

Ilaris® (canakinumab) (Subcutaneous)

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I. Length of Authorization

Coverage will be provided for 12 months and may be renewed, unless otherwise specified.

- Gout Flare: Coverage will be provided for 1 dose (12 weeks). Additional doses for retreatment of a new flare will be covered, provided that the criteria for re-treatment is met. *(Refer to Section III for specific re-treatment criteria)*

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- Ilaris 150 mg single-dose vial: 2 vials every 28 days

B. Max Units (per dose and over time) [HCPCS Unit]:

Cryopyrin-Associated Periodic Syndromes:

- 150 billable units every 8 weeks (56 days)

Gout Flare:

- 150 billable units every 12 weeks (84 days)

All Other Indications:

- 300 billable units every 4 weeks (28 days)

III. Initial Approval Criteria ¹

Coverage is provided in the following conditions:

- Patient is up to date with all vaccinations, in accordance with current vaccination guidelines, prior to initiating therapy; **AND**

Universal Criteria ¹

- Patient has been evaluated and screened for the presence of latent tuberculosis (TB) infection prior to initiating treatment and will receive ongoing monitoring for the presence of TB during treatment; **AND**

- Patient does not have an active infection, including clinically important localized infections; **AND**
- Will not be administered concurrently with live vaccines; **AND**
- Patient is not on concurrent therapy with other IL-1 blocking agents (e.g., anakinra, rilonacept, etc.): **AND**
- Patient is not on concurrent treatment with another TNF inhibitor, biologic response modifier or other non-biologic immunomodulating agent (e.g., abrocitinib, apremilast, tofacitinib, baricitinib, upadacitinib, deucravacitinib, etc.); **AND**

Cryopyrin-Associated Periodic Syndromes (CAPS) † Φ^{1,2,6,8,9}

- Patient is at least 4 years of age; **AND**
- Used as a single agent; **AND**
- Patient has documented baseline serum levels of inflammatory proteins (C-Reactive Protein [CRP] and/or Serum Amyloid A [SAA]); **AND**
- Patient has documented laboratory evidence of a genetic mutation in the Cold-Induced Auto-inflammatory Syndrome 1 (CIAS1), also known as NLRP3; **AND**
 - Diagnosis of Familial Cold Autoinflammatory Syndrome (FCAS); **OR**
 - Diagnosis of Muckle-Wells Syndrome (MWS); **AND**
- Patient has two or more of any of the CAPS-typical symptoms:
 - urticaria-like rash
 - cold-triggered episodes
 - sensorineural hearing loss
 - musculoskeletal symptoms
 - chronic aseptic meningitis
 - skeletal abnormalities

Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS) † Φ^{1,10}

- Patient is at least 2 years of age; **AND**
- Used as a single agent; **AND**
- Patient has the presence of a pathogenic mutation in the tumor necrosis factor receptor-1 (TNFR1) gene (*TNFRSF1A*); **AND**
- Patient has chronic or recurrent disease (defined as > 6 flares per year); **AND**
- Patient has documented baseline serum levels of C-Reactive Protein (CRP)

Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD) † Φ^{1,10, 12}

- Patient is at least 2 years of age; **AND**

- Used as a single agent; **AND**
- Patient has a confirmed diagnosis of HIDS/MKD by one of the following:
 - Patient has a pathogenic mutation in the MVK gene; **OR**
 - Patient has significantly elevated serum IgD levels; **AND**
- Patient has a documented history of at least three (3) febrile episodes within a 6 month period; **AND**
- Patient has documented baseline serum levels of C-Reactive Protein (CRP)

Familial Mediterranean Fever (FMF) † Φ^{1,10}

- Patient is at least 2 years of age; **AND**
- Used as a single agent; **AND**
- Patient has a confirmed diagnosis based on at least one known MEFV exon 10 mutation; **AND**
- Patient has failed on colchicine therapy or has a documented allergy or intolerance; **AND**
- Patient has active disease defined as at least one febrile episode per month; **AND**
- Patient has documented baseline serum levels of C-Reactive Protein (CRP)

Still's Disease (Adult-Onset Still's Disease [AOSD] and Systemic Juvenile Idiopathic Arthritis [SJIA]) †^{1,3,5,11}

