ILARIS COMPANION

ILARIS companion
Dedicated and dependable support

Dedicated and dependable support for patients throughout their ILARIS® (canakinumab) treatment journey

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

If you have questions about services, contact a program representative at

1-866-972-8315

Monday to Friday,
9 AM to 6 PM ET

INDICATIONS

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

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

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

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

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

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

Please see additional Important Safety Information throughout and full Prescribing Information, including Medication Guide.

ILARIS® (canakinumab)
150 mg subcutaneous injection

OVERVIEW OF ILARIS COMPANION

ILARIS START FORM
Physician submits form to initiate treatment and patient support services.

BENEFITS INVESTIGATION*
Verifies health care plan benefits and provides reimbursement policies for ILARIS.

COVERAGE REVIEW AND SUPPORT
Identifies financial support programs for uninsured and underinsured patients.

PRIOR AUTHORIZATION (PA) SUPPORT†
Assists in identifying plan-specific PA criteria, if required.

HIGH 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]

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 PA 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.

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.

ILARIS® (canakinumab) 150 mg subcutaneous injection

APPEALS SUPPORT†
Provides support with insurance appeals.

CO-PAY SAVINGS OFFER‡
Designed to make ILARIS more affordable for commercially insured patients.

- Eligible patients pay no more than $30 per month, subject to annual cap
- Patients who are insured through federal or state programs are not eligible

FIRST DOSE PROGRAM‡
- If a payer approval decision is delayed, physicians will be contacted to discuss program enrollment for the patient
- Ships the initial dose of ILARIS to eligible patients free of charge if a payer approval is not received within 2 weeks

SPECIALTY PHARMACY OUTREACH
Works with a patient's specialty pharmacy on patient follow-up.

PRODUCT DELIVERY SUPPORT
Works with a health care plan's preferred specialty pharmacy to support coordination and delivery of ILARIS to the patient's home or physician's office.

HOME HEALTH NURSE SERVICE
Patients can have their injections administered in their homes or at a location other than the physician's office.

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

Please see additional Important Safety Information throughout and full Prescribing Information, including Medication Guide.

COVERAGE AND AVAILABILITY

COMMERCIAL PLANS

Policies vary by plan. Always verify benefit coverage early.

- ILARIS can be covered on either the pharmacy benefit or medical benefit with flexible acquisition methods determined by your patient's health care coverage
- For patients covered under the pharmacy benefit, ILARIS will be acquired through a specialty pharmacy
- 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 a specialty pharmacy (through assignment of benefits)

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.

IMPORTANT SAFETY INFORMATION (cont)
WARNINGS AND PRECAUTIONS (cont)

Serious Infections (cont)

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.

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ILARIS is available through a select system of specialty pharmacies, specialty distributors, and group purchasing organizations (GPOs)*

ENTITY	FEATURES
Specialty Pharmacies Limited to those with URAC and/or ACHC accreditation	Provides access to ILARIS without a physician having to directly buy and bill.
Specialty Distributors **ASD Healthcare:** 1-800-746-6273 **Besse Medical**: 1-800-543-2111 **McKesson Specialty Care Distribution:** 1-855-477-9800 **McKesson Plasma and Biologics**: 1-877-625-2566 **CuraScript SD:** 1-877-599-7748 **Cardinal Health SD:** 1-855-855-0708 **Metro Medical:** 1-800-768-2002 **Oncology Supply:** 1-800-633-7555	Provides priority health care distribution of ILARIS for office or clinic administration. Integrated delivery services include: • Customer service and support • Payment terms • Ordering and shipping options
GPOs for Independent Outpatient and Infusion Sites **Cornerstone Rheumatology GPO/Mosaic GPO Solutions:** 1-800-768-2002 • For Cardinal Health SD/Metro Medical customers **Matrix GPO:** 1-888-263-9982 • For CuraScript SD customers **IPN:** 1-610-727-7000 • For ASD Healthcare and Besse Medical customers **Onmark GPO:** 1-800-482-6700 • For McKesson Specialty Care and Plasma and Biologics customers	Provides additional discounts and services for office or clinic administration of ILARIS. Other services can include: • Operational • Administrative • Financial • Analytics

*Novartis does not recommend the use of any particular distributor.
ACHC, Accreditation Commission for Health Care; URAC, Utilization Review Accreditation Commission.

Please see additional Important Safety Information throughout and full Prescribing Information, including Medication Guide.

PRE-APPROVAL PA PROCESS FOR GOUT FLARES

ILARIS is indicated for the symptomatic treatment of adult patients with gout flares in whom non-steroidal 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.[2]

Gout flares can cycle repeatedly and may last days or weeks.[3] Receiving authorization for a pre-approval PA prior to a flare—based on the physician's clinical judgment—helps ensure that ILARIS may be available when a flare occurs.

Pre-approval PA process overview

Pre-approval PAs are submitted, and approval is acquired, before a patient's next cyclical flare. This allows a provider to procure ILARIS to treat a flare.

Pre-approval 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 by health care plan.

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.

If you have any additional questions, please speak with your ILARIS Access & Reimbursement Manager (ARM).

IMPORTANT SAFETY INFORMATION (cont)

WARNINGS AND PRECAUTIONS (cont)

Serious Infections (cont)

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.

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Pre-approval PA process details

OFFICE STAFF SUBMITS PRE-APPROVAL PA

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

An ILARIS Companion Case Manager can help determine specific regional plan policies on pre-approval PAs prior to submission and proactively communicates with office staff to communicate process information and to help avoid unnecessary delays or denials.

PLAN REVIEWS REQUEST

The office staff submits a pre-approval PA request to the health care plan with an ILARIS Companion Case Manager.

An ILARIS Companion Case Manager may provide procedural information regarding the specific requirements of the health care plan.

