

Medical Policy:

Ilaris® (canakinumab) Subcutaneous

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.149	April 2, 2025	

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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.

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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, 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 Initial criteria for specific re-treatment criteria)

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. Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS)

- 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. Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD)

- 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. Familial Mediterranean Fever (FMF)

- 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. Gout Flares

- A. Patient is at least 18 years of age; **AND**
- B. Patient has not received treatment with canakinumab in the previous 12 weeks; **AND**
 - i. Patient has had ≥ 3 gout flares within the previous 12 months; **AND**
 - ii. Patient has failed on non-steroidal anti-inflammatory drugs (NSAIDs) therapy, unless contraindicated or intolerant; **AND**
 - iii. Patient has failed on colchicine therapy, unless contraindicated or intolerant; **AND**
 - iv. Patient is not a candidate for repeated courses of corticosteroids; **OR**
- C. 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**
 - i. Patient requires re-treatment for a new gout flare; **AND**
 - ii. Patient has not received treatment with canakinumab in the previous 12 weeks

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. **Cryopyrin-Associated Periodic Syndromes**
 - A. 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
4. **Adult-Onset Still’s Disease/Systemic Juvenile Idiopathic Arthritis**
 - A. 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]
5. **Tumor Necrosis Factor Receptor Associated Periodic Syndrome; Hyperimmunoglobulin D Syndrome/Mevalonate Kinase Deficiency; Familial Mediterranean Fever**
 - A. Disease response as indicated by improvement in patient’s symptoms from baseline **AND** improvement of serum levels of CRP
6. **Gout Flare**
 - A. *Refer to Initial Criteria for re-treatment criteria*

Dosing/Administration

Indication	Dose
Cryopyrin-Associated Periodic Syndromes	Weight greater than 40 kg 150 mg sq every 8 weeks Weight of 15 to 40 kg 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 4mg/kg (with a maximum of 300 mg) sq every 4 weeks.
Gout Flare	Administer 150 mg subcutaneously x 1 dose Note: In patients who require re-treatment, there should be an interval of at least 12 weeks before receiving another dose. (Refer to Initial criteria for re-treatment criteria)
All other indications	Weight greater than 40 kg 150 mg sq every 4 weeks. May increase dose to 300 mg if inadequate response. Weight less than or equal to 40 kg 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
E79.9	Disorder of purine and pyrimidine metabolism, unspecified
G63	Polyneuropathy in diseases classified elsewhere
M04.1	Periodic fever syndromes
M04.2	Cryopyrin-associated periodic syndromes
M04.9	Autoinflammatory syndrome, unspecified
M06.1	Adult-onset Still's disease
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
M08.29	Juvenile rheumatoid arthritis with systemic onset, multiple sites
M10.08	Idiopathic gout, vertebrae
M10.18	Lead-induced gout, vertebrae
M10.19	Lead-induced gout, multiple sites
M10.20	Drug-induced gout, unspecified site
M10.211	Drug-induced gout, right shoulder
M10.212	Drug-induced gout, left shoulder
M10.219	Drug-induced gout, unspecified shoulder
M10.221	Drug-induced gout, right elbow
M10.222	Drug-induced gout, left elbow
M10.229	Drug-induced gout, unspecified elbow
M10.231	Drug-induced gout, right wrist
M10.232	Drug-induced gout, left wrist
M10.239	Drug-induced gout, unspecified wrist

M10.241	Drug-induced gout, right hand
M10.242	Drug-induced gout, left hand
M10.249	Drug-induced gout, unspecified hand
M10.251	Drug-induced gout, right hip
M10.252	Drug-induced gout, left hip
M10.259	Drug-induced gout, unspecified hip
M10.261	Drug-induced gout, right knee
M10.262	Drug-induced gout, left knee
M10.269	Drug-induced gout, unspecified knee
M10.271	Drug-induced gout, right ankle and foot
M10.272	Drug-induced gout, left ankle and foot
M10.279	Drug-induced gout, unspecified ankle and foot
M10.28	Drug-induced gout, vertebrae
M10.29	Drug-induced gout, multiple sites
M10.30	Gout due to renal impairment, unspecified site
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
M10.48	Other secondary gout, vertebrae
M10.9	Gout, unspecified
M1A.00X0	Idiopathic chronic gout, unspecified site, without tophus (tophi)
M1A.00X1	Idiopathic chronic gout, unspecified site, with tophus (tophi)
M1A.0110	Idiopathic chronic gout, right shoulder, without tophus (tophi)
M1A.0111	Idiopathic chronic gout, right shoulder, with tophus (tophi)
M1A.0120	Idiopathic chronic gout, left shoulder, without tophus (tophi)
M1A.0121	Idiopathic chronic gout, left shoulder, with tophus (tophi)

