Original Effective Date: 04/2015
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Next Review Due By: 10/2024
Policy Number: C2435-A

Ilaris (canakinumab)

PRODUCTS AFFECTED

Ilaris (canakinumab)

COVERAGE POLICY

Coverage for services, procedures, medical devices, and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Still's disease [Adult-Onset Still's Disease and Systemic Juvenile Idiopathic Arthritis (SJIA)], Periodic fever syndromes [Cryopyrin-Associated Periodic Syndromes, Tumor Necrosis Factor Receptor (TNF) Associated Periodic Syndrome (TRAPS), Hyperimmunoglobulin D (Hyper-IgD) Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD), Familial Mediterranean Fever], Gout Flare

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing.
Coverage will be determined on a case-by case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

FOR ALL INDICATIONS:

1. (a) Prescriber attests, or clinical reviewer has found, member has had a negative TB screening* or TB test (if indicated)** result within the last 12 months for initial and continuation of therapy requests
   *MOLINA REVIEWER NOTE: TB SCREENING assesses patient for future or ongoing TB exposure or risk and includes reviewing if they have been exposed to tuberculosis, if they have resided or traveled to areas of endemic tuberculosis, if patient resides or works in a congregate setting (e.g., correctional facilities, long-term care facilities, homeless shelters), etc.
   **MOLINA REVIEWER NOTE: TB SKIN TEST (TST, PPD) AND TB BLOOD TEST (QuantiFERON TB Gold, T-Spot) are not required or recommended in those without risk factors for tuberculosis
   OR
   (b) For members who have a positive test for latent TB, provider documents member has completed a treatment course (a negative chest x-ray is also required every 12 months) OR that member has been cleared by an infectious disease specialist to begin treatment
   AND
2. Prescriber attests member has been evaluated and screened for the presence of hepatitis B virus (HBV) prior to initiating treatment
   AND
3. Member is not on concurrent treatment or will not be used in combination with TNF- inhibitor, biologic response modifier or other biologic DMARDs, Janus kinase Inhibitors, or Phosphodiesterase 4 inhibitor (i.e., apremilast, tofacitinib, baricitinib) as verified by prescriber attestation, member medication fill history, or submitted documentation
   AND
4. Prescriber attests member does not have an active infection, including clinically important localized infections

A. ACTIVE SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS (SJIA):
1. Documented diagnosis of systemic juvenile idiopathic arthritis (SJIA) in a pediatric member
   AND
2. Documentation of prescriber baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy [DOCUMENTATION REQUIRED]
   AND
3. Documentation of treatment failure, serious side effects or clinical contraindication to an adequate trial (12 weeks) of one NSAID or glucocorticoid

B. CRYOPYRIN-ASSOCIATED PERIODIC SYNDROMES:
1. Documented diagnosis of one Cryopyrin-Associated Periodic Syndromes (CAPS) disorder: Familial Cold Auto-inflammatory Syndrome (FCAS) or Muckle-Wells Syndrome (MWS)
   NOTE: Ilaris (canakinumab) is not indicated for use in patients with neonatal- onset multisystem inflammatory disorder (NOMID), another syndrome that is included in CAPS
   AND
2. Documentation diagnosis confirmed by one of the following [DOCUMENTATION REQUIRED]:
   (a) Raised inflammatory markers (C-reactive protein [CRP] and serum amyloid A) AND at least two of six typical CAPS manifestations: urticaria-like rash, cold-triggered episodes, sensorineural hearing loss, musculoskeletal symptoms, chronic aseptic meningitis, skeletal abnormalities
   OR
   (b) Confirmed by genetic testing for NLRP3 gene mutations (also called CIAS1)
   AND
3. Prescriber attests to significant functional impairment resulting in limitations of activities of daily living (ADLs)
   AND
4. Documentation of prescriber baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy at renewal [DOCUMENTATION REQUIRED]

