Secukinumab

Adjudication Guideline

Rule Category: Pharmaceutical	**Ref: No:** 2023-PH-022	**Version Control:** Version No. V1.0	**Effective Date:** 25th August 2023	**Last Update:** 25th July 2023
Approved by: Daman	**Responsible:** Medical Standards & Research	**Related Adjudication Guidelines:** NA		

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1. Abstract

1.1 For Members

Secukinumab is used for the treatment of psoriasis, ankylosing spondylitis, psoriatic arthritis, Non-Radiographic Axial Spondyloarthritis, Enthesitis-Related Arthritis and Hidradenitis suppurativa.

1.2 For Medical Professionals

Secukinumab is a human IgG1 monoclonal antibody that selectively binds to the interleukin-17A (IL-17A) cytokine and inhibits its interaction with the IL-17 receptor. IL-17A is a naturally occurring cytokine that is involved in normal inflammatory and immune.

2. Scope

This Adjudication Rule highlights the coverage and payment requirements by Daman as per policy terms and conditions for Secukinumab. It also highlights the medical criteria for coverage.

3. Adjudication Policy

3.1 Eligibility / Coverage Criteria

Medical Indications

1. **Moderate to severe plaque psoriasis** [1,2,4]

- 6 years of age or older
- Body Surface Area (BSA) of greater than 5% OR BSA less than 5% and there is involvement of the scalp, face, the palms and soles (i.e., palmoplantar disease), or genitals.
- Documentation of ONE of the following:
  - Failure to ONE of the following, unless contraindicated or intolerant:
    a. Topical therapy (for example, topical corticosteroids, topical vitamin D analogs, Tazorac)
    b. Systemic therapy (for example, methotrexate, cyclosporine, Soriatane)
    c. Phototherapy
  - Already tried a biologic or targeted synthetic DMARD for Plaque Psoriasis
- Medication is prescribed by, or in consultation with, a dermatologist.

2. **Active psoriatic arthritis (PsA)** [1,2,5,6]

- 2 years of age or older.
- Documentation of ONE of the following:
  - For Non-axial disease, failure to ONE disease-modifying anti-rheumatic drug (DMARD), unless contraindicated or intolerant
  - For Axial disease, failure to ONE disease-modifying anti-rheumatic drug (DMARD), OR a nonsteroidal anti-inflammatory drug (NSAID), unless contraindicated or intolerant

- Already tried a biologic or targeted synthetic DMARD.
- Medication is being prescribed by, or in consultation with a, rheumatologist or dermatology

3. **Adults with active ankylosing spondylitis (AS)** [1,2,4]

- Individual 18 years of age or older
- Documentation of ONE of the following:
  - Failure, contraindication or intolerance to ONE non-steroidal anti-inflammatory drug (NSAID)
  - Already tried a biologic or targeted synthetic DMARD.
- Medication is being prescribed by, or in consultation with, a rheumatologist

4. **Non-Radiographic Axial Spondyloarthritis** [1,2,4]

- Individual 18 years of age or older
- Has objective signs of inflammation, defined as ONE of the following:
  - C-reactive protein (CRP) elevated beyond the upper limit of normal for the reporting laboratory
  - Sacroiliitis reported on magnetic resonance imaging (MRI)
- Medication is being prescribed by, or in consultation with, a rheumatologist.

5. **Enthesitis-Related Arthritis** [1,2,5,6,3]

- 4 years of age or older
- Medication is prescribed by, or in consultation with, a rheumatologist.

6. **Hidradenitis suppurativa** [7]

Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency has adopted a positive opinion and recommended granting a marketing authorization for secukinumab in adults with active moderate to severe hidradenitis suppurativa (HS).

DOSAGE AND ADMINISTRATION [1,2,3,4,5,6]

1. **Plaque Psoriasis** [1,3]**:**

Adults: The recommended dosage is 300 mg by subcutaneous injection at Weeks 0, 1, 2, 3, and 4 followed by 300 mg every 4 weeks. Each 300 mg dosage is given as 2 subcutaneous injections of 150 mg. For some patients, a dose of 150 mg may be acceptable.

