# Medical Policy:

## Ilaris® (canakinumab) Subcutaneous

| POLICY NUMBER | LAST REVIEW | ORIGIN DATE |
|---|---|---|
| MG.MM.PH.149 | February 28, 2024 | |



The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as "EmblemHealth"), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

## Definitions

Canakinumab is a recombinant, human anti-human interleukin-1 beta (IL-1B) monoclonal antibody of the IgG1/kappa isotype. By binding to human IL-1B, canakinumab blocks the IL-1 receptor interaction and neutralizes overactive IL-1B activity.

## Length of Authorization

Coverage will be provided for 12 months and may be renewed

## Dosing Limits [Medical Benefit]

**Max Units (per dose and over time):**

- **Cryopyrin-Associated Periodic Syndromes (CAPS)** including: Familial Cold Autoinflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS)
  - 150 billable units every 8 weeks (56 days)
- **Active Still's disease** including**:** Adult-Onset and Systemic Juvenile Idiopathic Arthritis

- 300 billable units every 4 weeks (28 days)
- **Systemic Juvenile Idiopathic Arthritis**
  - 300 billable units every 4 weeks (28 days)
- **Tumor Necrosis Factor Receptor Associated Periodic Syndrome**
  - 300 billable units every 4 weeks (28 days)
- **Hyperimmunoglobulin D Syndrome/Mevalonate Kinase Deficiency**
  - 300 billable units every 4 weeks (28 days)
- **Familial Mediterranean Fever**
  - 300 billable units every 4 weeks (28 days)
- **Gout Flare:**
  - 150 billable units every 12 weeks (84 days)

## Guideline

### I. Initial Approval Criteria

***Ilaris*** *may be considered medically necessary if one of the below conditions are met* ***AND*** *use is consistent with the medical necessity criteria that follows:*

- Patient has been evaluated and screened for the presence of latent TB infection prior to initiating treatment; **AND**
- Patient does not have an active infection, including clinically important localized infections; **AND**
- Must 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 (i.e., apremilast, tofacitinib, baricitinib); **AND**

**1. Cryopyrin-Associated Periodic Syndromes (CAPS)**

A. Patient is 4 years of age or older; **AND**
B. Must be used as a single agent; **AND**
C. Patient has documented baseline serum levels of inflammatory proteins (C-Reactive Protein [CRP] and/or Serum Amyloid A [SAA]; **AND**
D. Patient has documented laboratory evidence of a genetic mutation in the Cold-Induced Auto-inflammatory Syndrome 1 (CIAS1), also known as NLRP3; **AND**
   i. Diagnosis of Familial Cold Autoinflammatory Syndrome (FCAS); **OR**
   ii. Diagnosis of Muckle-Wells Syndrome (MWS); **AND**
E. Patient has two or more of any of the CAPS-typical symptoms:
   i. Urticaria-like rash
   ii. Cold-triggered episodes
   iii. Sensorineural hearing loss
   iv. Musculoskeletal symptoms
   v. Chronic aseptic meningitis
   vi. Skeletal abnormalities

**2. Still's Disease (Adult-Onset Still's Disease [AOSD] and Systemic Juvenile Idiopathic Arthritis [SJIA]) †**

A. Patient has active disease; **AND**
B. Physician has assessed baseline disease severity utilizing an objective measure/tool; **AND**

C. 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**
   i. Patient is at least 18 years of age and has active Adult-Onset Still's Disease; **OR**
   ii. Patient is at least 2 years of age and has active Systemic Juvenile Idiopathic Arthritis

**3. <u>Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS)</u>**

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

**4. <u>Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD)</u>**

A. Patient 2 years of age or older; **AND**
B. Used as a single agent; **AND**
C. Patient has a confirmed diagnosis of HIDS/MKD by one of the following:
   i. Patient has a pathogenic mutation in the MVK gene; **OR**
   ii. Patient has significantly elevated serum IgD levels; **AND**
D. Patient has a documented prior history of greater than or equal to 3 febrile acute flares within a 6-month period; **AND**
E. Patient has documented baseline serum levels of C-Reactive Protein (CRP)