- Patient has active disease; **AND**
- Physician has assessed baseline disease severity utilizing an objective measure/tool; **AND**
- Patient has had at least a 1-month trial and failure (unless contraindicated or intolerant) of previous therapy with either oral non-steroidal anti-inflammatory drugs (NSAIDs) OR a systemic glucocorticoid (prednisone, methylprednisolone, etc.); **AND**
 - Patient is at least 18 years of age and has active Adult-Onset Still's Disease; **OR**
 - Patient is at least 2 years of age and has active Systemic Juvenile Idiopathic Arthritis

Gout Flare †^{1,13}

- Patient is at least 18 years of age; **AND**
 - Patient has NOT received previous treatment with canakinumab for gout flare(s); **AND**
 - Patient has had ≥ 3 gout flares within the previous 12 months; **AND**
 - Patient has failed on non-steroidal anti-inflammatory drugs (NSAIDs) therapy, unless contraindicated or intolerant; **AND**
 - Patient has failed on colchicine therapy, unless contraindicated or intolerant; **AND**
 - Patient is not a candidate for repeated courses of corticosteroids; **OR**

- Patient has received previous treatment with canakinumab for gout flare(s) resulting in a decrease or resolution of joint pain in the affected joints; **AND**
 - Patient requires re-treatment for a new gout flare; **AND**
 - Patient has not received treatment with canakinumab in the previous 12 weeks

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Ⓢ Orphan Drug

IV. Renewal Criteria ^{1,3,8-11}

Coverage can be renewed based upon the following criteria:

- Patient continues to meet universal and other indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in Section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: severe hypersensitivity reactions, serious infections (including but not limited to tuberculosis), and macrophage activation syndrome (MAS); **AND**

Cryopyrin-Associated Periodic Syndromes

- Disease response as indicated by improvement in patient's symptoms from baseline AND improvement in serum levels of inflammatory proteins (e.g. CRP and/or SAA, etc.) from baseline

Adult-Onset Still's Disease/Systemic Juvenile Idiopathic Arthritis

- Disease response as indicated by improvement in signs and symptoms compared to baseline such as the number of tender and swollen joint counts and/or an improvement on a disease activity scoring tool [e.g. an improvement on a composite scoring index such as Juvenile Arthritis Disease Activity Score (JADAS) or the American College of Rheumatology (ACR) Pediatric (ACR-Pedi 30) of at least 30% improvement from baseline in three of six variables]

Tumor Necrosis Factor Receptor Associated Periodic Syndrome; Hyperimmunoglobulin D Syndrome/Mevalonate Kinase Deficiency; Familial Mediterranean Fever

- Disease response as indicated by improvement in patient's symptoms from baseline AND improvement of serum levels of CRP

Gout Flare † ^{1,13}

- *Refer to Section III for re-treatment criteria*

V. Dosage/Administration ¹

Indication	Dose
CAPS	<p><u>Weight: > 40 kg</u></p> <ul style="list-style-type: none"> Administer 150 mg subcutaneously every 8 weeks <p><u>Weight: 15 to 40 kg</u></p> <ul style="list-style-type: none"> Administer 2 mg/kg subcutaneously every 8 weeks. May increase dose to 3 mg/kg if inadequate response.
AOSD and SJIA	<p><u>Weight: ≥ 7.5 kg</u></p> <ul style="list-style-type: none"> Administer 4 mg/kg (with a maximum of 300mg) subcutaneously every 4 weeks.
TRAPS, HIDS/MKD, and FMF	<p><u>Weight: > 40 kg</u></p> <ul style="list-style-type: none"> Administer 150 mg subcutaneously every 4 weeks. May increase dose to 300mg if inadequate response. <p><u>Weight: ≤ 40 kg</u></p> <ul style="list-style-type: none"> Administer 2 mg/kg subcutaneously every 4 weeks. May increase dose to 4 mg/kg if inadequate response.
Gout Flare	<p>Administer 150 mg subcutaneously x 1 dose</p> <ul style="list-style-type: none"> Note: In patients who require re-treatment, there should be an interval of at least 12 weeks before receiving another dose. (<i>Refer to Section III for re-treatment criteria</i>)

Administration is by healthcare provider

VI. Billing Code/Availability Information

HCPCS Code:

- J0638 – Injection, canakinumab, 1 mg : 1 billable unit = 1 mg

NDC:

- Ilaris 150 mg single-dose solution vial: 00078-0734-xx

VII. References

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Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
M04.1	Periodic fever syndromes
M04.2	Cryopyrin-associated periodic syndromes
M04.9	Autoinflammatory syndrome, unspecified