C. FAMILIAL MEDITERRANEAN FEVER (FMF):
1. Documented diagnosis of Familial Mediterranean Fever (FMF)
   AND
2. Documentation of prescriber baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy at renewal (e.g., recurrent fever, abdominal pain, chest pain, joint pain, erysipelas-like lesions, other manifestations) [DOCUMENTATION REQUIRED]
   AND
3. Documentation of an inadequate response, serious side effects, or contraindication to colchicine

D. HYPERIMMUNOGLOBULIN D SYNDROME/MEVALONATE KINASE DEFICIENCY:
1. Documented diagnosis of hyperimmunoglobulin d syndrome (HIDS)/Mevalonate Kinase Deficiency
   AND
2. Documentation of an elevated immunoglobulin D level OR a MVK gene mutation associated with HIDS (see Appendix) [DOCUMENTATION REQUIRED]
   AND
3. Documentation of one or more of the following features consistent with HIDS: Age at onset < 2 years, aphthous stomatitis, generalized enlargement of lymph nodes or splenomegaly, painful lymph nodes, diarrhea, absence of chest pain
   AND
4. Documentation of prescriber baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy at renewal [DOCUMENTATION REQUIRED]

E. TUMOR NECROSIS FACTOR RECEPTOR ASSOCIATED PERIODIC SYNDROME (TRAPS):
1. Documented diagnosis of tumor necrosis factor receptor associated periodic syndrome (TRAPS)
   AND
2. Documentation diagnosis confirmed by genetic testing for disease-associated mutations (pathogenic variants) in the tumor necrosis factor receptor-1 (TNFR1) gene (TNFRSF1A) [DOCUMENTATION REQUIRED]
   AND
3. Documentation of prescriber baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy at renewal [DOCUMENTATION REQUIRED]

F. ACTIVE STILL'S DISEASE:
1. Documented diagnosis of adult onset Still's Disease
   AND
2. Documentation of treatment failure or labeled contraindication to: (i) TWO formulary non-steroidal anti-inflammatory drugs (after 14 days of treatment) AND (ii) methotrexate (after 2 months of treatment at maximally tolerated dose)
   AND
3. Documentation of prescriber baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy at renewal [DOCUMENTATION REQUIRED]

G. GOUT FLARES:
1. Documented diagnosis of gout
   AND
2. Documentation member has experienced at least 3 gout flares in the previous 12 months
   AND
3. Documented treatment failure, serious side effects or clinical contraindication to NSAIDs AND colchicine
   AND
4. Prescriber attests that repeated courses of corticosteroids (oral, injectable, intraarticular) are not appropriate for the member
   AND

5. Documentation of prescriber baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy at renewal (e.g., number of flares, pain intensity, time between flares, etc.) [DOCUMENTATION REQUIRED]

CONTINUATION OF THERAPY:

A. FOR ALL INDICATIONS:

1. Adherence to therapy at least 85% of the time as verified by the prescriber or member's medication fill history OR adherence less than 85% of the time due to the need for surgery or treatment of an infection, causing temporary discontinuation
   AND
2. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity
   AND
3. Documentation of positive clinical response as demonstrated by low disease activity and/or improvements in the condition's signs and symptoms. [DOCUMENTATION REQUIRED]
   AND
4. (a) Prescriber attests, or clinical reviewer has found, member has had a negative TB screening* or TB test (if indicated)** result within the last 12 months for initial and continuation of therapy requests
   *MOLINA REVIEWER NOTE: TB SCREENING assesses patient for future or ongoing TB exposure or risk and includes reviewing if they have been exposed to tuberculosis, if they have resided or traveled to areas of endemic tuberculosis, if patient resides or works in a congregate setting (e.g., correctional facilities, long-term care facilities, homeless shelters), etc.
   **MOLINA REVIEWER NOTE: TB SKIN TEST (TST, PPD) AND TB BLOOD TEST (QuantiFERON TB Gold, T-Spot) are not required or recommended in those without risk factors for tuberculosis
   OR
   (b) For members who have a positive test for latent TB, provider documents member has completed a treatment course (a negative chest x-ray is also required every 12 months) OR that member has been cleared by an infectious disease specialist to begin treatment

DURATION OF APPROVAL:

Initial authorization: 6 months, Continuation of treatment: 12 months

PRESCRIBER REQUIREMENTS:

