Market Applicability															
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**LA**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	X	NA	NA	NA

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Ilaris (canakinumab)

CG-DRUG-74

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Ilaris (canakinumab)	May be subject to quantity limit

APPROVAL CRITERIA

I. Ilaris (canakinumab) may be approved for the treatment of any of the following periodic fever syndromes when the following criteria are met:
   A. Cryopyrin-associated periodic syndromes (CAPS) in an individual 4 years of age or older with **either** of the following:
      1. Familial cold auto inflammatory syndrome (FCAS); **OR**
      2. Muckle-Wells syndrome (MWS);

   OR
   B. Familial Mediterranean fever (FMF) in an individual who meets the following criteria:
      1. Has active type 1 FMF disease with genetic confirmation of the diagnosis (*MEFV* gene exon 10 mutation); **AND**
      2. Has documented recurrent, active disease (that is, at least one flare per month); **AND**
      3. Has failed to respond to, or is intolerant of colchicine therapy;

   OR
   C. Hyperimmunoglobulin D syndrome (HIDS)/mevalonate kinase deficiency (MKD) in an individual who meets the following criteria:
      1. Has HIDS with genetic confirmation of the diagnosis by deoxyribonucleic acid (DNA) analysis **or** enzymatic studies (that is, mutations in the *MVK* gene **or** markedly reduced mevalonate kinase activity); **AND**
      2. Has documented prior history of greater than or equal to three febrile acute flares within a 6-month period when not receiving prophylactic treatment;

   OR
   D. Tumor necrosis factor receptor associated periodic syndrome (TRAPS) in an individual who meets the following criteria:

Market Applicability															
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**LA**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	X	NA	NA	NA

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1. Has TRAPS with genetic confirmation of the diagnosis (*TNFRSF1A* gene mutation); **AND**
2. Has chronic or recurrent disease activity defined as six flares in a 12-month period.

OR

II. Ilaris (canakinumab) may be approved for the treatment of active systemic juvenile idiopathic arthritis (SJIA) when **all** of the following criteria are met:
   A. Individual is 2 years of age or older; **AND**
   B. Agent is used for any of the following reasons:
      1. To reduce signs or symptoms; **OR**
      2. To induce or maintain clinical response;

   AND
   C. Individual has failed to respond to, is intolerant of, or has a medical contraindication to one or more corticosteroids or nonsteroidal anti-inflammatory drugs (NSAIDs); **AND**
   D. May be used alone or in combination with corticosteroids, methotrexate (MTX), or NSAIDs.

Ilaris (canakinumab) may **not** be approved for an individual with **any** of the following:

1. Use of canakinumab in combination other biologic disease-modifying antirheumatic drugs (DMARDs) such as IL-1R antagonists, IL-6 receptor antagonists, Janus kinase inhibitors (for example, Xeljanz [tofacitinib citrate]), or tumor necrosis factor (TNF) antagonists; **or**
2. Tuberculosis, invasive fungal infection, or other active serious infections or a history of recurrent infections; **or**
3. Individual has not had a tuberculin skin test (TST) or Centers for Disease Control and Prevention (CDC)-recommended equivalent to evaluate for latent tuberculosis prior to initiating canakinumab.

Ilaris (canakinumab) may **not** be approved when the criteria are not met and for all other indications, including but not limited to the treatment of:

1. Adult onset Still's disease (AOSD)
2. Behçet's disease
3. Cardiovascular risk reduction and disorder prevention
4. Chronic obstructive pulmonary disease (COPD)
5. Diabetes, Type 1 and Type 2
6. Gout

Market Applicability															
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**LA**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	X	NA	NA	NA

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7. Gouty arthritis
8. Heart failure
9. Majeed syndrome
10. Neonatal-onset multisystem inflammatory disease (NOMID)
11. Polyarticular juvenile idiopathic arthritis (PJIA)
12. Rheumatoid arthritis (RA)
13. Schnitzler syndrome

State Specific Mandates		
State name N/A	Date effective N/A	Mandate details (including specific bill if applicable) N/A

Key References:

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