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Canakinumab

Adjudication Guideline

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Approved by:
Daman

Responsible:
Medical Standards & Research

Related Adjudication Guidelines: NA

Abstract

For Members

Canakinumab is used to treat Periodic Fever Syndromes such as Cryopyrin-Associated Periodic Syndromes (CAPS) and Familial Mediterranean Fever (FMF), and also to treat active Systemic Juvenile Idiopathic Arthritis (SJIA).

For Medical Professionals

Canakinumab is an interleukin-1β (IL-1β) blocker, which works to suppress the production of an inflammatory protein in the body. IL-1β is a pro-inflammatory protein released in states of infection and inflammation. Overproduction of IL-1β creates inflammation in the body resulting in symptoms such as fever, joint pain, and rashes. Canakinumab is a human monoclonal antibody which binds to the IL-1β protein and prevents it from attaching to its cellular receptor.

Scope

The scope of this adjudication rule is to highlight the medical indications, and coverage details for Canakinumab as per the policy terms and conditions of each health insurance plan administered by Daman.

Adjudication Policy

Eligibility / Coverage Criteria

Canakinumab is an interleukin-1β blocker indicated for the treatment of the following [1,2]:

1. autoinflammatory Periodic Fever Syndromes in adults, adolescents and children aged 2 years and older:

   a) Cryopyrin-associated periodic syndromes (CAPS):
   Canakinumab is indicated for the treatment of cryopyrin-associated periodic syndromes (CAPS) including:
   - Muckle-Wells syndrome (MWS),
   - Neonatal-onset multisystem inflammatory disease (NOMID) / chronic infantile neurological, cutaneous, articular syndrome (CINCA),
   - Severe forms of familial cold autoinflammatory syndrome (FCAS) / familial cold urticaria (FCU) presenting with signs and symptoms beyond cold-induced urticarial skin rash.

   b) Tumour necrosis factor receptor associated periodic syndrome (TRAPS):
   Canakinumab is indicated for the treatment of tumour necrosis factor (TNF) receptor associated periodic syndrome (TRAPS). Physician's Global Assessment score greater than or equal to 2, or C-reactive protein (CRP) greater than 10 mg/L [1].

   c) Hyperimmunoglobulin D syndrome (HIDS)/mevalonate kinase deficiency (MKD):
   Canakinumab is indicated for the treatment of hyperimmunoglobulin D syndrome (HIDS)/mevalonate kinase deficiency (MKD). Physician's Global Assessment score greater than or equal to 2, or C-reactive protein (CRP) greater than 10 mg/L [1].

   d) Familial Mediterranean fever (FMF):
   Canakinumab is indicated for the treatment of Familial Mediterranean Fever (FMF). It should be given in combination with colchicine, if appropriate. Physician's Global Assessment score greater than or equal to 2, or C-reactive protein (CRP) greater than 10 mg/L [1].

2. Still's disease
Canakinumab is indicated for the treatment of active Still's disease including adult-onset Still's disease (AOSD).

3. Systemic juvenile idiopathic arthritis (SJIA) in patients aged 2 years and older who have responded inadequately to previous therapy with non-steroidal anti-inflammatory drugs (NSAIDs) and systemic corticosteroids. Canakinumab can be given as monotherapy or in combination with methotrexate.

4. Gouty arthritis:
   Canakinumab is indicated for the symptomatic treatment of adult patients with frequent gouty arthritis attack (at least 3 attacks in the previous 12 months) 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.

Assessment Prior to Initiating

- Tuberculosis (TB) test within the past 12 months is negative, or if positive, active TB has been ruled out and the patient has received treatment for latent TB infection [1,2].
- Known hypersensitivity to any component of Canakinumab.
- Active infection, including localized infections.

Requirements for Coverage

- Failure to submit, upon request or when requesting a clinical history, indication the need for testing will result in rejection of claim.
- Kindly code the ICD-10 and the CPT codes to the highest level of specificity
- Eligible clinician specialities

Eligible clinician specialities
Rheumatologist
Internal medicine
Paediatrics

Non-Coverage

- Non- FDA approved indication
- Age less than 2 years

Payment and Coding Rules

Kindly apply DOH payment rules and regulations and relevant coding manuals for ICD, Drugs.

Denial codes

Regulator denial codes with description are elaborated for reference. These are specialized codes directed by regulator, that explains the reason of rejection of the service by DAMAN to the providers.

Code	Code description
CODE-010	Activity/diagnosis inconsistent with clinician's speciality
MNEC-003	Service is not clinically indicated based on good clinical practice
MNEC-004	Service is not clinically indicated based on good clinical practice, without additional supporting diagnosis/activities
MNEC-005	Service/supply may be appropriate, but too frequent
CLAI-012	Submission not compliant with contractual agreement between provider & payer
PRCE-002	Payment is included in the allowance for another service.
CODE-013	Invalid principal diagnosis (for example E-codes)

Appendices

A. References

1. *https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/BLA125319_858687lbl.pdf*
2. *https://www.ema.europa.eu/en/documents/product-information/ilaris-epar-product-information_en.pdf*

B. Revision History

Date	Change(s)
27/12/2022	Release of V1.0