Pediatric Patients
The recommended dose is based on body weight and administered by subcutaneous injection with initial dosing at weeks 0, 1, 2, 3 and 4, followed by monthly maintenance dosing. Each 75 mg dose is given as one subcutaneous injection of 75 mg. Each 150 mg dose is given as one subcutaneous injection of 150 mg. Each 300 mg dose is given as one subcutaneous injection of 300 mg or as two subcutaneous injections of 150 mg

Body Weight at Time of Dosing	Recommended Dose
<25 kg	75 mg
25 to <50 kg	75 mg
≥50 kg	150 mg (*may be increased to 300 mg)

**Some patients may derive additional benefit from the higher dose.*

2. **Psoriatic Arthritis [1]:** For psoriatic arthritis patients with coexistent moderate to severe plaque psoriasis, use the dosage and administration for plaque psoriasis. For other psoriatic arthritis patients administer with or without a loading dosage. The recommended dosage:

    - With a loading dosage is 150 mg at weeks 0, 1, 2, 3, and 4 and every 4 weeks thereafter.
    - Without a loading dosage is 150 mg every 4 weeks.
    - If a patient continues to have active psoriatic arthritis, consider a dosage of 300mg every 4 weeks.

    Note: *Secukinumab may be administered with or without methotrexate.*

3. **Ankylosing Spondylitis [1]:** Administer with or without a loading dosage. The recommended dosage:

    - With a loading dosage is 150 mg at weeks 0, 1, 2, 3, and 4 and every 4 weeks thereafter.
    - Without a loading dosage is 150 mg every 4 weeks
    - If a patient continues to have active ankylosing spondylitis, consider a dosage of 300 mg every 4 weeks.

4. **Non-Radiographic Axial Spondyloarthritis [3]:**

    Administer with or without a loading dosage by subcutaneous injection. The recommended dosage:

    - With a loading dosage is 150 mg at Weeks 0, 1, 2, 3, and 4 and every 4 weeks thereafter.
    - Without a loading dosage is 150 mg every 4 weeks.

5. **Juvenile idiopathic arthritis (JIA) [3]:**

Enthesitis-related arthritis (ERA) and juvenile psoriatic arthritis (JPsA) The recommended dose is based on body weight (Table 2) and administered by subcutaneous injection at weeks 0, 1, 2, 3, and 4, followed by monthly maintenance dosing. Each 75 mg dose is given as one subcutaneous injection of 75 mg. Each 150 mg dose is given as one subcutaneous injection of 150 mg.

Body Weight at Time of Dosing	Recommended Dose
<50 kg	75 mg
≥50 kg	150 mg

Immunizations[1,2]: Prior to initiating therapy with secukinumab, consider completion of all age appropriate immunizations according to current immunization guidelines. Secukinumab may alter a patient`s immune response to live vaccines. Avoid use of live vaccines in patients treated with secukinumab.
Patients treated with secukinumab may receive non-live vaccinations. The clinical effectiveness of meningococcal and influenza vaccines has not been assessed in patients undergoing treatment with secukinumab.

Prior to Treatment [2]: Evaluate patients for tuberculosis (TB) infection prior to initiating treatment with secukinumab. Avoid administration of secukinumab to patients with active TB infection. Initiate treatment of latent TB prior to administering secukinumab. Consider anti-TB therapy prior to initiation of secukinumab in patients with a past history of latent or active TB in whom an adequate course of

treatment cannot be confirmed. Monitor patients closely for signs and symptoms of active TB during and after treatment.

Eligible clinical specialities

Eligible clinical specialities
Dermatologist
Rheumatologist

3.2 Requirements for Coverage

- Failure to submit, upon request or when requesting a clinical history, an indication and the need for testing will result in the rejection of the claim.

3.3 Non-Coverage

- Secukinumab is not covered when the above criteria are not met.
- Coverage as per member SOB

3.4 Payment and Coding Rules

- Please apply regulator payment rules and regulations and relevant coding manuals for ICD, CPT, etc.

4. Denial Codes

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

Code	Code Description
MNEC003	Diagnoses are not covered
MNEC004	Service is not clinically indicated based on good clinical practice
CODE-010	Activity/diagnosis inconsistent with clinician's specialty
CLN-001	Activity/diagnosis inconsistent with clinician's specialty
NCOV-003	Service(s) is (are) not covered
Auth-001	Prior approval is required and was not obtained

5. Appendices

5.1 References

1. *https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/125504s013lbl.pdf*
2. *https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/125504s043lbl.pdf*
3. *https://www.ema.europa.eu/en/documents/product-information/cosentyx-epar-product-information_en.pdf*

5.2 Revision History

Date	Change(s)
25/07/2023	Release of V1.0

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