of denial and medical notes in response to the denials
- ☐ If required, attach a Letter of Medical Necessity

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SUBMITTING AN APPEAL

If a patient's PA or exception request has been denied, their plan will provide a written explanation and include information about how to request an appeal. There can be multiple levels of appeal. Please refer to the plan's specific appeals guidelines.

Some plans may require that a Letter of Medical Necessity be submitted along with an appeal to support the choice of ILARIS over agents that are on formulary. A Letter of Medical Necessity can also accompany a Formulary Exception Request Letter or Tiering Exception Request Letter.

Additional tips:

- Promptly submit the appeal upon receipt of the denial to help avoid delays
- Clearly respond to the plan's specific reason(s) for denial within your appeal letter
- Provide clinical support for your recommendation (eg, clinical trial data from the ILARIS Prescribing Information)
- Review the appeals process for your patient's plan
- If required, attach a Letter of Medical Necessity
  - State why treatment with ILARIS is medically necessary, supporting your recommendation with information, such as:
    - Patient's history, diagnosis, current condition, and symptoms
    - Include copies of relevant medical records, including test results (plans may want to know if any infections, allergies, or comorbidities are present)
  - Close the letter by summarizing your recommendation and provide a phone number should any additional information be required

NOTE: At each stage of appeal, plans may require that their own forms (or the universal forms required by some states) be submitted along with your letter.

ILARIS Companion is here to help

- Your ILARIS ARM can help you find and understand your patient's health care coverage criteria and provide sample letter templates upon request
  - If you or your patient need help writing to the plan, contact ILARIS Companion for support

The information herein is provided for educational purposes only. Novartis cannot guarantee insurance coverage or reimbursement. Coverage and reimbursement may vary significantly by payer, plan, patient, and setting of care. It is the sole responsibility of the health care provider to select the proper codes and ensure the accuracy of all statements used in seeking coverage and reimbursement for an individual patient.

PREPARING AN APPEAL

Appeal submission checklist

- ☐ Include relevant patient information:
  - ☐ Patient's name, policy number, and date of birth
  - ☐ PA denial reference number and date of denial
  - ☐ Specify a single diagnosis
  - ☐ Describe severity of condition
  - ☐ Weights should be precise. Do not round
- ☐ Conduct a benefits investigation to confirm and document that:
  - ☐ All PA requirements of the plan have been met
  - ☐ The patient has satisfied any step edit requirements
- ☐ Include the necessary clinical support:
  - ☐ Patient's medical records (patient history, diagnosis, current condition, and symptoms)
  - ☐ Copies of relevant medical records (plans may want to know if any infections, allergies, or comorbidities are present)
  - ☐ List previous therapies (explain why each therapy was discontinued, and specify the duration of therapy for each agent)
  - ☐ If applicable, explain why formulary preferred agents are not appropriate (if they have not already been listed as previous therapies)

NOTE: Patients can also write and submit their own appeal letters to help with coverage. ILARIS Companion can help patients who need guidance writing to their health care plan.

The information herein is provided for educational purposes only. Novartis cannot guarantee insurance coverage or reimbursement. Coverage and reimbursement may vary significantly by payer, plan, patient, and setting of care. It is the sole responsibility of the health care provider to select the proper codes and ensure the accuracy of all statements used in seeking coverage and reimbursement for an individual patient.

CONSIDERATIONS FOR GOUT FLARES

Overview of gout flares

Gout flares can cycle repeatedly and may last days or weeks.[1] When they do not respond to traditional treatment methods (like NSAIDs, corticosteroids, or colchicine), patients have few other options for relief.[1] ILARIS is indicated for the symptomatic treatment of adult patients with gout flares in whom 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.[2] For these patients, treatment with ILARIS can help provide relief from these painful flares.

PA options for gout flares

Physicians can submit either a standard prior authorization (PA) or pre-approval PA. While both methods can authorize access to ILARIS, a pre-approval PA may be the better option, given flares are painful and unpredictable. This process can help ensure that ILARIS is promptly accessible to patients when needed.