ICD-10	ICD-10 Description
M06.1	Adult-onset Still's disease
M08.0A	Unspecified juvenile rheumatoid arthritis, other specified site
M08.011	Unspecified juvenile rheumatoid arthritis, right shoulder
M08.012	Unspecified juvenile rheumatoid arthritis, left shoulder
M08.019	Unspecified juvenile rheumatoid arthritis, unspecified shoulder
M08.021	Unspecified juvenile rheumatoid arthritis, right elbow
M08.022	Unspecified juvenile rheumatoid arthritis, left elbow
M08.029	Unspecified juvenile rheumatoid arthritis, unspecified elbow
M08.031	Unspecified juvenile rheumatoid arthritis, right wrist
M08.032	Unspecified juvenile rheumatoid arthritis, left wrist
M08.039	Unspecified juvenile rheumatoid arthritis, unspecified wrist
M08.041	Unspecified juvenile rheumatoid arthritis, right hand
M08.042	Unspecified juvenile rheumatoid arthritis, left hand
M08.049	Unspecified juvenile rheumatoid arthritis, unspecified hand
M08.051	Unspecified juvenile rheumatoid arthritis, right hip
M08.052	Unspecified juvenile rheumatoid arthritis, left hip
M08.059	Unspecified juvenile rheumatoid arthritis, unspecified hip
M08.061	Unspecified juvenile rheumatoid arthritis, right knee
M08.062	Unspecified juvenile rheumatoid arthritis, left knee
M08.069	Unspecified juvenile rheumatoid arthritis, unspecified knee
M08.071	Unspecified juvenile rheumatoid arthritis, right ankle and foot
M08.072	Unspecified juvenile rheumatoid arthritis, left ankle and foot
M08.079	Unspecified juvenile rheumatoid arthritis, unspecified ankle and foot
M08.08	Unspecified juvenile rheumatoid arthritis, vertebrae
M08.09	Unspecified juvenile rheumatoid arthritis, multiple sites
M08.2A	Juvenile rheumatoid arthritis with systemic onset, other specified site
M08.211	Juvenile rheumatoid arthritis with systemic onset, right shoulder
M08.212	Juvenile rheumatoid arthritis with systemic onset, left shoulder
M08.219	Juvenile rheumatoid arthritis with systemic onset, unspecified shoulder
M08.221	Juvenile rheumatoid arthritis with systemic onset, right elbow
M08.222	Juvenile rheumatoid arthritis with systemic onset, left elbow
M08.229	Juvenile rheumatoid arthritis with systemic onset, unspecified elbow
M08.231	Juvenile rheumatoid arthritis with systemic onset, right wrist
M08.232	Juvenile rheumatoid arthritis with systemic onset, left wrist
M08.239	Juvenile rheumatoid arthritis with systemic onset, unspecified wrist
M08.241	Juvenile rheumatoid arthritis with systemic onset, right hand