**5. <u>Familial Mediterranean Fever (FMF)</u>**

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

**6. <u>Gout Flares</u>**

A. Patient is at least 18 years of age; **AND**
B. Patient has had ≥ 3 gout flares within the previous 12 months; **AND**
C. Patient has failed on non-steroidal anti-inflammatory drugs (NSAIDs) therapy, unless contraindicated or intolerant; **AND**
D. Patient has failed on colchicine therapy, unless contraindicated or intolerant; **AND**
E. Patient is not a candidate for repeated courses of corticosteroids; **OR**
F. Patient requires re-treatment for a new gout flare; **AND**
G. Patient has not received treatment with canakinumab in the previous 12 weeks; **AND**
H. According to the prescriber, patient is receiving or will be taking concomitant urate lowering medication for the prevention of gout unless contraindicated
   *Note: Examples of uric acid lowering drugs include allopurinol, febuxostat, or probenecid.*

### Limitations/Exclusions

Ilaris is not considered medically necessary for indications not listed in INITIAL APPROVAL CRITERIA:

**II. Renewal Criteria**

Coverage can be renewed if patient continues to meet INITIAL APPROVAL CRITERIA; **AND**

1. Absence of unacceptable toxicity from the drug; **AND**
2. Patient is free of TB or active infections; **AND**
3. Disease response as indicated by improvement in patient's symptoms from baseline.

**Dosing/Administration**

| Indication | Dose |
|---|---|
| Cryopyrin-Associated Periodic Syndromes | Weight greater than 40 kg<br>150 mg sq every 8 weeks<br>Weight of 15 to 40 kg<br>2 mg/kg subcutaneously every 8 weeks. May be increased to 3 mg/kg if inadequate response. |
| Systemic Juvenile Idiopathic Arthritis & Still's disease | Weight is greater than or equal to 7.5 kg<br>4mg/kg (with a maximum of 300 mg) sq every 4 weeks. |
| Gout Flare | Administer 150 mg subcutaneously x 1 dose<br>Note: In patients who require re-treatment, there should be an interval of at least 12 weeks before receiving another dose. (Refer to Section I for re-treatment criteria) |
| All other indications | Weight greater than 40 kg<br>150 mg sq every 4 weeks. May increase dose to 300 mg if inadequate response.<br>Weight less than or equal to 40 kg<br>2 mg/kg subcutaneously every 4 weeks. May be increased to 4 mg/kg if inadequate response. |

## Applicable Procedure Codes

| Code | Description |
|---|---|
| J0638 | Injection, canakinumab, 1 mg, 1 billable unit = 1 mg |

## Applicable NDCs

| Code | Description |
|---|---|
| 00078-0734-xx | Ilaris 150 mg single dose solution vial |

## ICD-10 Diagnoses

| Code | Description |
|---|---|
| M04.1 | Periodic fever syndromes |
| M04.2 | Cryopyrin-associated periodic syndromes |
| M04.9 | Autoinflammatory syndrome, unspecified |
| M06.1 | Adult-onset Still's disease |
| M08.00 | Unspecified juvenile rheumatoid arthritis of unspecified site |

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|---|---|
| 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 |
| M08.20 | Juvenile rheumatoid arthritis with systemic onset, unspecified 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 |
| 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 |

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| M08.29 | Juvenile rheumatoid arthritis with systemic onset, multiple sites |
| M08.3 | Juvenile rheumatoid polyarthritis (seronegative) |
| M08.40 | Pauciarticular juvenile rheumatoid arthritis, unspecified 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 |
| 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 |

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| M08.879 | Other juvenile arthritis, unspecified ankle and foot |
| M08.88 | Other juvenile arthritis, other specified site |
| M08.89 | Other juvenile arthritis, multiple sites |
| M08.90 | Juvenile arthritis, unspecified, unspecified 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 |
| 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 |

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| 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 |
| 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 |
| 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 |

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|---|---|
| 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 |