Receiving authorization for a pre-approval PA prior to a flare—based on the physician's clinical judgment—helps ensure that ILARIS is available when a flare occurs. While commercial and Medicare Advantage patients will likely need a pre-approval PA to get coverage for ILARIS, Medicare covers ILARIS to label without a pre-approval PA.

Pre-approval PA process guidelines

- Pre-approval PAs are submitted, and approval is acquired, before a patient's next cyclical flare.* This allows a physician to procure ILARIS quickly and treat a flare
- These PAs are assessed based on evidence of need for future use. They are only valid for a limited amount of time before they need to be resubmitted, and time frames vary from plan to plan
- Pre-approval PAs do not typically have their own form. Within the form, office staff should indicate the submission is a pre-approval PA request

NOTE: Some plans may choose to authorize ILARIS following administration of the first dose using a post-authorization approval. Closely examine all plan-specific requirements before administering ILARIS.

*The recommended dose of ILARIS for adult patients with a gout flare 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.[2]

If you have any additional questions, please contact your ILARIS Access and Reimbursement Manager (ARM).

NSAID, nonsteroidal anti-inflammatory drug.

References: 1. Centers for Disease Prevention and Control. Gout. Accessed July 31, 2023. https://www.cdc.gov/arthritis/basics/gout.html **2.** Ilaris. Prescribing information. Novartis Pharmaceuticals Corp.

PRE-APPROVAL PA PROCESS FOR GOUT FLARES

1 Office staff submits pre-approval PA

This is the initiating step of the pre-approval PA submission process and is primarily handled by the office staff.

- ILARIS Companion can help determine specific regional plan policies on pre-approval PAs prior to submission and proactively communicate with the office staff to help avoid unnecessary delays or denials

2 Health care plan reviews request

The office staff submits a pre-approval PA request to the plan. After the office staff has submitted a pre-approval PA request to the plan, the plan may request additional information from the physician.

- ILARIS Companion can provide informational assistance to help the office with submitting a pre-approval PA

3 Request authorized

At this step, the request is authorized by the plan, and the physician may now procure ILARIS in the event of a patient flare. A pre-approval PA can be valid for anywhere from 3 to 6 months, depending on the plan.

Some plans may allow the physician to purchase ILARIS and keep it on hand in anticipation of a flare. The physician would then submit for reimbursement upon use of ILARIS for the authorized patient. Check plan-specific information before pre-purchasing ILARIS.

If the request is denied:

In the event a pre-approval PA is denied, you need to either correct submission mistakes or provide additional documentation to the plan. Reasons for denial may include missing prerequisites of coverage or the need for additional documentation of medical necessity. Reach out to your ILARIS ARM for help ensuring all plan pre-approval PA requirements have been documented and submitted appropriately.

If the pre-approval PA submission is complete and correct, and you are unable to identify the reason for denial, ILARIS Companion can provide further assistance. An ILARIS ARM can also assist in escalating the issue for resolution.

4 Physician uses or must renew pre-approval PA

Once authorized, the physician either uses their pre-approval PA to procure ILARIS for a patient having a flare or must renew the PA once the authorization period expires.

Reauthorizations should be filed immediately after the previous authorization expires to ensure continuous coverage.

For pre-approval PA support, please contact ILARIS Companion by calling 1-866-972-8315.

BILLING AND ACQUISITION FOR GOUT FLARES

ILARIS is available to order and ship immediately through specialty pharmacies, specialty distributors, and group purchasing organizations for independent outpatient and infusion sites. For details about ordering ILARIS, visit the **Product Distribution and Delivery** section.

If a physician purchases ILARIS before a patient's next flare using a pre-approval PA, most plans will not reimburse for a drug that has not yet been administered. Physicians will most likely only be reimbursed once they administer ILARIS and submit proof of administration to the plan, along with any other regional plan claim requirements.

Physician reimbursement for ILARIS and its administration under commercial insurance, Medicare, and Medicaid will vary by health care plan. Eligible patients may also be able to receive reimbursement for their OOP costs. Refer to the **Patient Support and Affordability Options** section for more information.