M1A.0190	Idiopathic chronic gout, unspecified shoulder, without tophus (tophi)
M1A.0191	Idiopathic chronic gout, unspecified shoulder, with tophus (tophi)
M1A.0210	Idiopathic chronic gout, right elbow, without tophus (tophi)
M1A.0211	Idiopathic chronic gout, right elbow, with tophus (tophi)
M1A.0220	Idiopathic chronic gout, left elbow, without tophus (tophi)
M1A.0221	Idiopathic chronic gout, left elbow, with tophus (tophi)
M1A.0290	Idiopathic chronic gout, unspecified elbow, without tophus (tophi)
M1A.0291	Idiopathic chronic gout, unspecified elbow, with tophus (tophi)
M1A.0310	Idiopathic chronic gout, right wrist, without tophus (tophi)
M1A.0311	Idiopathic chronic gout, right wrist, with tophus (tophi)
M1A.0320	Idiopathic chronic gout, left wrist, without tophus (tophi)
M1A.0321	Idiopathic chronic gout, left wrist, with tophus (tophi)
M1A.0390	Idiopathic chronic gout, unspecified wrist, without tophus (tophi)
M1A.0391	Idiopathic chronic gout, unspecified wrist, with tophus (tophi)
M1A.0410	Idiopathic chronic gout, right hand, without tophus (tophi)
M1A.0411	Idiopathic chronic gout, right hand, with tophus (tophi)
M1A.0420	Idiopathic chronic gout, left hand, without tophus (tophi)
M1A.0421	Idiopathic chronic gout, left hand, with tophus (tophi)
M1A.0490	Idiopathic chronic gout, unspecified hand, without tophus (tophi)
M1A.0491	Idiopathic chronic gout, unspecified hand, with tophus (tophi)
M1A.0510	Idiopathic chronic gout, right hip, without tophus (tophi)
M1A.0511	Idiopathic chronic gout, right hip, with tophus (tophi)
M1A.0520	Idiopathic chronic gout, left hip, without tophus (tophi)
M1A.0521	Idiopathic chronic gout, left hip, with tophus (tophi)
M1A.0590	Idiopathic chronic gout, unspecified hip, without tophus (tophi)
M1A.0591	Idiopathic chronic gout, unspecified hip, with tophus (tophi)
M1A.0610	Idiopathic chronic gout, right knee, without tophus (tophi)
M1A.0611	Idiopathic chronic gout, right knee, with tophus (tophi)
M1A.0620	Idiopathic chronic gout, left knee, without tophus (tophi)
M1A.0621	Idiopathic chronic gout, left knee, with tophus (tophi)
M1A.0690	Idiopathic chronic gout, unspecified knee, without tophus (tophi)
M1A.0691	Idiopathic chronic gout, unspecified knee, with tophus (tophi)
M1A.0710	Idiopathic chronic gout, right ankle and foot, without tophus (tophi)
M1A.0711	Idiopathic chronic gout, right ankle and foot, with tophus (tophi)
M1A.0720	Idiopathic chronic gout, left ankle and foot, without tophus (tophi)
M1A.0721	Idiopathic chronic gout, left ankle and foot, with tophus (tophi)
M1A.0790	Idiopathic chronic gout, unspecified ankle and foot, without tophus (tophi)
M1A.0791	Idiopathic chronic gout, unspecified ankle and foot, with tophus (tophi)
M1A.08X0	Idiopathic chronic gout, vertebrae, without tophus (tophi)
M1A.08X1	Idiopathic chronic gout, vertebrae, with tophus (tophi)
M1A.09X0	Idiopathic chronic gout, multiple sites, without tophus (tophi)
M1A.09X1	Idiopathic chronic gout, multiple sites, with tophus (tophi)
M1A.10X0	Lead-induced chronic gout, unspecified site, without tophus (tophi)
M1A.10X1	Lead-induced chronic gout, unspecified site, with tophus (tophi)
M1A.1110	Lead-induced chronic gout, right shoulder, without tophus (tophi)
M1A.1111	Lead-induced chronic gout, right shoulder, with tophus (tophi)