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

REQUEST AUTHORIZED

At this step, the request is authorized by the plan, and the provider may now procure ILARIS in the event of a patient flare.

A pre-approval PA is valid for a predefined period of time as determined by the plan.

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

PROVIDER USES OR MUST RENEW PRE-APPROVAL PA

Once authorized, the provider 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. The decision to seek pre-approval must be based on the physician's clinical judgment.

Pre-approval PAs are assessed based on evidence of need for future use.

For pre-approval PA support, please contact an ILARIS Companion representative at 1-866-972-8315.

Please see additional Important Safety Information throughout and full Prescribing Information, including Medication Guide.

REIMBURSEMENT

These diagnosis and service and administration codes apply to claims for ILARIS in the health care provider office setting. This coding information is provided for educational purposes and does not guarantee reimbursement.

Diagnosis codes

ICD-10-CM codes[4]	
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: Insert appropriate code* and site, if applicable

For M08.2, M08.9, and M10.0-M10.4, be sure to insert a single digit in the hundredths place to specify anatomical site followed by another single digit in the thousandths place to specify laterality of the site affected.

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

Service and administration codes

NDC[2]	
0078-0734-61	Carton of 1 vial of ILARIS injection. Each single-dose vial contains a concentration of 150 mg/mL
HCPCS code[5]	
J0638	Injection, canakinumab, 1 mg
CPT code[6]	
96372	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular
JW and JZ modifiers[7]	
JW	Drug amount discarded/not administered to any patient
JZ	Zero drug amount discarded/full amount administered to any patient

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.

IMPORTANT SAFETY INFORMATION (cont)

WARNINGS AND PRECAUTIONS (cont)

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.

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Insurers may require additional support for a claim

Clinical documentation supporting the appropriateness of ILARIS

Letter of medical necessity from the physician to the insurer

Consider including the following information:

- ☑ Patient's diagnosis, condition, and symptoms, including any systemic issues
- ☑ Patient's case history and clinical course, including level of response and satisfaction with previous treatments
- ☑ Relevant laboratory values or tests
- ☑ Logistical considerations that may impact the patient's ability to take medication as prescribed

For more information, refer to the ILARIS Acquisition and Reimbursement Guide, which can be downloaded at www.ilarishcp.com.

You can also contact an ILARIS Companion representative at 1-866-972-8315.

Billing for wastage

Because ILARIS is dosed by weight for all indications except gout flares, the contents of a vial may not be completely utilized, and so 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 payers may differ; therefore, verification is recommended from the specific health care plan
  - Some payers request that the physician identify a discarded product using the JW modifier in the HCPCS code on a separate line[7]

AOSD, adult-onset Still's disease; CAPS, cryopyrin-associated periodic syndromes; CPT, Current Procedural Terminology; FCAS, familial cold autoinflammatory syndrome; FMF, familial Mediterranean fever; HCPCS, Healthcare Common Procedure Coding System; HIDS, hyperimmunoglobulin D syndrome; ICD-10, International Classification of Diseases, Tenth Revision; MKD, mevalonate kinase deficiency; MWS, Muckle-Wells syndrome; NDC, National Drug Code; NOS, not otherwise specified; SJIA, systemic juvenile idiopathic arthritis; TRAPS, tumor necrosis factor receptor–associated periodic syndrome.

Please see additional Important Safety Information throughout and full Prescribing Information, including Medication Guide.

IMPORTANT SAFETY INFORMATION (cont)

WARNINGS AND PRECAUTIONS (cont)

Hypersensitivity Reactions

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

Immunizations

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

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

Macrophage Activation Syndrome

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

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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.

References: 1. Data on file. ILARIS Companion CRM Statistics Updates 2023. Novartis Pharmaceuticals Corporation; 2023. **2.** Ilaris. Prescribing information. Novartis Pharmaceuticals Corp. **3.** Centers for Disease Control and Prevention. Gout. Accessed June 26, 2023. https://www.cdc.gov/arthritis/basics/gout.html **4.** AAPC. *2022 ICD-10-CM Expert: Diagnosis Codes for Providers & Facilities.* 2021. Accessed June 26, 2023. https://aapc.vitalsource.com/#/ **5.** AAPC. *2022 HCPCS Level II Expert: Service/Supply Codes for Caregivers & Suppliers.* 2021. Accessed June 21, 2023. https://aapc.vitalsource.com/#/ **6.** American Medical Association. *CPT 2023 Professional Edition.* 2022. **7.** Centers for Medicare & Medicaid Services. Medicare program: discarded drugs and biologicals – JW modifier and JZ modifier policy frequently asked questions. Accessed June 13, 2023. https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps/downloads/jw-modifier-faqs.pdf

Please see additional Important Safety Information throughout and full Prescribing Information, including Medication Guide.

TREATMENT BEGINS WITH THE ILARIS START FORM

ILARIS companion
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A missing patient signature will delay the start of program services. If patients are unavailable to sign the Start Form, they can provide consent at www.hipaaconsent.com.

SUBMIT A START FORM IN 2 EASY STEPS

1. Download and fill out the Start Form, available at www.ilarishcp.com/access or from your **Account Manager** or **Access & Reimbursement Manager**
2. Print and fax the completed Start Form, signed by you AND your patient, to **1-866-972-8316**

Purpose of the Start Form

- Enrolls the patient in ILARIS Companion
- Serves as the prescription for treatment with ILARIS and provides the option for enrollment into select services
- Identifies patient eligibility for patient assistance programs to reduce out-of-pocket costs

Required Information for the Start Form

- 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)

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

Please see Important Safety Information throughout and full Prescribing Information, including Medication Guide.

NOVARTIS

ILARIS® (canakinumab) 150 mg subcutaneous injection

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