Suggestions for submitting PA requests for gout flares

Be sure to familiarize yourself with the plan's requirements for a standard/pre-approval PA prior to submission. Confirm you have completed the following when requesting an exception:

Gout flares PA submission checklist

- ☐ Include any information and documentation related to failure of previous treatments used for gout flare management
- ☐ Ensure the PA is marked as urgent if there is a section on the form to do so
- ☐ Specify a single diagnosis
- ☐ Since pre-approval PAs do not typically have their own form, be sure to indicate the submission is a pre-approval PA request within the form

Gout flares PA submission tips

- Be sure to check/validate coverage for appropriate patients; contact ILARIS Companion for help

DOSING INFORMATION

ILARIS is administered subcutaneously by a physician and dosed according to body weight, except for gout flares.

BODY WEIGHT	RECOMMENDED DOSE	RECOMMENDED TITRATION
PFS (FMF, HIDS/MKD, and TRAPS): Dosed once monthly		
≤40 kg	2 mg/kg every 4 weeks	Dose can be increased to 4 mg/kg every 4 weeks*
>40 kg	150 mg every 4 weeks	Dose can be increased to 300 mg every 4 weeks*
PFS (CAPS [FCAS and MWS]): Dosed once every 2 months		
≥15 kg to ≤40 kg	2 mg/kg every 8 weeks	Dose can be increased to 3 mg/kg every 8 weeks* in pediatric patients
>40 kg	150 mg every 8 weeks	X
Still's disease (AOSD and SJIA): Dosed once monthly		
≥7.5 kg	4 mg/kg (with a maximum of 300 mg) every 4 weeks	X
Gout flares		
N/A	The recommended dose of ILARIS for adult patients with a gout flare 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	X

*If clinical response is inadequate.

Refer to the full Prescribing Information for ILARIS for detailed preparation and administration instructions.

AOSD, adult-onset Still's disease; CAPS, cryopyrin-associated periodic syndromes; FCAS, familial cold autoinflammatory syndrome; FMF, familial Mediterranean fever; HIDS/MKD, hyperimmunoglobulin D syndrome/mevalonate kinase deficiency; MWS, Muckle-Wells syndrome; PFS, periodic fever syndrome; SJIA, systemic juvenile idiopathic arthritis; TRAPS, tumor necrosis factor receptor-associated periodic syndrome.

Reference: Ilaris. Prescribing information. Novartis Pharmaceuticals Corp.

Please see Important Safety Information on pages 1, 40, and 41 and full Prescribing Information, including Medication Guide.

ILARIS® (canakinumab) 150 mg subcutaneous injection

CODING AND REIMBURSEMENT

The code examples included in this section are for general informational purposes only. They are not intended to be directive, a guarantee of coverage, or a substitute for an independent clinical decision.

Examples of relevant ICD-10-CM codes for patients prescribed ILARIS[1]

ICD-10-CM code	Description
M04.1	FMF, HIDS/MKD, and TRAPS
M04.2	CAPS (includes FCAS and MWS)
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.X-	Gout flares: include appropriate code* and site, if applicable

ICD-10-CM, International Classification of Diseases, 10th Revision, Clinical Modification; NOS, not otherwise specified.

Add a single digit in the hundredths place for codes M08.2, M08.9, and M10.0-M10.4 to specify anatomical site followed by another single digit in the thousandths place to specify laterality of the site affected. Numbers coding for anatomical site include unspecified-0, shoulder-1, elbow-2, wrist-3, hand-4, hip-5, knee-6, ankle and foot-7, vertebrae-8, and multiple-9. Numbers coding for laterality include right-1, left-2, and unspecified-9. For example, M08.261 codes for juvenile rheumatoid arthritis with the right knee affected.[1]

*0=Idiopathic gout; 1=Lead-induced gout; 2=Drug-induced gout; 3=Gout due to renal impairment; 4=Other secondary gout; 9=Gout unspecified.

Coverage and reimbursement may vary significantly by payer, plan, patient, and setting of care. It is the sole responsibility of the health care provider to select the proper codes and ensure the accuracy of all statements used in seeking coverage and reimbursement for an individual patient.