Prescribed by, or in consultation with, a board-certified rheumatologist, geneticist, or pediatric rheumatologist, [If prescribed in consultation, consultation notes must be submitted with initial request and reauthorization requests]

AGE RESTRICTIONS:

TRAPS, HIDS/MKD, FMF, SJIA: 2 years of age and older
CAPS: 4 years of age and older
Adult-Onset Still's Disease (AOSD), Gout Flares: 18 years of age and older

QUANTITY:

CAPS:
>40 kg: 150 mg/dose subcutaneously every 8 weeks
15 kg to 40 kg: 2 mg/kg subcutaneously every 8 weeks (max 3 mg/kg/dose)

TRAPS, HIDS/MKD, FMF:
> 40 kg: 150 mg subcutaneously every 4 weeks (max 300 mg)
40 kg or less: 2 mg/kg/dose subcutaneously every 4 weeks (max 4 mg/kg/dose)

ACTIVE STILL'S DISEASE (AOSD and SJIA):
≥ 7.5 kg: 4 mg/kg subcutaneously every 4 weeks (max 300mg)

GOUT FLARES:
150mg once; if re-treatment is required, an interval of at least 12 weeks must pass before a new dose of Ilaris may be administered

PLACE OF ADMINISTRATION:
The recommendation is that injectable medications in this policy will be for pharmacy or medical benefit coverage and the subcutaneous injectable products administered in a place of service that is a non-hospital facility-based location as per the Molina Health Care Site of Care program.

Note: Site of Care Utilization Management Policy applies for Ilaris (canakinumab). For information on site of care, see Specialty Medication Administration Site of Care Coverage Criteria (molinamarketplace.com)

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Subcutaneous

DRUG CLASS:
Interleukin-1beta Blockers

FDA-APPROVED USES:
Indicated for the treatment of:

- Periodic Fever Syndromes:
  - Cryopyrin-Associated Periodic Syndromes (CAPS), in adults and children 4 years of age and older including:
    - Familial Cold Autoinflammatory Syndrome (FCAS)
    - Muckle-Wells Syndrome (MWS)
  - Tumor Necrosis Factor (TNF) receptor Associated Periodic Syndrome (TRAPS) in adult and pediatric patients
  - Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD) in adult and pediatric patients
  - Familial Mediterranean Fever (FMF) in adult and pediatric patients
- Active Still's disease, including Adult-Onset Still's Disease (AOSD) and Systemic Juvenile Idiopathic Arthritis (SJIA) in patients aged 2 years and older
- Gout flares in adults in whom non-steroidal anti-inflammatory drugs (NSAIDs) and colchicine are contraindicated, are not tolerated, or do not provide an adequate response, and in whom repeated courses of corticosteroids are not appropriate

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX

APPENDIX:
Reserved for State specific information. *Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria.*

State Specific Information
State Marketplace
Texas (Source: Texas Statutes, Insurance Code)
"Sec. 1369.654. PROHIBITION ON MULTIPLE PRIOR AUTHORIZATIONS.
(a) A health benefit plan issuer that provides prescription drug benefits *may not require an enrollee to receive more than one prior authorization annually* of the prescription drug benefit for *a prescription drug*

prescribed to treat an autoimmune disease, hemophilia, or Von Willebrand disease.

(b) This section does not apply to:

(1) opioids, benzodiazepines, barbiturates, or carisoprodol;

(2) prescription drugs that have a typical treatment period of less than 12 months;