## Revision History

| Company(ies) | DATE | REVISION |
|---|---|---|
| EmblemHealth & ConnectiCare | 2/28/2024 | Annual Review: Initial Criteria:<br>Cryopyrin-Associated Periodic Syndromes (CAPS)- clarified wording on age<br>Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS)- clarified wording on age<br>Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD)- clarified wording on age and added: "Used as a single agent; AND"<br>Familial Mediterranean Fever (FMF) clarified wording on age<br>Gout Flares- Removed: "Patient has NOT received previous treatment with canakinumab for gout flare(s); AND 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"<br>Added: "According to the prescriber, patient is receiving or will be taking concomitant urate lowering medication for the prevention of gout unless contraindicated<br>*Note: Examples of uric acid lowering drugs include allopurinol, febuxostat, or probenecid."* |
| EmblemHealth & ConnectiCare | 10/04/2023 | Update: Added Gout Flares indication and criteria, updated dosing chart and codes to include gout |
| EmblemHealth & ConnectiCare | 6/26/2023 | Annual Review:<br>Active Still's disease Initial Criteria: removed:<br>"a. Patient is 2 years of age or older; AND<br>b. Patient has adult onset OR systemic juvenile idiopathic arthritis; AND<br>c. 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.)."<br>Systemic Juvenile Idiopathic Arthritis (sJIA): Initial Criteria: removed<br>"a. Patient is over the age of 2; AND<br>b. Patient has active Systemic Juvenile Idiopathic Arthritis (sJIA); AND<br>c. 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 combined the two indications to add "2. Still's Disease (Adult-Onset Still's Disease [AOSD] and Systemic Juvenile Idiopathic Arthritis [SJIA]) †<br>a. Patient has active disease; AND<br>b. Physician has assessed baseline disease severity utilizing an objective measure/tool; AND<br>c. Patient has had at least a 1-month trial and failure (unless contraindicated or intolerant)<br>of previous therapy with either oral non-steroidal anti-inflammatory |

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|---|---|---|
| | | drugs (NSAIDs) OR a<br>systemic glucocorticoid (prednisone, methylprednisolone, etc.); AND<br>Patient is at least 18 years of age and has active Adult-Onset Still's Disease; OR<br>ii. Patient is at least 2 years of age and has active Systemic Juvenile Idiopathic Arthritis"<br><u>Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS): Initial Criteria: added:</u><br>**a.** "Used as a single agent; **AND**<br>b. Patient has the presence of a pathogenic mutation in the tumor necrosis factor receptor-1 (TNFR1) gene (TNFRSF1A); **AND"**<br><u>Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD)</u><br>Removed" Patient has a confirmed diagnosis based on genetic/enzymatic laboratory findings; **AND"** and Added<br>c. "Patient has a confirmed diagnosis of HIDS/MKD by one of the following:<br>**i.** Patient has a pathogenic mutation in the MVK gene; **OR**<br>ii. Patient has significantly elevated serum IgD levels; **AND**<br>d. Patient has documented baseline serum levels of C-Reactive Protein (CRP)"<br><br><u>Familial Mediterranean Fever (FMF): Initial Criteria: Added:</u><br><br>e. "Used as a single agent; AND<br>f. Patient has a confirmed diagnosis based on at least one known MEFV exon 10 mutation; AND<br>g. Patient has documented baseline serum levels of C-Reactive Protein (CRP)" |
| EmblemHealth & ConnectiCare | 7/6/2022 | Transferred policy to new template |
| EmblemHealth & ConnectiCare | 6/23/2020 | Added New FDA approved indication: Active Still's disease<br>Updated billable units for Active Still's disease<br>Updated Initial approval criteria for Active Still's disease<br>Added ICD 10 code M06.1<br>Updated dosage/administration |

## References


1. Ilaris [package insert]. East Hanover, NJ; Novartis Pharmaceuticals Corporation; December 2016. Accessed July 2018.
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3. Ruperto N, Brunner H, Quartier P, et al. Two Randomized Trials of Canakinumab in Systemic Juvenile Idiopathic Arthritis. N Engl J Med 2012; 367:2396-2406.
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5. DeWitt EM, Kimura Y, Beukelman T, et al. Consensus treatment plans for new-onset systemic juvenile idiopathic arthritis. Arthritis Care Res (Hoboken). 2012 Jul;64(7):1001-10.

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