Novartis does not guarantee payment or coverage for any product or service. It is always the provider's responsibility to determine the appropriate health care setting and to submit true and correct claims for the products and services rendered.

Reference: 1. AAPC. *2022 ICD-10-CM Expert: Diagnosis Codes for Providers & Facilities.* 2021. Accessed July 31, 2023. https://aapc.vitalsource.com/#/

Please see Important Safety Information on pages 1, 40, and 41 and full Prescribing Information, including Medication Guide.

CODING AND REIMBURSEMENT (cont)

The code examples included in this section are for general informational purposes only. They are not intended to be directive, a guarantee of coverage, or a substitute for an independent clinical decision.

Service and administration codes

NDC[1]	
10-digit: 0078-0734-61	Carton of 1 vial of ILARIS injection. Each single-dose vial contains a concentration of 150 mg/mL
11-digit: 00078-0734-61	
HCPCS code[2]	
J0638	Injection, canakinumab, 1 mg
CPT code[3]	
96372	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular
JW and JZ modifiers[4]	
JW	Drug amount discarded/not administered to any patient
JZ	Zero drug amount discarded/full amount administered to any patient

As of July 1, 2023, the JZ modifier is required when there are no discarded amounts of a single-dose container drug that is separately payable under Medicare Part B, for which the JW modifier would be required if there were discarded amounts. Starting October 1, 2023, claims for drugs from single-dose containers that do not use the modifiers as appropriate may be returned as unprocessable until claims are properly resubmitted.

Billing for wastage

- Because ILARIS is dosed by patient weight for all indications except gout flares, the contents of a vial may not be completely utilized, so health care plans may reimburse for the remainder of the vial's contents if it is not administered and is discarded
- Drug wastage should be documented in the patient's medical record with the date, time, amount wasted, and reason for wastage
- Policies among plans may differ; therefore, verification is recommended from the specific plan—some request that the physician identify a discarded product using the JW modifier in the HCPCS code on a separate line[4]

Coverage and reimbursement may vary significantly by payer, plan, patient, and setting of care. It is the sole responsibility of the health care provider to select the proper codes and ensure the accuracy of all statements used in seeking coverage and reimbursement for an individual patient.

Novartis does not guarantee payment or coverage for any product or service. It is always the provider's responsibility to determine the appropriate health care setting and to submit true and correct claims for the products and services rendered.

CPT, Current Procedural Terminology; HCPCS, Healthcare Common Procedure Coding System; NDC, National Drug Code.