M1A.1120	Lead-induced chronic gout, left shoulder, without tophus (tophi)
M1A.1121	Lead-induced chronic gout, left shoulder, with tophus (tophi)
M1A.1190	Lead-induced chronic gout, unspecified shoulder, without tophus (tophi)
M1A.1191	Lead-induced chronic gout, unspecified shoulder, with tophus (tophi)
M1A.1210	Lead-induced chronic gout, right elbow, without tophus (tophi)
M1A.1211	Lead-induced chronic gout, right elbow, with tophus (tophi)
M1A.1220	Lead-induced chronic gout, left elbow, without tophus (tophi)
M1A.1221	Lead-induced chronic gout, left elbow, with tophus (tophi)
M1A.1290	Lead-induced chronic gout, unspecified elbow, without tophus (tophi)
M1A.1291	Lead-induced chronic gout, unspecified elbow, with tophus (tophi)
M1A.1310	Lead-induced chronic gout, right wrist, without tophus (tophi)
M1A.1311	Lead-induced chronic gout, right wrist, with tophus (tophi)
M1A.1320	Lead-induced chronic gout, left wrist, without tophus (tophi)
M1A.1321	Lead-induced chronic gout, left wrist, with tophus (tophi)
M1A.1390	Lead-induced chronic gout, unspecified wrist, without tophus (tophi)
M1A.1391	Lead-induced chronic gout, unspecified wrist, with tophus (tophi)
M1A.1410	Lead-induced chronic gout, right hand, without tophus (tophi)
M1A.1411	Lead-induced chronic gout, right hand, with tophus (tophi)
M1A.1420	Lead-induced chronic gout, left hand, without tophus (tophi)
M1A.1421	Lead-induced chronic gout, left hand, with tophus (tophi)
M1A.1490	Lead-induced chronic gout, unspecified hand, without tophus (tophi)
M1A.1491	Lead-induced chronic gout, unspecified hand, with tophus (tophi)
M1A.1510	Lead-induced chronic gout, right hip, without tophus (tophi)
M1A.1511	Lead-induced chronic gout, right hip, with tophus (tophi)
M1A.1520	Lead-induced chronic gout, left hip, without tophus (tophi)
M1A.1521	Lead-induced chronic gout, left hip, with tophus (tophi)
M1A.1590	Lead-induced chronic gout, unspecified hip, without tophus (tophi)
M1A.1591	Lead-induced chronic gout, unspecified hip, with tophus (tophi)
M1A.1610	Lead-induced chronic gout, right knee, without tophus (tophi)
M1A.1611	Lead-induced chronic gout, right knee, with tophus (tophi)
M1A.1620	Lead-induced chronic gout, left knee, without tophus (tophi)
M1A.1621	Lead-induced chronic gout, left knee, with tophus (tophi)
M1A.1690	Lead-induced chronic gout, unspecified knee, without tophus (tophi)
M1A.1691	Lead-induced chronic gout, unspecified knee, with tophus (tophi)
M1A.1710	Lead-induced chronic gout, right ankle and foot, without tophus (tophi)
M1A.1711	Lead-induced chronic gout, right ankle and foot, with tophus (tophi)
M1A.1720	Lead-induced chronic gout, left ankle and foot, without tophus (tophi)
M1A.1721	Lead-induced chronic gout, left ankle and foot, with tophus (tophi)
M1A.1790	Lead-induced chronic gout, unspecified ankle and foot, without tophus (tophi)
M1A.1791	Lead-induced chronic gout, unspecified ankle and foot, with tophus (tophi)
M1A.18X0	Lead-induced chronic gout, vertebrae, without tophus (tophi)
M1A.18X1	Lead-induced chronic gout, vertebrae, with tophus (tophi)
M1A.19X0	Lead-induced chronic gout, multiple sites, without tophus (tophi)
M1A.19X1	Lead-induced chronic gout, multiple sites, with tophus (tophi)
M1A.20X0	Drug-induced chronic gout, unspecified site, without tophus (tophi)
M1A.20X1	Drug-induced chronic gout, unspecified site, with tophus (tophi)