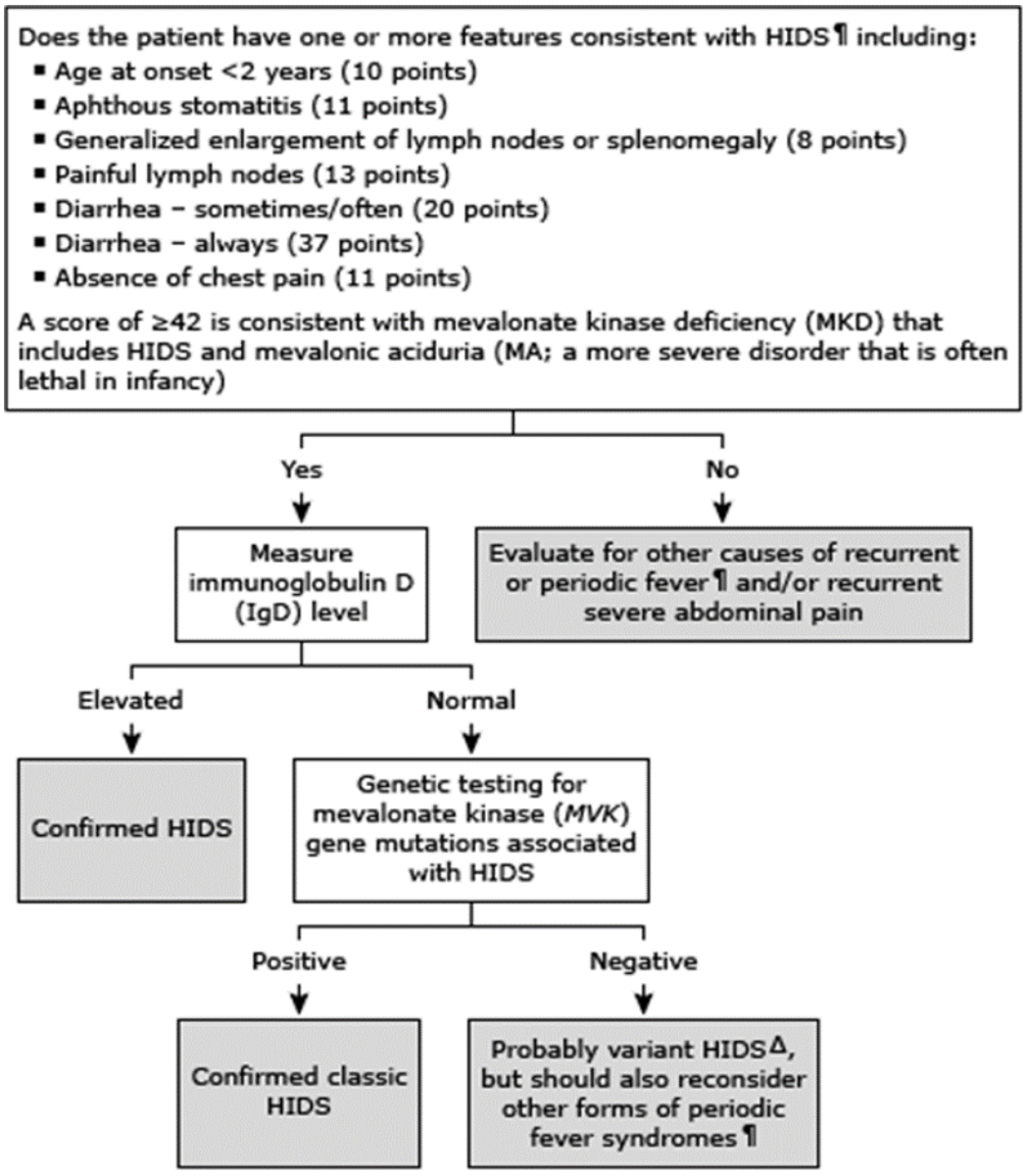
(3) drugs that:

(A) have a boxed warning assigned by the United States Food and Drug Administration for use; and

(B) must have specific provider assessment; or

(4) the use of a drug approved for use by the United States Food and Drug Administration in a manner other than the approved use."

APPENDIX 1:



BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:

Ilaris is indicated for the treatment of MWS or FCAS in patients ≥ 4 years of age.1 CAPS is a rare inherited inflammatory disease associated with overproduction of IL-1. CAPS encompass three rare genetic syndromes. FCAS, MWS, and NOMID are thought to be one condition along a spectrum of disease severity. NOMID was previously known as CINCA. FCAS is the mildest phenotype and NOMID is the most severe.