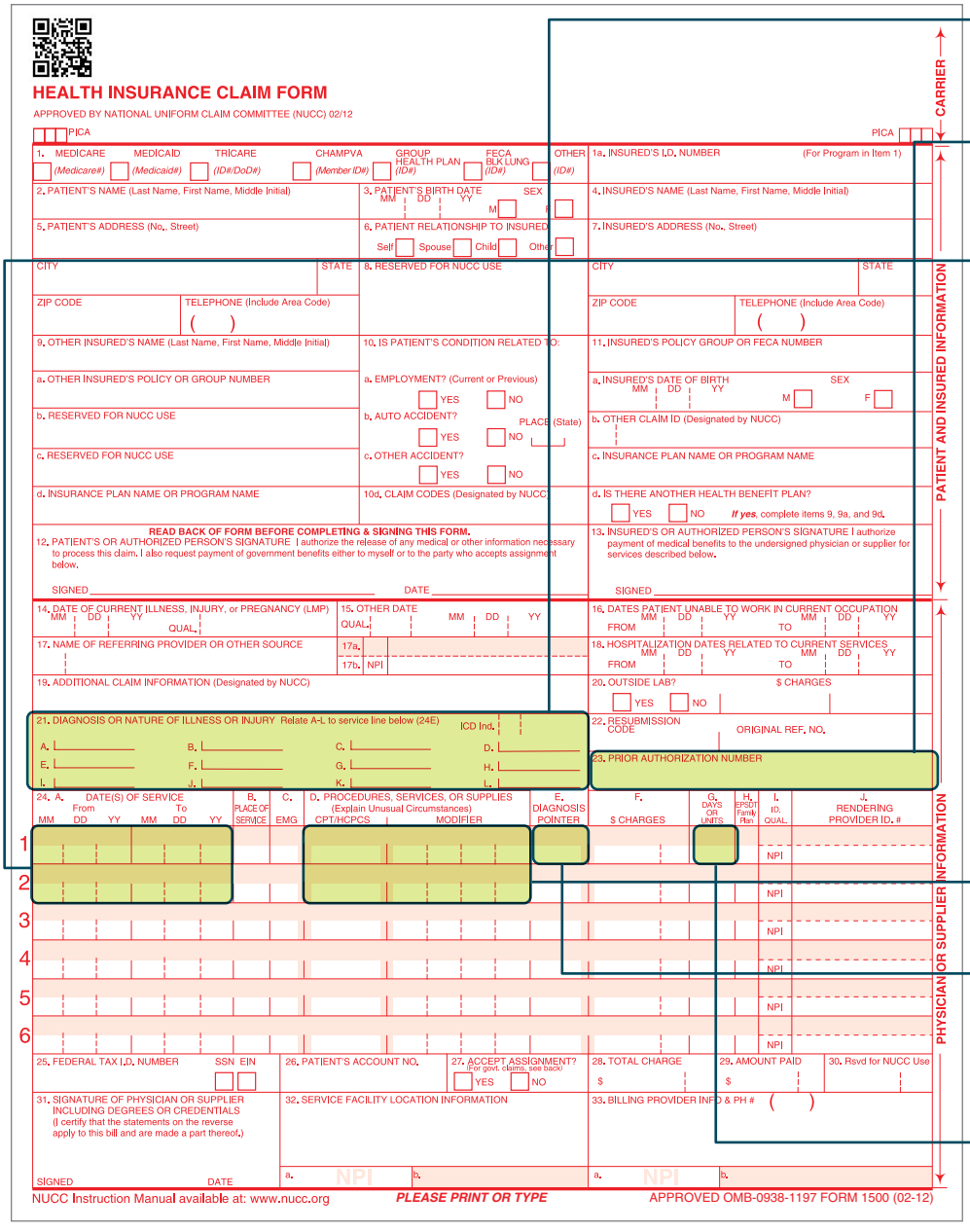
References: 1. Ilaris. Prescribing information. Novartis Pharmaceuticals Corp. **2.** AAPC. *2022 HCPCS Level II Expert: Service/Supply Codes for Caregivers & Suppliers.* 2021. Accessed July 31, 2023. https://aapc.vitalsource.com/#/ **3.** American Medical Association. *CPT 2022 Professional Edition.* 2021. Accessed July 31, 2023. https://aapc.vitalsource.com/#/ **4.** Centers for Medicare & Medicaid Services. Medicare program: discarded drugs and biologicals – JW modifier and JZ modifier policy frequently asked questions. Accessed July 31, 2023. https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps/downloads/jw-modifier-faqs.pdf

Please see Important Safety Information on pages 1, 40, and 41 and full Prescribing Information, including Medication Guide.

SAMPLE CLAIMS FORMS

CMS-1500 sample claim form for ILARIS

Physicians use this form when billing insurers for medication administered in the physician's office and for their professional services.



HEALTH INSURANCE CLAIM FORM

APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12

PICA

1. MEDICARE (Medicare#) | MEDICAID (Medicaid#) | TRICARE (ID#/DoD#) | CHAMPVA (Member ID#) | GROUP HEALTH PLAN (ID#) | FECA BLK LUNG (ID#) | OTHER (ID#)

1a. INSURED'S I.D. NUMBER (For Program in Item 1)

2. PATIENT'S NAME (Last Name, First Name, Middle Initial)

3. PATIENT'S BIRTH DATE MM DD YY SEX M F

4. INSURED'S NAME (Last Name, First Name, Middle Initial)

5. PATIENT'S ADDRESS (No., Street)

6. PATIENT RELATIONSHIP TO INSURED Self Spouse Child Other

7. INSURED'S ADDRESS (No., Street)

CITY STATE

8. RESERVED FOR NUCC USE

CITY STATE

ZIP CODE TELEPHONE (Include Area Code) ( )