M1A.2110	Drug-induced chronic gout, right shoulder, without tophus (tophi)
M1A.2111	Drug-induced chronic gout, right shoulder, with tophus (tophi)
M1A.2120	Drug-induced chronic gout, left shoulder, without tophus (tophi)
M1A.2121	Drug-induced chronic gout, left shoulder, with tophus (tophi)
M1A.2190	Drug-induced chronic gout, unspecified shoulder, without tophus (tophi)
M1A.2191	Drug-induced chronic gout, unspecified shoulder, with tophus (tophi)
M1A.2210	Drug-induced chronic gout, right elbow, without tophus (tophi)
M1A.2211	Drug-induced chronic gout, right elbow, with tophus (tophi)
M1A.2220	Drug-induced chronic gout, left elbow, without tophus (tophi)
M1A.2221	Drug-induced chronic gout, left elbow, with tophus (tophi)
M1A.2290	Drug-induced chronic gout, unspecified elbow, without tophus (tophi)
M1A.2291	Drug-induced chronic gout, unspecified elbow, with tophus (tophi)
M1A.2310	Drug-induced chronic gout, right wrist, without tophus (tophi)
M1A.2311	Drug-induced chronic gout, right wrist, with tophus (tophi)
M1A.2320	Drug-induced chronic gout, left wrist, without tophus (tophi)
M1A.2321	Drug-induced chronic gout, left wrist, with tophus (tophi)
M1A.2390	Drug-induced chronic gout, unspecified wrist, without tophus (tophi)
M1A.2391	Drug-induced chronic gout, unspecified wrist, with tophus (tophi)
M1A.2410	Drug-induced chronic gout, right hand, without tophus (tophi)
M1A.2411	Drug-induced chronic gout, right hand, with tophus (tophi)
M1A.2420	Drug-induced chronic gout, left hand, without tophus (tophi)
M1A.2421	Drug-induced chronic gout, left hand, with tophus (tophi)
M1A.2490	Drug-induced chronic gout, unspecified hand, without tophus (tophi)
M1A.2491	Drug-induced chronic gout, unspecified hand, with tophus (tophi)
M1A.2510	Drug-induced chronic gout, right hip, without tophus (tophi)
M1A.2511	Drug-induced chronic gout, right hip, with tophus (tophi)
M1A.2520	Drug-induced chronic gout, left hip, without tophus (tophi)
M1A.2521	Drug-induced chronic gout, left hip, with tophus (tophi)
M1A.2590	Drug-induced chronic gout, unspecified hip, without tophus (tophi)
M1A.2591	Drug-induced chronic gout, unspecified hip, with tophus (tophi)
M1A.2610	Drug-induced chronic gout, right knee, without tophus (tophi)
M1A.2611	Drug-induced chronic gout, right knee, with tophus (tophi)
M1A.2620	Drug-induced chronic gout, left knee, without tophus (tophi)
M1A.2621	Drug-induced chronic gout, left knee, with tophus (tophi)
M1A.2690	Drug-induced chronic gout, unspecified knee, without tophus (tophi)
M1A.2691	Drug-induced chronic gout, unspecified knee, with tophus (tophi)
M1A.2710	Drug-induced chronic gout, right ankle and foot, without tophus (tophi)
M1A.2711	Drug-induced chronic gout, right ankle and foot, with tophus (tophi)
M1A.2720	Drug-induced chronic gout, left ankle and foot, without tophus (tophi)
M1A.2721	Drug-induced chronic gout, left ankle and foot, with tophus (tophi)
M1A.2790	Drug-induced chronic gout, unspecified ankle and foot, without tophus (tophi)
M1A.2791	Drug-induced chronic gout, unspecified ankle and foot, with tophus (tophi)
M1A.28X0	Drug-induced chronic gout, vertebrae, without tophus (tophi)
M1A.28X1	Drug-induced chronic gout, vertebrae, with tophus (tophi)
M1A.29X0	Drug-induced chronic gout, multiple sites, without tophus (tophi)
M1A.29X1	Drug-induced chronic gout, multiple sites, with tophus (tophi)

M1A.30X0	Chronic gout due to renal impairment, unspecified site, without tophus (tophi)
M1A.30X1	Chronic gout due to renal impairment, unspecified site, with tophus (tophi)
M1A.3110	Chronic gout due to renal impairment, right shoulder, without tophus (tophi)
M1A.3111	Chronic gout due to renal impairment, right shoulder, with tophus (tophi)
M1A.3120	Chronic gout due to renal impairment, left shoulder, without tophus (tophi)
M1A.3121	Chronic gout due to renal impairment, left shoulder, with tophus (tophi)
M1A.3190	Chronic gout due to renal impairment, unspecified shoulder, without tophus (tophi)
M1A.3191	Chronic gout due to renal impairment, unspecified shoulder, with tophus (tophi)
M1A.3210	Chronic gout due to renal impairment, right elbow, without tophus (tophi)
M1A.3211	Chronic gout due to renal impairment, right elbow, with tophus (tophi)
M1A.3220	Chronic gout due to renal impairment, left elbow, without tophus (tophi)
M1A.3221	Chronic gout due to renal impairment, left elbow, with tophus (tophi)
M1A.3290	Chronic gout due to renal impairment, unspecified elbow, without tophus (tophi)
M1A.3291	Chronic gout due to renal impairment, unspecified elbow, with tophus (tophi)
M1A.3310	Chronic gout due to renal impairment, right wrist, without tophus (tophi)
M1A.3311	Chronic gout due to renal impairment, right wrist, with tophus (tophi)
M1A.3320	Chronic gout due to renal impairment, left wrist, without tophus (tophi)
M1A.3321	Chronic gout due to renal impairment, left wrist, with tophus (tophi)
M1A.3390	Chronic gout due to renal impairment, unspecified wrist, without tophus (tophi)
M1A.3391	Chronic gout due to renal impairment, unspecified wrist, with tophus (tophi)
M1A.3410	Chronic gout due to renal impairment, right hand, without tophus (tophi)
M1A.3411	Chronic gout due to renal impairment, right hand, with tophus (tophi)
M1A.3420	Chronic gout due to renal impairment, left hand, without tophus (tophi)
M1A.3421	Chronic gout due to renal impairment, left hand, with tophus (tophi)
M1A.3490	Chronic gout due to renal impairment, unspecified hand, without tophus (tophi)
M1A.3491	Chronic gout due to renal impairment, unspecified hand, with tophus (tophi)
M1A.3510	Chronic gout due to renal impairment, right hip, without tophus (tophi)
M1A.3511	Chronic gout due to renal impairment, right hip, with tophus (tophi)
M1A.3520	Chronic gout due to renal impairment, left hip, without tophus (tophi)
M1A.3521	Chronic gout due to renal impairment, left hip, with tophus (tophi)
M1A.3590	Chronic gout due to renal impairment, unspecified hip, without tophus (tophi)
M1A.3591	Chronic gout due to renal impairment, unspecified hip, with tophus (tophi)
M1A.3610	Chronic gout due to renal impairment, right knee, without tophus (tophi)
M1A.3611	Chronic gout due to renal impairment, right knee, with tophus (tophi)
M1A.3620	Chronic gout due to renal impairment, left knee, without tophus (tophi)
M1A.3621	Chronic gout due to renal impairment, left knee, with tophus (tophi)
M1A.3690	Chronic gout due to renal impairment, unspecified knee, without tophus (tophi)
M1A.3691	Chronic gout due to renal impairment, unspecified knee, with tophus (tophi)
M1A.3710	Chronic gout due to renal impairment, right ankle and foot, without tophus (tophi)
M1A.3711	Chronic gout due to renal impairment, right ankle and foot, with tophus (tophi)
M1A.3720	Chronic gout due to renal impairment, left ankle and foot, without tophus (tophi)
M1A.3721	Chronic gout due to renal impairment, left ankle and foot, with tophus (tophi)
M1A.3790	Chronic gout due to renal impairment, unspecified ankle and foot, without tophus (tophi)
M1A.3791	Chronic gout due to renal impairment, unspecified ankle and foot, with tophus (tophi)
M1A.38X0	Chronic gout due to renal impairment, vertebrae, without tophus (tophi)
M1A.38X1	Chronic gout due to renal impairment, vertebrae, with tophus (tophi)

M1A.39X0	Chronic gout due to renal impairment, multiple sites, without tophus (tophi)
M1A.39X1	Chronic gout due to renal impairment, multiple sites, with tophus (tophi)
M1A.40X0	Other secondary chronic gout, unspecified site, without tophus (tophi)
M1A.40X1	Other secondary chronic gout, unspecified site, with tophus (tophi)
M1A.4110	Other secondary chronic gout, right shoulder, without tophus (tophi)
M1A.4111	Other secondary chronic gout, right shoulder, with tophus (tophi)
M1A.4120	Other secondary chronic gout, left shoulder, without tophus (tophi)
M1A.4121	Other secondary chronic gout, left shoulder, with tophus (tophi)
M1A.4190	Other secondary chronic gout, unspecified shoulder, without tophus (tophi)
M1A.4191	Other secondary chronic gout, unspecified shoulder, with tophus (tophi)
M1A.4210	Other secondary chronic gout, right elbow, without tophus (tophi)
M1A.4211	Other secondary chronic gout, right elbow, with tophus (tophi)
M1A.4220	Other secondary chronic gout, left elbow, without tophus (tophi)
M1A.4221	Other secondary chronic gout, left elbow, with tophus (tophi)
M1A.4290	Other secondary chronic gout, unspecified elbow, without tophus (tophi)
M1A.4291	Other secondary chronic gout, unspecified elbow, with tophus (tophi)
M1A.4310	Other secondary chronic gout, right wrist, without tophus (tophi)
M1A.4311	Other secondary chronic gout, right wrist, with tophus (tophi)
M1A.4320	Other secondary chronic gout, left wrist, without tophus (tophi)
M1A.4321	Other secondary chronic gout, left wrist, with tophus (tophi)
M1A.4390	Other secondary chronic gout, unspecified wrist, without tophus (tophi)
M1A.4391	Other secondary chronic gout, unspecified wrist, with tophus (tophi)
M1A.4410	Other secondary chronic gout, right hand, without tophus (tophi)
M1A.4411	Other secondary chronic gout, right hand, with tophus (tophi)
M1A.4420	Other secondary chronic gout, left hand, without tophus (tophi)
M1A.4421	Other secondary chronic gout, left hand, with tophus (tophi)
M1A.4490	Other secondary chronic gout, unspecified hand, without tophus (tophi)
M1A.4491	Other secondary chronic gout, unspecified hand, with tophus (tophi)
M1A.4510	Other secondary chronic gout, right hip, without tophus (tophi)
M1A.4511	Other secondary chronic gout, right hip, with tophus (tophi)
M1A.4520	Other secondary chronic gout, left hip, without tophus (tophi)
M1A.4521	Other secondary chronic gout, left hip, with tophus (tophi)
M1A.4590	Other secondary chronic gout, unspecified hip, without tophus (tophi)
M1A.4591	Other secondary chronic gout, unspecified hip, with tophus (tophi)
M1A.4610	Other secondary chronic gout, right knee, without tophus (tophi)
M1A.4611	Other secondary chronic gout, right knee, with tophus (tophi)
M1A.4620	Other secondary chronic gout, left knee, without tophus (tophi)
M1A.4621	Other secondary chronic gout, left knee, with tophus (tophi)
M1A.4690	Other secondary chronic gout, unspecified knee, without tophus (tophi)
M1A.4691	Other secondary chronic gout, unspecified knee, with tophus (tophi)
M1A.4710	Other secondary chronic gout, right ankle and foot, without tophus (tophi)
M1A.4711	Other secondary chronic gout, right ankle and foot, with tophus (tophi)
M1A.4720	Other secondary chronic gout, left ankle and foot, without tophus (tophi)
M1A.4721	Other secondary chronic gout, left ankle and foot, with tophus (tophi)
M1A.4790	Other secondary chronic gout, unspecified ankle and foot, without tophus (tophi)
M1A.4791	Other secondary chronic gout, unspecified ankle and foot, with tophus (tophi)

M1A.48X0	Other secondary chronic gout, vertebrae, without tophus (tophi)
M1A.48X1	Other secondary chronic gout, vertebrae, with tophus (tophi)
M1A.49X0	Other secondary chronic gout, multiple sites, without tophus (tophi)
M1A.49X1	Other secondary chronic gout, multiple sites, with tophus (tophi)
M1A.9XX0	Chronic gout, unspecified, without tophus (tophi)
M1A.9XX1	Chronic gout, unspecified, with tophus (tophi)
N28.9	Disorder of kidney and ureter, unspecified