ICD-10	ICD-10 Description
M08.242	Juvenile rheumatoid arthritis with systemic onset, left hand
M08.249	Juvenile rheumatoid arthritis with systemic onset, unspecified hand
M08.251	Juvenile rheumatoid arthritis with systemic onset, right hip
M08.252	Juvenile rheumatoid arthritis with systemic onset, left hip
M08.259	Juvenile rheumatoid arthritis with systemic onset, unspecified hip
M08.261	Juvenile rheumatoid arthritis with systemic onset, right knee
M08.262	Juvenile rheumatoid arthritis with systemic onset, left knee
M08.269	Juvenile rheumatoid arthritis with systemic onset, unspecified knee
M08.271	Juvenile rheumatoid arthritis with systemic onset, right ankle and foot
M08.272	Juvenile rheumatoid arthritis with systemic onset, left ankle and foot
M08.279	Juvenile rheumatoid arthritis with systemic onset, unspecified ankle and foot
M08.28	Juvenile rheumatoid arthritis with systemic onset, vertebrae
M08.29	Juvenile rheumatoid arthritis with systemic onset, multiple sites
M08.3	Juvenile rheumatoid polyarthritis (seronegative)
M08.4A	Pauciarticular juvenile rheumatoid arthritis, other specified site
M08.411	Pauciarticular juvenile rheumatoid arthritis, right shoulder
M08.412	Pauciarticular juvenile rheumatoid arthritis, left shoulder
M08.419	Pauciarticular juvenile rheumatoid arthritis, unspecified shoulder
M08.421	Pauciarticular juvenile rheumatoid arthritis, right elbow
M08.422	Pauciarticular juvenile rheumatoid arthritis, left elbow
M08.429	Pauciarticular juvenile rheumatoid arthritis, unspecified elbow
M08.431	Pauciarticular juvenile rheumatoid arthritis, right wrist
M08.432	Pauciarticular juvenile rheumatoid arthritis, left wrist
M08.439	Pauciarticular juvenile rheumatoid arthritis, unspecified wrist
M08.441	Pauciarticular juvenile rheumatoid arthritis, right hand
M08.442	Pauciarticular juvenile rheumatoid arthritis, left hand
M08.449	Pauciarticular juvenile rheumatoid arthritis, unspecified hand
M08.451	Pauciarticular juvenile rheumatoid arthritis, right hip
M08.452	Pauciarticular juvenile rheumatoid arthritis, left hip
M08.459	Pauciarticular juvenile rheumatoid arthritis, unspecified hip
M08.461	Pauciarticular juvenile rheumatoid arthritis, right knee
M08.462	Pauciarticular juvenile rheumatoid arthritis, left knee
M08.469	Pauciarticular juvenile rheumatoid arthritis, unspecified knee
M08.471	Pauciarticular juvenile rheumatoid arthritis, right ankle and foot
M08.472	Pauciarticular juvenile rheumatoid arthritis, left ankle and foot
M08.479	Pauciarticular juvenile rheumatoid arthritis, unspecified ankle and foot

ICD-10	ICD-10 Description
M08.48	Pauciarticular juvenile rheumatoid arthritis, vertebrae
M08.80	Other juvenile arthritis, unspecified site
M08.811	Other juvenile arthritis, right shoulder
M08.812	Other juvenile arthritis, left shoulder
M08.819	Other juvenile arthritis, unspecified shoulder
M08.821	Other juvenile arthritis, right elbow
M08.822	Other juvenile arthritis, left elbow
M08.829	Other juvenile arthritis, unspecified elbow
M08.831	Other juvenile arthritis, right wrist
M08.832	Other juvenile arthritis, left wrist
M08.839	Other juvenile arthritis, unspecified wrist
M08.841	Other juvenile arthritis, right hand
M08.842	Other juvenile arthritis, left hand
M08.849	Other juvenile arthritis, unspecified hand
M08.851	Other juvenile arthritis, right hip
M08.852	Other juvenile arthritis, left hip
M08.859	Other juvenile arthritis, unspecified hip
M08.861	Other juvenile arthritis, right knee
M08.862	Other juvenile arthritis, left knee
M08.869	Other juvenile arthritis, unspecified knee
M08.871	Other juvenile arthritis, right ankle and foot
M08.872	Other juvenile arthritis, left ankle and foot
M08.879	Other juvenile arthritis, unspecified ankle and foot
M08.88	Other juvenile arthritis, other specified site
M08.89	Other juvenile arthritis, multiple sites
M08.9A	Juvenile arthritis, unspecified, other specified site
M08.911	Juvenile arthritis, unspecified, right shoulder
M08.912	Juvenile arthritis, unspecified, left shoulder
M08.919	Juvenile arthritis, unspecified, unspecified shoulder
M08.921	Juvenile arthritis, unspecified, right elbow
M08.922	Juvenile arthritis, unspecified, left elbow
M08.929	Juvenile arthritis, unspecified, unspecified elbow
M08.931	Juvenile arthritis, unspecified, right wrist
M08.932	Juvenile arthritis, unspecified, left wrist
M08.939	Juvenile arthritis, unspecified, unspecified wrist
M08.941	Juvenile arthritis, unspecified, right hand