ZIP CODE TELEPHONE (Include Area Code) ( )

9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)

10. IS PATIENT'S CONDITION RELATED TO:

11. INSURED'S POLICY GROUP OR FECA NUMBER

a. OTHER INSURED'S POLICY OR GROUP NUMBER

a. EMPLOYMENT? (Current or Previous) YES NO

a. INSURED'S DATE OF BIRTH MM DD YY SEX M F

b. RESERVED FOR NUCC USE

b. AUTO ACCIDENT? YES NO PLACE (State)

b. OTHER CLAIM ID (Designated by NUCC)

c. RESERVED FOR NUCC USE

c. OTHER ACCIDENT? YES NO

c. INSURANCE PLAN NAME OR PROGRAM NAME

d. INSURANCE PLAN NAME OR PROGRAM NAME

10d. CLAIM CODES (Designated by NUCC)

d. IS THERE ANOTHER HEALTH BENEFIT PLAN? YES NO *If yes*, complete items 9, 9a, and 9d.

READ BACK OF FORM BEFORE COMPLETING & SIGNING THIS FORM.

12. PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE I authorize the release of any medical or other information necessary to process this claim. I also request payment of government benefits either to myself or to the party who accepts assignment below.

SIGNED DATE

13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE I authorize payment of medical benefits to the undersigned physician or supplier for services described below.

SIGNED

14. DATE OF CURRENT ILLNESS, INJURY, or PREGNANCY (LMP) MM DD YY QUAL.

15. OTHER DATE QUAL. MM DD YY

16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION MM DD YY FROM TO

17. NAME OF REFERRING PROVIDER OR OTHER SOURCE

17a.

17b. NPI

18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES MM DD YY FROM TO

19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)

20. OUTSIDE LAB? YES NO $ CHARGES

21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E) ICD Ind.

A. B. C. D. E. F. G. H. I. J. K. L.

22. RESUBMISSION CODE ORIGINAL REF. NO.

23. PRIOR AUTHORIZATION NUMBER

24. A. DATE(S) OF SERVICE From MM DD YY	To MM DD YY	B. PLACE OF SERVICE	C. EMG	D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS	MODIFIER	E. DIAGNOSIS POINTER	F. $ CHARGES	G. DAYS OR UNITS	H. EPSDT Family Plan	I. ID. QUAL.	J. RENDERING PROVIDER ID. #
1										NPI	
2										NPI	
3										NPI	
4										NPI	
5										NPI	
6										NPI	

25. FEDERAL TAX I.D. NUMBER SSN EIN

26. PATIENT'S ACCOUNT NO.

27. ACCEPT ASSIGNMENT? (For govt. claims, see back) YES NO

28. TOTAL CHARGE $

29. AMOUNT PAID $

30. Rsvd for NUCC Use

31. SIGNATURE OF PHYSICIAN OR SUPPLIER INCLUDING DEGREES OR CREDENTIALS (I certify that the statements on the reverse apply to this bill and are made a part thereof.)

SIGNED DATE

32. SERVICE FACILITY LOCATION INFORMATION

a. NPI b.

33. BILLING PROVIDER INFO & PH # ( )

a. NPI b.

NUCC Instruction Manual available at: www.nucc.org

PLEASE PRINT OR TYPE

APPROVED OMB-0938-1197 FORM 1500 (02-12)

CARRIER

PATIENT AND INSURED INFORMATION

PHYSICIAN OR SUPPLIER INFORMATION

BOX 21

Enter any relevant ICD-10-CM diagnosis code(s).

BOX 23

Enter the prior authorization number, if available.

BOX 24A

Provide a detailed drug description. List the N4 indicator followed by the 11-digit NDC, unit of measurement qualifier, and unit quantity.

BOX 24D

Enter the appropriate HCPCS code J0638 for ILARIS use as required by the payer. The HCPCS code must be accompanied by the appropriate modifier. Include the appropriate CPT code to report the administration procedure, 96372.

BOX 24E

Enter the diagnosis code reference letter as shown in Box 21 to relate the date of service and procedures performed to the primary diagnosis.

If there is more than one diagnosis required for a procedure code, only reference one letter from Box 21.

BOX 24G

Include the appropriate number of billing units for ILARIS.

The coding, coverage, and payment information contained herein is gathered from various resources, general in nature, and subject to change without notice. Third-party payment for medical products and services is affected by numerous factors. It is always the provider's responsibility to determine the appropriate health care setting and to submit true and correct claims for those products and services rendered. Providers should contact third-party payers for specific information on their coding, coverage, and payment policies. Information and materials are provided to assist health care providers, but the responsibility to determine coverage, reimbursement, and appropriate coding for a particular patient and/or procedure remains, at all times, with the provider. This form should be completed by the physician or appropriate office staff member only.

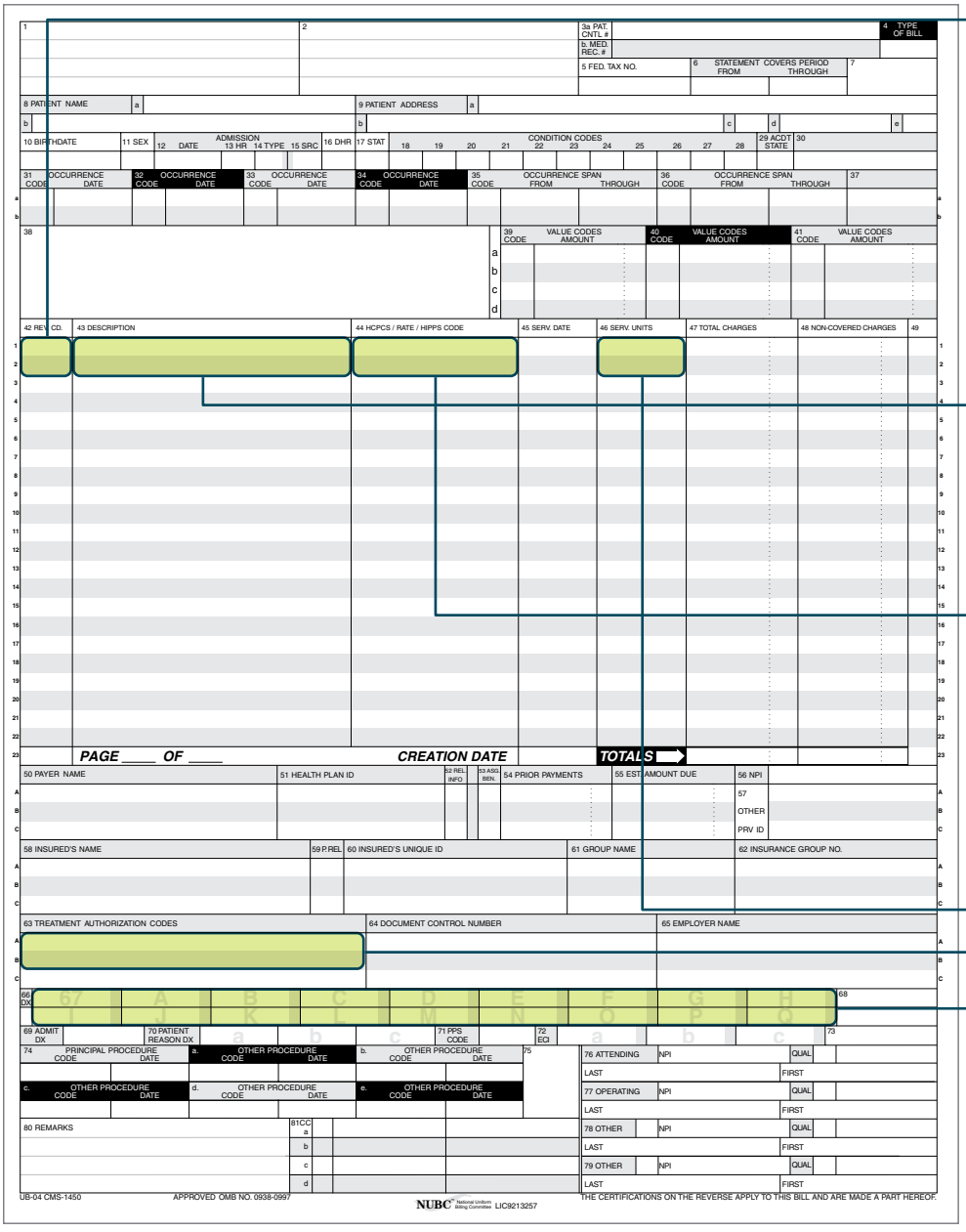
Please see Important Safety Information on pages 1, 40, and 41 and full Prescribing Information, including Medication Guide.

