Pharmacy Drug Policy & Procedure

Policy Name:	Ilaris (canakinumab)	Policy#:	2388P

Purpose of the Policy

The purpose of this policy is to define coverage criteria for Ilaris (canakinumab).

Statement of the Policy

Health Alliance Medical Plans will approve the use of Ilaris (canakinumab) under the specialty medical benefit if the following criteria are met.

Criteria

1. Coverage Criteria for Periodic Fever Syndromes

1.1 Diagnosis of one of the following Periodic Fever Syndromes
- Cryopyrin-Associated Periodic Syndromes (CAPS)
- Familial Mediterranean Fever
- Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD)
- Tumor Necrosis Factor (TNF) Receptor-Associated Periodic Syndrome

1.2 Age 4 years or older

2. Coverage Criteria for Systemic Juvenile Idiopathic Arthritis (SJIA)

2.1 Diagnosis of Systemic Juvenile Idiopathic Arthritis (SJIA)

2.2 Age 2 years or older

2.3 Ordered by a Rheumatologist (musculoskeletal doctor)

2.4 Documentation to support one of following:
- Documented trial and failure of one non-steroidal anti-inflammatory drug (NSAID, such as ibuprofen or naproxen) for at least 2 weeks
- Documentation the patient has moderate-to-severe disease including any one of the following symptoms:
  - Fever
  - Serositis (tissue inflammation)
  - Early Macrophage Activation Syndrome (MAS)

3. Coverage Criteria for Adult-Onset Still's Disease (AOSD)

3.1 Diagnosis of Adult-Onset Still's Disease (AOSD) that is considered to be moderate to severe in nature

3.2 Documentation the patient has moderate-to-severe disease including any one of the following symptoms:
- Fever
- Rash
- Arthritis or arthralgia (joint aches or inflammation)

3.3 Ordered by a Rheumatologist (musculoskeletal doctor)

3.4 For patients with moderate disease that has primarily systemic symptoms with no joint erosions:
- Documented failure to respond, intolerance, or contraindication to non-steroidal anti-inflammatory drugs (NSAIDs, such as ibuprofen or naproxen)
- Documented failure to respond, intolerance, or contraindication to glucocorticoids

- Failure to respond defined as requiring prednisone greater than 10mg daily to remain symptoms free

3.5 For patients with severe disease such as life-threatening organ involvement and/or conditions such as severe hepatic (liver) involvement, cardiac tamponade (serious medical condition in which blood or fluids fill the space between the sac that encases the heart and the heart muscle), and/or disseminated intravascular coagulation (condition in which blood clots form throughout the body, blocking small blood vessels);

- Documented failure to respond, intolerance, or contraindication to glucocorticoids

4. Coverage Criteria for Gout Flares

4.1 Diagnosis of gout flares

4.2 Prescribed by or in consultation with a rheumatologist

4.3 Age 18 years or older

4.4 Trial and failure contraindication, or intolerance to ALL of the following:

- Nonsteroidal anti-inflammatory drugs (NSAIDs) (e.g., ibuprofen, naproxen)
- Colchicine
- Corticosteroids (e.g., prednisone

5. Exclusion Criteria

5.1 Inadequate response to initial or previous canakinumab therapy

5.2 Health Alliance does not cover concurrent therapy with other immunomodulators based upon the possible increased risk for infections and other potential pharmacological interactions.

6. Approval Time

6.1 Initial Authorization:12 months

6.2 Subsequent authorizations: 12 months, with documentation of positive clinical response to therapy

CPT Codes	
HCPCS Codes	
J0638	Injection, canakinumab, 1 mg

References

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Idiopathic Arthritis," N Engl J Med, 2012, 367(25):2396-406.
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Created Date: 10/17/15
Effective Date: 10/17/15
Posted to Website: 01/01/22
Revision Date: 04/02/25