The inflammatory symptoms in these patients include atypical urticaria, rash that is worse in the evening, fever, chills, severe fatigue, arthralgia, and conjunctival erythema. Exacerbations or flares can be triggered by exposure to cold, stress, exercise, or other stimuli.

Patients with NOMID may have sensorineural hearing impairment, increased intracranial pressure, and joint abnormalities. One-fourth of patients with MWS may develop systemic amyloid A (AA) amyloidosis which usually presents with renal impairment and nephrotic syndrome; amyloidosis is less common in the other forms of CAPS. In the published pivotal trial, only patients with a sustained complete response during the initial 8 weeks of the study were eligible for continuation in the trial. A complete clinical response was observed in 71% of patients 1 week after starting therapy and in 97% of patients (n = 34/35) by Week 8. A single-center observational study found that 9 out of 10 patients with CAPS (n= 8 [MWS]; n = 2 [CINCA]) improved following one dose of Ilaris; results were sustained at median follow- up of 21 months.8 NOMID is the most severe form of the CAPS. Two patients in the published pivotal CAPS trial had both MWS and NOMID. An open-label, multicenter, Phase III study evaluated the use of Ilaris in patients with all phenotypes of CAPS (n = 166) and included 32 patients with NOMID. Of the Ilaris- naïve patients, 78% of patients (n = 85/109) achieved a complete response by Day 21 and an additional 23 patients achieved a partial response (e.g., decrease in C-reactive protein [CRP], serum amyloid A [SAA] levels, disease activity, and/or skin rash). For the entire study population, CRP and SAA normalized while on Ilaris, and by Week 8, 79% of patients had absent/mild disease and 21% of patients had mild to moderate disease. At baseline, four NOMID/CINCA patients reported abnormal neurological findings; following 2 years of treatment with Ilaris, one member showed normalization of these findings. Resolution of macular edema was noted in one eye of aNOMID/CINCA patient, and improvement in blepharitis was recorded in another patient. It is notable that higher doses of Ilaris were required for NOMID/CINCA patients and patients ≤ 40 kg compared with other patients in the cohort. In an open-label Phase I/II study evaluating Ilaris in patients with NOMID (n = 7), no patients had full remission at Month 6 (primary endpoint), but four patients achieved inflammatory remission based on disease activity diary scores and normal CRP. At Month 12 and 18, 100% of patients (n = 4/4 at Month 12 and n = 3/3 for Month 18) were in inflammatory remission. Median duration in the trial was 615 days (range, 232 to 749 days). Data are available in two other patients with NOMID treated with Ilaris with long- term moderate efficacy (per the physician's global assessment [PGA]) [exposure of 120 to 463 days] Ilaris is indicated for treatment of adult and pediatric patients with FMF. Patients with FMF experience recurring bouts of fever, often with severe abdominal pain due to peritonitis. Typical episodes last 12 to 72 hours and the length of time between attacks can range from days to years. Without treatment, amyloidosis may occur.

Guidelines from the European League Against Rheumatism (EULAR) [2016] note that treatment goals are to prevent the clinical attacks and to suppress chronic subclinical inflammation. Colchicine is recommended as soon as a diagnosis is made. IL-1 blockade is mentioned as a treatment option for patients with protracted febrile myalgia. In patients who develop AA amyloidosis, the maximal tolerated dose of colchicine and biologics (especially IL-1 blockade) are recommended. A Phase III study enrolled patients with FMF (n = 63) between the ages of 2 and 69 years with documented active disease despite colchicine therapy or documented intolerance to effective doses of colchicine; 76% of patients did not have a fever at baseline.

Active disease was defined as at least one flare per month; the median number of flares per year was 18. CRP was required to be at least 10 mg/mL (median, 94 mg/mL). Patients were allowed to continue on stable colchicine dose. Of the patients treated with Ilaris, 32% had the dose increased from 150 mg every 4 weeks to 300 mg every 4 weeks. In all, 84% of patients assigned to placebo (n = 27/32) crossed over to receive Ilaris. At Day 15, 81% of patients treated with Ilaris (n =25/31) had resolution of flare vs. 31% of patients (n = 10/32) treated with placebo.