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	04/02/2025	Annual Review: Length of authorization: added: "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 Initial criteria for specific re-treatment criteria)" Initial Criteria: Updated Gout flares: added: "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 has not received treatment with canakinumab in the previous 12 weeks" removed: "According to the prescriber, patient is receiving or will be taking concomitant urate lowering medication for the prevention of gout unless contraindicated <i>Note: Examples of uric acid lowering drugs include allopurinol, febuxostat, or probenecid.</i> " Updated ICD-10 codes. Renewal Criteria: Reworded the following for clarity: "Disease response as indicated by improvement in patient's symptoms from baseline." Added: "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 <i>Refer to Initial Criteria for re-treatment criteria</i> "
EmblemHealth & ConnectiCare	2/28/2024	Annual Review: Initial Criteria: Cryopyrin-Associated Periodic Syndromes (CAPS)- clarified wording on age Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS)- clarified wording on age Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD)- clarified wording on age and added: "Used as a single agent; AND" Familial Mediterranean Fever (FMF) clarified wording on age 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" Added: "According to the prescriber, patient is receiving or will be taking concomitant urate lowering medication for the prevention of gout unless contraindicated <i>Note: Examples of uric acid lowering drugs include allopurinol, febuxostat, or</i>

		<i>probenecid.”</i>
EmblemHealth & ConnectiCare	10/04/2023	Update: Added <u>Gout Flares</u> indication and criteria, updated dosing chart and codes to include gout
EmblemHealth & ConnectiCare	6/26/2023	<p>Annual Review:</p> <p><u>Active Still’s disease</u> Initial Criteria: removed:</p> <p>“a. Patient is 2 years of age or older; AND</p> <p>b. Patient has adult onset OR systemic juvenile idiopathic arthritis; AND</p> <p>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.)”</p> <p><u>Systemic Juvenile Idiopathic Arthritis (sJIA)</u>: Initial Criteria: removed</p> <p>“a. Patient is over the age of 2; AND</p> <p>b. Patient has active Systemic Juvenile Idiopathic Arthritis (sJIA); AND</p> <p>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. <u>Still’s Disease (Adult-Onset Still’s Disease [AOSD] and Systemic Juvenile Idiopathic Arthritis [SJIA])</u> †</p> <p>a. Patient has active disease; AND</p> <p>b. Physician has assessed baseline disease severity utilizing an objective measure/tool; AND</p> <p>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</p> <p>Patient is at least 18 years of age and has active Adult-Onset Still’s Disease; OR</p> <p>ii. Patient is at least 2 years of age and has active Systemic Juvenile Idiopathic Arthritis”</p> <p><u>Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS): Initial Criteria: added:</u></p> <p>a. “Used as a single agent; AND</p> <p>b. Patient has the presence of a pathogenic mutation in the tumor necrosis factor receptor-1 (TNFR1) gene (TNFRSF1A); AND”</p> <p><u>Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD) Removed”</u> Patient has a confirmed diagnosis based on genetic/enzymatic laboratory findings; AND” and Added</p> <p>c. “Patient has a confirmed diagnosis of HIDS/MKD by one of the following:</p> <p>i. Patient has a pathogenic mutation in the MVK gene; OR</p> <p>ii. Patient has significantly elevated serum IgD levels; AND</p> <p>d. Patient has documented baseline serum levels of C-Reactive Protein (CRP)”</p> <p><u>Familial Mediterranean Fever (FMF): Initial Criteria: Added:</u></p> <p>e. “Used as a single agent; AND</p> <p>f. Patient has a confirmed diagnosis based on at least one known MEFV exon 10 mutation; AND</p> <p>g. Patient has documented baseline serum levels of C-Reactive Protein (CRP)”</p>

EmblemHealth & ConnectiCare	7/6/2022	Transferred policy to new template
EmblemHealth & ConnectiCare	6/23/2020	Added New FDA approved indication: Active Still's disease Updated billable units for Active Still's disease Updated Initial approval criteria for Active Still's disease Added ICD 10 code M06.1 Updated dosage/administration

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