ICD-10	ICD-10 Description
M08.942	Juvenile arthritis, unspecified, left hand
M08.949	Juvenile arthritis, unspecified, unspecified hand
M08.951	Juvenile arthritis, unspecified, right hip
M08.952	Juvenile arthritis, unspecified, left hip
M08.959	Juvenile arthritis, unspecified, unspecified hip
M08.961	Juvenile arthritis, unspecified, right knee
M08.962	Juvenile arthritis, unspecified, left knee
M08.969	Juvenile arthritis, unspecified, unspecified knee
M08.971	Juvenile arthritis, unspecified, right ankle and foot
M08.972	Juvenile arthritis, unspecified, left ankle and foot
M08.979	Juvenile arthritis, unspecified, unspecified ankle and foot
M08.98	Juvenile arthritis, unspecified, vertebrae
M08.99	Juvenile arthritis, unspecified, multiple sites
M10.00	Idiopathic gout, unspecified site
M10.011	Idiopathic gout, right shoulder
M10.012	Idiopathic gout, left shoulder
M10.019	Idiopathic gout, unspecified shoulder
M10.021	Idiopathic gout, right elbow
M10.022	Idiopathic gout, left elbow
M10.029	Idiopathic gout, unspecified elbow
M10.031	Idiopathic gout, right wrist
M10.032	Idiopathic gout, left wrist
M10.039	Idiopathic gout, unspecified wrist
M10.041	Idiopathic gout, right hand
M10.042	Idiopathic gout, left hand
M10.049	Idiopathic gout, unspecified hand
M10.051	Idiopathic gout, right hip
M10.052	Idiopathic gout, left hip
M10.059	Idiopathic gout, unspecified hip
M10.061	Idiopathic gout, right knee
M10.062	Idiopathic gout, left knee
M10.069	Idiopathic gout, unspecified knee
M10.071	Idiopathic gout, right ankle and foot
M10.072	Idiopathic gout, left ankle and foot
M10.079	Idiopathic gout, unspecified ankle and foot
M10.08	Idiopathic gout, vertebrae

ICD-10	ICD-10 Description
M10.09	Idiopathic gout, multiple sites
M10.311	Gout due to renal impairment, right shoulder
M10.312	Gout due to renal impairment, left shoulder
M10.319	Gout due to renal impairment, unspecified shoulder
M10.321	Gout due to renal impairment, right elbow
M10.322	Gout due to renal impairment, left elbow
M10.329	Gout due to renal impairment, unspecified elbow
M10.331	Gout due to renal impairment, right wrist
M10.332	Gout due to renal impairment, left wrist
M10.339	Gout due to renal impairment, unspecified wrist
M10.341	Gout due to renal impairment, right hand
M10.342	Gout due to renal impairment, left hand
M10.349	Gout due to renal impairment, unspecified hand
M10.351	Gout due to renal impairment, right hip
M10.352	Gout due to renal impairment, left hip
M10.359	Gout due to renal impairment, unspecified hip
M10.361	Gout due to renal impairment, right knee
M10.362	Gout due to renal impairment, left knee
M10.369	Gout due to renal impairment, unspecified knee
M10.371	Gout due to renal impairment, right ankle and foot
M10.372	Gout due to renal impairment, left ankle and foot
M10.379	Gout due to renal impairment, unspecified ankle and foot
M10.38	Gout due to renal impairment, vertebrae
M10.39	Gout due to renal impairment, multiple sites
M10.40	Other secondary gout, unspecified site
M10.411	Other secondary gout, right shoulder
M10.412	Other secondary gout, left shoulder
M10.419	Other secondary gout, unspecified shoulder
M10.421	Other secondary gout, right elbow
M10.422	Other secondary gout, left elbow
M10.429	Other secondary gout, unspecified elbow
M10.431	Other secondary gout, right wrist
M10.432	Other secondary gout, left wrist
M10.439	Other secondary gout, unspecified wrist
M10.441	Other secondary gout, right hand
M10.442	Other secondary gout, left hand

ICD-10	ICD-10 Description
M10.449	Other secondary gout, unspecified hand
M10.451	Other secondary gout, right hip
M10.452	Other secondary gout, left hip
M10.459	Other secondary gout, unspecified hip
M10.461	Other secondary gout, right knee
M10.462	Other secondary gout, left knee
M10.469	Other secondary gout, unspecified knee
M10.471	Other secondary gout, right ankle and foot
M10.472	Other secondary gout, left ankle and foot
M10.479	Other secondary gout, unspecified ankle and foot
M10.48	Other secondary gout, vertebrae
M10.49	Other secondary gout, multiple sites
M10.9	Gout, unspecified

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD), Local Coverage Determinations (LCDs), and Local Coverage Articles (LCAs) may exist and compliance with these policies is required where applicable. They can be found at: <http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx>. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC