Ilaris® (canakinumab)
(Subcutaneous)

Effective Date: 01/01/2020
Review Date: 09/25/2019, 12/18/19, 1/29/20, 9/9/2020, 5/20/2021, 3/3/2022, 9/8/2022, 4/27/2023, 12/07/2023, 01/10/2024, 02/28/2024, 05/21/2025, 04/21/2026

Scope: Medicaid, Commercial, Medicare=

I. Length of Authorization

Coverage will be provided for 6 months and may be renewed for 6 months.

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.

II. Dosing Limits

A. 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. Summary of Evidence

Clinical trials support the efficacy and safety of Ilaris (canakinumab) in the treatment of various inflammatory conditions, including systemic juvenile idiopathic arthritis (SJIA), adult-onset Still's disease (AOSD), periodic fever syndromes including Cryopyrin-Associated Periodic Syndromes (CAPS), Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS), Hyperimmunoglobulin D Syndrome (HIDS), Mevalonate Kinase Deficiency (MKD), and Familial Mediterranean Fever (FMF), and gout flares. In a randomized, placebo-controlled study of patients with TRAPS, HIDS/MKD, and FMF (n=185), Ilaris significantly improved complete response rates at 16 weeks compared with placebo, defined as resolution of the index flare by day 15 with no subsequent flares. Complete response rates were 45.5% vs 8.3% in TRAPS (OR 9.17; p=0.005), 35.1% vs 5.7% in HIDS/MKD (OR 8.94; p=0.002), and 61.3% vs 6.3% in FMF (OR 23.75; p<0.001). Ilaris also resulted in significantly higher proportions of patients achieving normalization of inflammatory markers (CRP ≤ 10 mg/L and low disease activity score by day 15. In CAPS randomized study, patients achieved rapid and durable disease control, with 97% attaining complete clinical response by week 8 and 0% experiencing disease flares during

double-blind period, compared with 81% of placebo-controlled patients. In SJIA, two phase 3 trials demonstrated rapid and sustained disease control. In Study 1, 84% of Ilaris-treated patients achieved a pediatric ACR30 response with absence of fever at day 15 compared with 10% on placebo. In SJIA study 2, Ilasris reduced the risk of disease flare by 64% versus placebo (HR 0.36; 95% CI 0.17-0.75) and enabled successful corticosteroid tapering or discontinuation in a substantial proportion of patients. Efficacy in AOSD is supported via evidence from SJIA. In gout flares, patients unable to use NSAIDs or colchicine, Ilaris significantly reduced pain intensity at 72 hours post-dose compared with triamcinolone acetonide (mean VAS reductions ranging from -9 to -22 mm) and significantly prolonged time to first new flare, with relative risk reductions up to 91% and hazard ratios as low as 0.09. Studies have demonstrated significant reductions in disease activity, including the number of active joints and levels of inflammatory markers, in patients treated with Ilaris compared to placebo or other standard treatments. Ilaris has also been shown to improve quality of life and reduce the frequency and severity of flares in patients with these conditions. The most commonly reported adverse drug reactions included infections (most frequently nasopharyngitis and upper respiratory tract infections), injection-site reactions, and gastrointestinal events such as diarrhea and nausea. Other commonly reported adverse reactions included headache, musculoskeletal pain, weight increase, UTI, and vertigo.

IV. Initial Approval Criteria

Coverage is provided in the following conditions:

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

Universal Criteria

Medicare members who have previously received this medication within the past 365 days are not subject to Step Therapy Requirements.

- Member 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**
- Member does not have an active infection, including clinically important localized infections; **AND**
- Will not be administered concurrently with live vaccines; **AND**
- Member is not on concurrent treatment with another biologic therapy, such as an IL-inhibitor (e.g., Cosentyx (secukinumab), ustekinumab, Tremfya (guselkumab), etc), TNF-inhibitor (e.g., Humira (adalimumab), Enbrel (etanercept), Remicade (infliximab), etc.), integrin receptor antagonist (e.g., Tysabri(natalizumab), T cell costimulation modulator (e.g., Orenica (abatacept), etc. or targeted synthetic therapy (e.g., tofacitinib, baricitinib, upadacitinib, etc);