Complete response, defined as resolution of index flare by Day 15 which was maintained through Week 16, was achieved in 61% of patients (n = 19/31) treated with Ilaris vs. 6% of patients (n = 2/32) treated with placebo (P < 0.0001).

Ilaris is indicated in adult and pediatric patients with HIDS/MKD.1 MKD typically begins during infancy. Fevers last from 3 to 6 days and occur as often as 25 times per year.12 During episodes of fever, patients usually experience lymphadenopathy, abdominal pain, joint pain, diarrhea, skin rashes, and headache; amyloidosis may develop. Fever episodes may be triggered by vaccinations, surgery, injury, or stress. Of note, HIDS is considered a less severe type of MKD. Patients with a severe phenotype of MKD may experience growth retardation, ataxia, and cognitive impairment.14 European guidelines for autoinflammatory disorders (2015) note that colchicine is not effective.

Short-term use of IL-1 blockers should be considered for termination of attacks and should be considered to limit or prevent steroid adverse events. Maintenance therapy with an IL-1 blocker maybe used in patients with frequent attacks and/or subclinical inflammation between attacks. A Phase III study enrolled patients (n = 72) with HIDS/MKD who were between the ages of 2 and 47 years. At baseline, 58% of patients did not have a fever. Patients had confirmed diagnosis according to known genetic MVK/enzymatic (MKD) findings and had a history of more than three febrile acute flares within a 6- month period (median of 12 flares per year). CRP was required to be at least 10 mg/mL (median, 113.5 mg/mL). In all, 51% of patients randomized to Ilaris had the dose titrated from 150 mg every 4 weeks to 300 mg every 4 weeks; 87% of patients (n = 31/35) who were randomized to placebo crossed over to receive Ilaris. At Day 15, 65% of patients (n = 24/37) experienced resolution of the index flare.

Complete response, defined as resolution of index flare by Day 15 which was maintained through Week 16, was achieved in 35% of patients treated with Ilaris vs. 6% of patients who received placebo.

Ilaris is indicated in adult and pediatric patients with TRAPS. TRAPS is a rare condition with an estimated prevalence of one case per million individuals. It is categorized by recurrent episodes of fever which can last from days to months. The frequency of the fevers varies and may occur anywhere between every 6 weeks to every few years. Fever may be spontaneous but may also be triggered by events such as a minor injury, infection, stress, exercise, or hormonal changes.

Additional signs and symptoms that may accompany fever include abdominal and muscle pain, spreading skin rash (typically on the limbs), periorbital edema, joint pain, and inflammation in various areas of the body.

Amyloidosis is estimated to occur in 15% to 20% of patients with TRAPS. European recommendations for treatment of autoinflammatory disorders (2015) note that IL-1 blockade is beneficial for the majority of patients with TRAPS. Maintenance therapy with IL-1 blockade, which may limit corticosteroid exposure, is recommended for patients with frequent attacks and/or subclinical inflammation between attacks. A Phase III study enrolled patients (n = 46) between the ages of 2 and 76 years with chronic or recurrent disease activity, defined as six flares per year (median, 9 flares/year); 58% of patients did not have fever at baseline.1 Baseline CRP was required to be at least 10 mg/mL (median, 112.5 mg/mL). In patients treated with Ilaris, 50% of patients (n = 11/22) had their dose increased from 150 mg every 4 weeks to 300 mg every 4 weeks during the16-week treatment period; 87.5% of patients randomized to placebo (n = 21/24) crossed over to receive Ilaris. By Day 15, 63% of patients treated with Ilaris vs. 21% of patients treated with placebo had resolution of the index flare. The proportion of patients who achieved a complete response, defined as resolution of index flare by Day 15 that was maintained through Week 16, was 46% with Ilaris vs. 8% with placebo (P = 0.005).

