

GCHP Medi-Cal Clinical Guidelines Canakinumab (Ilaris™)

PA Criteria	Criteria Details
Covered Uses (FDA Approved Indication)	<ul style="list-style-type: none"> Periodic fever syndrome <ul style="list-style-type: none"> Cryopyrin-associated periodic syndromes (CAPS) including familial cold auto-inflammatory syndrome (FCAS) and mucklewells syndrome (MWS). Tumor necrosis factor receptor associated periodic syndrome (TRAPS). Hyperimmunoglobulin D syndrome (HIDS)/Mevalonate kinase deficiency (MKD). Familial mediterranean fever (FMF). Active still's disease including adult-onset still's disease (AOSD) and systemic juvenile idiopathic arthritis (SJIA). Gout flares in whom 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.
Exclusion Criteria	<ul style="list-style-type: none"> Serious active infection Untreated latent or active tuberculosis Concurrent treatment with tumor necrosis factor (TNF) inhibitor
Required Medical Information	<p>CAPS – specialist clinic notes confirming active disease</p> <p>TRAPS – specialist clinic notes confirming chronic or recurrent disease with greater than six febrile episodes per year.</p> <p>HIDS/MKDS – specialist clinic notes confirming at least three febrile episodes in six-month periods.</p> <p>FMF – specialist clinic notes confirming at least one or more febrile episodes per month despite treatment with or unacceptable side effects to colchicine.</p> <p>AOSD</p> <ul style="list-style-type: none"> Specialist clinic notes confirming the diagnosis AND Active adult-onset still disease with active arthritis in four or more joints AND Inadequate response to biologic DMARDs, conventional DMARDs (e.g., methotrexate), glucocorticoids, or NSAIDs. <p>SJIA</p> <ul style="list-style-type: none"> Active arthritis involving one or more joints AND Fever for at least two weeks AND Signs or symptoms as indicated by at least one or more of the following: (i) evanescent erythematous rash, (ii) generalized lymphadenopathy, (iii) hepatomegaly or splenomegaly, or (iv) pericarditis, pleuritis, or peritonitis.



	Gout flares <ul style="list-style-type: none">• NSAIDs and colchicine are contraindicated, are not tolerated, or do not provide an adequate response AND• Repeated courses of corticosteroids are not appropriate.						
Age Restriction	FMF, HID/MKD, TRAPS, AOSD and SJIA: 2 years of age and older CAPS, FCAS, MWS: 4 years of age and older Gout flares: 18 years of age and older						
Prescriber Restrictions	CAPS, FCAS, MWS, FMF, HID/MKD, TRAPS, AOSD or SJIA: Prescribed or recommended by a rheumatologist, or immunologist.						
Coverage Duration	Initial: Six months: Renewal: 12 months						
Other Criteria / Information	<div>Criteria adapted from DHCS March 2024 & MCG.</div> <table><tr><th>HCPCS</th><th>Description</th><th>Dosing, Units</th></tr><tr><td>J0638</td><td>Injection, canakinumab, 1mg (Ilaris™)</td><td>CAPS: > 40kg – 150mg subcutaneous every eight weeks; < 40kg and ≥ 15kg – 2mg/kg every eight weeks (in peds may increase to 3mg/kg). TRAPS, HIDS/MKD & FMF: > 40kg – 150mg every four weeks (may increase up to 300mg); ≤ 40kg – 2mg/kg every four weeks (may increase to 4mg/kg every four weeks). AOSD & SJIA: ≥ 7.5kg – 4mg/kg (max dose of 300mg) every four weeks. Gout flares: 150mg x one dose. Re-treatment at interval of at least 12 weeks.</td></tr></table>	HCPCS	Description	Dosing, Units	J0638	Injection, canakinumab, 1mg (Ilaris™)	CAPS: > 40kg – 150mg subcutaneous every eight weeks; < 40kg and ≥ 15kg – 2mg/kg every eight weeks (in peds may increase to 3mg/kg). TRAPS, HIDS/MKD & FMF: > 40kg – 150mg every four weeks (may increase up to 300mg); ≤ 40kg – 2mg/kg every four weeks (may increase to 4mg/kg every four weeks). AOSD & SJIA: ≥ 7.5kg – 4mg/kg (max dose of 300mg) every four weeks. Gout flares: 150mg x one dose. Re-treatment at interval of at least 12 weeks.
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STATUS	DATE REVISED	REVIEW DATE	APPROVED / REVIEWED BY	EFFECTIVE DATE
Created	5/1/2024	5/1/2024	Yoonhee Kim, Clinical Programs Pharmacist Lily Yip, Director of Pharmacy Services	N/A
Approved	N/A	5/15/2024	Pharmacy & Therapeutics (P&T) Committee	3/1/2025
Approved	N/A	7/18/2024	Medical Advisory Committee (MAC)	3/1/2025



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