ILARIS® (canakinumab) 150 mg subcutaneous injection

SAMPLE CLAIMS FORMS (cont)

CMS-1450 (UB-04) sample claim form for ILARIS

Hospitals use this form when billing insurers for medication administered in the inpatient or outpatient setting. Outpatient hospitals should bill with the appropriate revenue code.



BOX 42

Enter the appropriate revenue code corresponding with the HCPCS code in Box 44. Then enter the appropriate revenue code corresponding with the CPT code in Box 44.

BOX 43

Provide a detailed drug description. List the N4 indicator followed by the 11-digit NDC, unit of measurement qualifier, and unit quantity.

BOX 44

Enter the appropriate HCPCS code J0638 for ILARIS use as required by the payer. The HCPCS code must be accompanied by the appropriate modifier. Include the appropriate CPT code to report the administration procedure, 96372.

BOX 46

Include the appropriate number of billing units for ILARIS.

BOX 63

Enter any treatment authorization codes.

BOX 66

Enter any relevant ICD-10-CM diagnosis code(s).

The coding, coverage, and payment information contained herein is gathered from various resources, general in nature, and subject to change without notice. Third-party payment for medical products and services is affected by numerous factors. It is always the provider's responsibility to determine the appropriate health care setting and to submit true and correct claims for those products and services rendered. Providers should contact third-party payers for specific information on their coding, coverage, and payment policies. Information and materials are provided to assist health care providers, but the responsibility to determine coverage, reimbursement, and appropriate coding for a particular patient and/or procedure remains, at all times, with the provider. This form should be completed by the physician or appropriate office staff member only.

Please see Important Safety Information on pages 1, 40, and 41 and full Prescribing Information, including Medication Guide.

GLOSSARY OF TERMS

APPEAL

A request to a patient's health care plan to reconsider its decision to deny coverage.

CO-PAYMENT

A cost-sharing arrangement in which a covered person pays a specified charge when they receive a covered service—like doctor visits, prescription medications, and other health care services.

EXCEPTION

A coverage request made to a patient's health care plan to remove a plan restriction placed on a treatment.

FORMULARY

A list of prescription medications that are covered by a health care plan.

ILARIS COMPANION

A personal support program that provides resources to the patient and practice to help patients get started on ILARIS.

LETTER OF MEDICAL NECESSITY

This letter is written by a physician to present his or her clinical judgment supporting the diagnosis and the need for a specific therapy.

NATIONAL DRUG CODE (NDC)

Universal product identifier with a unique set of numbers used for human drugs in the United States.

PRIOR AUTHORIZATION (PA)

Also called preauthorization, an administrative tool used by health care plans to determine if they will cover a prescribed procedure, service, or medication based on the patient's medical necessity.

IMPORTANT SAFETY INFORMATION (cont)

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

Hypersensitivity reactions have been reported with ILARIS therapy. 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. If a severe hypersensitivity reaction occurs, administration of ILARIS should be discontinued and appropriate therapy initiated.

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.

Please see additional Important Safety Information on pages 1 and 41 and full Prescribing Information, including Medication Guide.

IMPORTANT SAFETY INFORMATION (cont)

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 full Prescribing Information, including Medication Guide.

If you have questions about ILARIS Companion services, contact a program representative, **Monday to Friday, 9 AM to 6 PM ET.**

1-866-972-8315

NOVARTIS

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9/23 288031

ILARIS® (canakinumab) 150 mg subcutaneous injection