Ilaris is indicated for the treatment of active SJIA in patients ≥ 2 years of age.1 There are standardized treatment plans published for use of biologic disease-modifying antirheumatic drugs (DMARDs), including Actemra, Kineret, and Ilaris, for use in patients with SJIA.15-16 For Ilaris, the recommendation is to assess at Week 1 or 2 and Month 1, and adjust other therapies (e.g., corticosteroids) if disease is unchanged or worsening. Patients should be reassessed at Month 3, when patients with unchanged or worsening disease or patients whose steroid dose is > 50% of the starting dose should have an increase in

prednisone plus either addition of methotrexate (MTX) OR change to Actemra. Note that when discontinuing Ilaris, patients should wait between 1 and 2 months after discontinuation before switching to a different biologic DMARD. Guidelines from the American College of Rheumatology (ACR) for the management of SJIA (2013) mention Ilaris as a treatment alternative, depending upon the manifestations of SJIA being treated.5 While there are a number of other effective options for treating synovitis in patients with active SJIA, effective options for treatment of MAS are much more limited.
Recommended options for treatment of MAS are limited and include Kineret, calcineurin inhibitors, and systemic corticosteroids (no preferential sequencing noted). The SJIA guidelines note that use of Ilaris is uncertain in MAS in some situations, such as for initial therapy in patients with a poor physician's assessment; however, MAS is a potentially life- threatening situation with limited treatment options. In Phase III studies evaluating Ilaris in patients with SJIA, 56% to 66% of patients had previously tried a biologic therapy.17 At Day 15, 84% of patients receiving Ilaris (n = 36/43) had an adapted JIA ACR 30 response compared with 10%of patients receiving placebo (n = 4/41) [P < 0.001]. In SJIA, Ilaris is administered every 4 weeks.
Adult Onset Stills Disease (AOSD)
The efficacy of ILARIS in adults with AOSD is based on the pharmacokinetic exposure and extrapolation of the established efficacy of ILARIS in SJIA patients. Efficacy of ILARIS was also assessed in a randomized, double-blind, placebo-controlled study that enrolled 36 patients (22 to 70 years old) diagnosed with AOSD. The efficacy data were generally consistent with the results of a pooled efficacy analysis of SJIA patients.

Ilaris received expanded indication to treat gout flares in adults who cannot tolerate or have contraindications to NSAIDs and colchicine and in whom repeated corticosteroids are not appropriate. Safety and effectiveness was determined in two 12 week, randomized, double-blind, active comparator studies in patients with gout flares for whom NSAIDs and/or colchicine were contraindicated, not tolerated or ineffective, and who had experienced at least three gout flares in the previous year. Pain intensity in the most affected joint (based on VAS) was lower for patients treated with Ilaris compared with Triamcinolone 40mg IM. Ilaris also showed a reduction in risk of a new flare over 12 weeks compared with Triamcinolone 40mg IM. 2020 ACR guidelines for the management of gout recommend oral colchicine, NSAIDs, or glucocorticoids (oral, intraarticular, or intramuscular) as appropriate first-line therapy for gout flares over IL-1 inhibitors. For patients experiencing a gout flare for whom other antiinflammatory therapies are poorly tolerated or contraindicated, conditionally recommend using IL-1 inhibition over no therapy (beyond supportive/analgesic treatment). For patients who are NPO, strongly recommend glucocorticoids (intramuscular, intravenous, or intraarticular) over IL-1 inhibitors.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of Ilaris (canakinumab) are considered experimental/investigational and therefore, will follow Molina's Off-Label policy. Contraindications to Ilaris (canakinumab) include: hypersensitivity to the active substance or to any of the excipients, concurrent use with live virus vaccines.

OTHER SPECIAL CONSIDERATIONS:
None

CODING/BILLING INFORMATION

Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

HCPCS CODE	DESCRIPTION
J0638	Injection, canakinumab, 1mg

AVAILABLE DOSAGE FORMS:
Ilaris SOLN 150MG/ML single-dose vial

REFERENCES

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SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Diagnosis Required Medical Information Continuation of Therapy Age Restrictions Place of Administration FDA-Approved Uses Background Contraindications/Exclusions/Discontinuation References	Q4 2023
REVISION- Notable revisions: Required Medical Information Continuation of Therapy Prescriber Requirements FDA-Approved Uses Contraindications/Exclusions/Discontinuation References	Q4 2022
Q2 2022 Established tracking in new format	Historical changes on file