Cryopyrin-Associated Periodic Syndromes (CAPS) † Φ

- Member is at least 4 years of age; **AND**

- Used as a single agent; **AND**
- Member has documented baseline serum levels of inflammatory proteins (C-Reactive Protein [CRP] and/or Serum Amyloid A [SAA]; **AND**
- Member 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**
- Member 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 (TNF) Receptor Associated Periodic Syndrome (TRAPS) † Φ

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

Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD) † Φ

- Member is at least 2 years of age; **AND**
- Used as a single agent; **AND**
- Member has a confirmed diagnosis of HIDS/MKD by one of the following:
    - Member has a pathogenic mutation in the MVK gene; **OR**
    - Member has significantly elevated serum IgD levels; **AND**
- Member has a documented history of at least three (3) febrile episodes within a 6-month period; **AND**
- Member has documented baseline serum levels of C-Reactive Protein (CRP)

Familial Mediterranean Fever (FMF) † Φ

- Member is at least 2 years of age; **AND**
- Used as a single agent; **AND**
- Member has a confirmed diagnosis based on at least one known MEFV exon 10 mutation; **AND**
- Member has failed on colchicine therapy or has a documented allergy or intolerance; **AND**
- Member has active disease defined as at least one febrile episode per month; **AND**
- Member 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]) †

- Member has one of the following:
  - Active Adult-Onset Still's Disease with age ≥ 18 years; **OR**
  - Active Systemic Juvenile Idiopathic Arthritis with age ≥ 2 years; **AND**
- Physician has assessed baseline disease severity utilizing an objective measure/tool; **AND**
- Member 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.); **OR** Member is already established on biologic or targeted synthetic therapy for the treatment of AOSD or SJIA

Gout Flare †

- Member is at least 18 years of age; **AND**
  - Member has NOT received previous treatment with canakinumab for gout flare(s); **AND**
    - Member has had ≥ 3 gout flares within the previous 12 months; **AND**
    - Member has failed on non-steroidal anti-inflammatory drugs (NSAIDs) therapy, unless contraindicated or intolerant; **AND**
    - Member has failed on colchicine therapy, unless contraindicated or intolerant; **AND**
    - Member is not a candidate for repeated courses of corticosteroids: **OR**
  - Member has received previous treatment with Ilaris (canakinumab) for gout flare(s) resulting in a decrease or resolution of joint pain in the affected joints; **AND**
    - Member requires re-treatment for a new gout flare; **AND**
    - Member has not received treatment with Ilaris (canakinumab) in the previous 12 weeks

† FDA Approved Indication(s); **Φ** Orphan Drug

V. Renewal Criteria

Coverage can be renewed based upon the following criteria:

- Member 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 IV; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include severe hypersensitivity reactions, serious infections (including but not limited to tuberculosis), macrophage activation syndrome (MAS), etc.; **AND**

Cryopyrin-Associated Periodic Syndromes

Disease response as indicated by improvement in member'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, reduction of C-reactive protein, 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 Flares:

- Refer to Section IV for re-treatment criteria

VI. Dosage/Administration

Indication	Dose
CAPS	Weight: > 40 kg • 150 mg subcutaneously every 8 weeks Weight: 15 to 40 kg • 2 mg/kg subcutaneously every 8 weeks. May increase dose to 3 mg/kg if inadequate response.

Indication	Dose
AOSD and SJIA	Weight: ≥ 7.5 kg • 4 mg/kg (with a maximum of 300mg) subcutaneously every 4 weeks.
TRAPS, HIDS/MKD, and FMF	Weight: > 40 kg • 150 mg subcutaneously every 4 weeks. May increase dose to 300mg if inadequate response. Weight: ≤ 40 kg • 2 mg/kg subcutaneously every 4 weeks. May increase dose to 4 mg/kg if inadequate response.
Gout Flare	• 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 Section III for re-treatment criteria)*

VII. 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

VIII. References

1. Ilaris [package insert]. East Hanover, NJ; Novartis Pharmaceuticals Corporation; November 2024. Accessed April 2026.
2. Lachmann, HJ, Kone-Paut, I, Kuemmerle-Deschner, JB, et al. Use of canakinumab in the cryopyrin-associated periodic syndrome. *N Engl J Med.* 2009 Jun 4; 360(23):2416-25.
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.
4. Ringold, S., Weiss, P. F., Beukelman, T., DeWitt, E. M., Ilowite, N. T., Kimura, Y., Laxer, R. M., Lovell, D. J., Nigrovic, P. A., Robinson, A. B. and Vehe, R. K. (2013), 2013 Update of the 2011 American College of Rheumatology Recommendations for the Treatment of Juvenile Idiopathic Arthritis: Recommendations for the Medical Therapy of Children With Systemic Juvenile Idiopathic Arthritis and Tuberculosis Screening Among Children Receiving Biologic Medications. Arthritis & Rheumatism, 65: 2499–2512. doi: 10.1002/art.38092
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.

6. Kuemmerle-Deschner JB, Ozen S, Tyrrell PN, et al. Diagnostic criteria for cryopyrin-associated periodic syndrome (CAPS). Ann Rheum Dis. 2017 Jun;76(6):942-947. doi: 10.1136/annrheumdis-2016-209686.
7. Terreri MT, Bernardo WM, Len CA, et al. Guidelines for the management and treatment of periodic fever syndromes: Cryopyrin-associated periodic syndromes (cryopyrinopathies - CAPS). Rev Bras Reumatol Engl Ed. 2016 Jan-Feb;56(1):44-51. doi: 10.1016/j.rbre.2015.08.020.
8. Koné-Paut I, Lachmann HJ, Kuemmerle-Deschner JB, et al. Sustained remission of symptoms and improved health-related quality of life in patients with cryopyrin-associated periodic syndrome treated with canakinumab: results of a double-blind placebo-controlled randomized withdrawal study. Arthritis Res Ther. 2011;13(6):R202. doi:10.1186/ar3535.
9. Kuemmerle-Deschner JB, Hachulla E, Cartwright R, et al. Two-year results from an open-label, multicentre, phase III study evaluating the safety and efficacy of canakinumab in patients with cryopyrin-associated periodic syndrome across different severity phenotypes. Ann Rheum Dis. 2011;70(12):2095-2102. doi:10.1136/ard.2011.152728.
10. De Benedetti F, Gattorno M, Anton J, et al. Canakinumab for the Treatment of Autoinflammatory Recurrent Fever Syndromes. N Engl J Med. 2018;378(20):1908-1919. doi:10.1056/NEJMoa1706314.
11. Nirmala N, Brachat A, Feist E, et al. Gene-expression analysis of adult-onset Still's disease and systemic juvenile idiopathic arthritis is consistent with a continuum of a single disease entity. *Pediatr Rheumatol Online J*. 2015;13:50. Published 2015 Nov 20. doi:10.1186/s12969-015-0047-3.
12. Drenth JP, van der Meer JW. Hereditary periodic fever. N Engl J Med. 2001;345(24):1748.
13. Schlesinger N, Alten RE, Bardin T, et al. Canakinumab for acute gouty arthritis in patients with limited treatment options: results from two randomised, multicentre, active-controlled, double-blind trials and their initial extensions. Ann Rheum Dis. 2012 Nov;71(11):1839-48. doi: 10.1136/annrheumdis-2011-200908. Epub 2012

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
M06.1	Adult-onset Still's disease
M08.00	Unspecified juvenile rheumatoid arthritis of unspecified 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

ICD-10	ICD-10 Description
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

ICD-10	ICD-10 Description
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)
M08.40	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

ICD-10	ICD-10 Description
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
M08.90	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

ICD-10	ICD-10 Description
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
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

ICD-10	ICD-10 Description
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
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.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC

Policy Rationale: Ilaris was reviewed by the Neighborhood Health Plan of Rhode Island Pharmacy & Therapeutics (P&T) Committee. Neighborhood adopted the following clinical coverage criteria to ensure that its members use Ilaris according to Food and Drug Administration (FDA) approved labeling and/or relevant clinical literature. Neighborhood worked with network prescribers and pharmacists to draft these criteria. These criteria will help ensure its members are using this drug for a medically accepted indication, while minimizing the risk for adverse effects and ensuring more cost effective options are used first, if applicable and appropriate. For Medicare members, these coverage criteria will only apply in the absence of National Coverage Determination (NCD) or Local Coverage Determination (LCD) criteria. Neighborhood will give individual consideration to each request it reviews based on the information submitted by the prescriber and other information available to the plan.