ILARIS companion

Dedicated and dependable support

ILARIS COMPANION

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

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

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

[866-972-8315]

Monday to Friday, 9:00 AM to 6:00 PM ET

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® (canakinumab) 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.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATION

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

Please see additional Important Safety Information throughout and click here for the full Prescribing Information, including Medication Guide, for ILARIS.

ILARIS® (canakinumab) 150 mg subcutaneous injection

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OVERVIEW OF ILARIS COMPANION

PRIOR AUTHORIZATION SUPPORT

Assists in identifying payer-specific prior authorization criteria, if required.

BENEFITS INVESTIGATION*

Verifies health plan benefits and provides reimbursement policies for ILARIS®.

CLINICAL APPEALS

Provides support with insurance appeals.

PRODUCT DELIVERY SUPPORT

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

CODING INFORMATION

Provides codes for indications and administration of ILARIS that may be useful when completing claims.

HOME HEALTH NURSE SERVICE

Patients can have their injections administered in their homes or at another location outside of the physician's office.

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

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 with insurance through federal or state programs are not eligible

COVERAGE REVIEW AND SUPPORT

Identifies financial support programs for uninsured and underinsured patients.

SPECIALTY PHARMACY OUTREACH

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

FIRST DOSE PROGRAM†

Ships the initial dose of ILARIS to eligible patients free of charge, if a payer approval is not received within 2 weeks.

- If a payer approval decision is delayed, prescribers will be contacted to discuss program enrollment for the patient

HIGH PA APPROVAL RATE

≈80% of prior authorization (PA) requests are approved[1]

TREATMENT IN 30 DAYS OR LESS

≈70% of patients receive a commercial dispense of ILARIS within 1 month[2]

*Allows patients to learn about the coverage and cost of ILARIS.
†Limitations apply. See Program Terms and Conditions on the Service Request Form (SRF) available at www.ilaris-support.com. **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

WARNINGS AND PRECAUTIONS

Serious Infections

ILARIS has been associated with an increased risk of serious infections. Physicians should exercise caution when administering ILARIS to patients with infections, a history of recurring infections or underlying conditions, which may predispose them to infections.

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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 codes[3]	
M04.2	CAPS (includes FCAS and MWS)
M04.1	FMF, HIDS/MKD, and TRAPS
M06.1	AOSD
M08.2-	SJIA (Still's disease NOS)*

*Add a number after M08.2 to specify anatomical site followed by another number 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 Still's disease with the right knee affected.[3]

Service and administration codes

NDC numbers[4]	
0078-0734-61	Carton of 1 vial of ILARIS solution. Each single-use vial contains a concentration of 150 mg/mL
0078-0582-61	Carton of 1 vial of ILARIS lyophilized powder. Each single-use vial contains 150 mg of sterile powder, resulting in 150 mg/mL after reconstitution
HCPCS code[5]	
J0638	Injection, canakinumab, 1 mg
CPT code[6]	
96372	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular

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

WARNINGS AND PRECAUTIONS

Serious Infections (cont)

ILARIS should not be administered to patients during an active infection requiring medical intervention. Administration of ILARIS should be discontinued if a patient develops a serious infection.

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Insurers may require additional support for a claim

Clinical documentation on 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

Billing for wastage

Because ILARIS is dosed by patient weight, the contents of a vial may not be completely utilized, and so payers may reimburse for the remainder of the vial's contents if it's 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 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.

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COVERAGE AND AVAILABILITY

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COMMERCIAL PAYERS

Policies vary by payer and will note the covered uses for ILARIS® and other relevant information.

- Some plans may cover ILARIS under the medical benefit
- Most commercial payers will allow or require assignment of benefits through a specialty pharmacy that will purchase ILARIS and then bill the payer; providers will then only bill payers for administering the injection

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.

ILARIS is available through a select system of specialty pharmacies and a specialty distributor

Entity	Features
Specialty Pharmacies [Accredo] [CVS Specialty] [Walgreens]	Provide access to ILARIS without a physician having to directly purchase or bill for a product.
Specialty Distributor [CuraScript SD]	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

MAXIMIZING PATIENT ACCESS

≈90% of commercial patients are covered on ILARIS[8*]

*For SJIA only. Based on combined lives across Pharmacy and Medical plans. Only includes plans where data are available through Managed Markets Insights & Technology (MMIT).

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

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.

IMPORTANT SAFETY INFORMATION

Serious Infections (cont)

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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IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Serious Infections (cont)

Prior to initiating immunomodulatory therapies, including ILARIS®, patients should be evaluated 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. Patients testing positive in TB screening should be treated by standard medical practice prior to therapy with ILARIS. All patients should be instructed 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.

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

Live vaccines should not be given concurrently with ILARIS. Prior to initiation of therapy with ILARIS, patients should receive all recommended vaccinations. 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.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Macrophage Activation Syndrome

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

ADVERSE REACTIONS

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

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

References: 1. Data on file. ILARIS CRM Executive Summary Report 12/1/2018-12/31/2019. Novartis Pharmaceuticals Corporation; 2019. **2.** Data on file. ILARIS Dispense Analysis (Time to Dispense) 1/2019-12/2019. Novartis Pharmaceuticals Corporation; 2020. **3.** 2020 ICD-10-CM. Centers for Medicare & Medicaid Services website. Updated March 31, 2020. Accessed April 8, 2020. https://www.cms.gov/Medicare/Coding/ICD10/2020-ICD-10-CM **4.** ILARIS [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; 2020. **5.** 2020 Table of Drugs. Centers for Medicare & Medicaid Services website. Updated February 3, 2020. Accessed April 8, 2020. https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/Downloads/2020-Table-of-Drugs.pdf **6.** American Medical Association. *CPT® 2020 Professional Edition*. American Medical Association; 2020. **7.** Methodology for Medicare Part B Discarded Drug Units Report. Centers for Medicare & Medicaid Services website. Updated December 19, 2019. Accessed April 8, 2020. https://www.cms.gov/files/document/medicare-part-b-discarded-drug-units-report-methodology.pdf **8.** Data on file. ILARIS Commercial Access Coverage 6/20. Novartis Pharmaceuticals Corporation; 2020.

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TREATMENT BEGINS WITH THE SERVICE REQUEST FORM (SRF)

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

SUBMIT AN SRF IN 2 EASY STEPS

1. Download and fill out the SRF, available at **www.ilaris-support.com** or from **your Account Manager**
2. Print and fax the completed SRF, signed by you AND your patient, to **[866-972-8316]**

Role of the SRF

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

Required Information for the SRF

- Physician AND patient signatures
- ICD-10 code
- Number of ILARIS vials
- Number of refills
- Patient's insurance information
- Dosage and administration instructions
- Place of administration (at home by a nurse or at a physician's office)

IMPORTANT SAFETY INFORMATION

ADVERSE REACTIONS

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.

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NOVARTIS

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