Ixekizumab

Adjudication Guideline

Rule Category: Pharmaceutical	**Ref: No:** 2023-PH-23	**Version Control:** Version No. V1.0	**Effective Date:** 25th August 2023	**Last Update** 1st November 2024
Approved by: Daman	**Responsible:** Medical Standards & Research	**Related Adjudication Guidelines:** NA		

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1. Abstract

1.1 For Members

Ixekizumab is a biologic medication used to treat psoriatic arthritis, plaque psoriasis, ankylosing spondylitis, and non-radiographic axial Spondylarthritis.

1.2 For Medical Professionals

Ixekizumab is a humanized interleukin-17A antagonist.

2. Scope

This adjudication rule highlights the coverage and payment requirements by Daman as per policy terms and conditions for Ixekizumab. It also highlights the medical criteria for coverage.

3. Adjudication Policy

3.1 Eligibility / Coverage Criteria

Medical Indications

1. **Plaque psoriasis**: is indicated for the treatment of patients 6 years of age and older with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy.
   - Involvement of body surface area (BSA) of greater than 5%.
   - Failure to ONE of the following, unless contraindicated or intolerant:
     - Topical therapy (for example, topical corticosteroids, topical vitamin D analogs, Tazorac)
     - Systemic therapy (for example, methotrexate, cyclosporine, acitretin)
     - Phototherapy
   - Medication is being prescribed by, or in consultation with, a dermatologist

2. **Psoriatic arthritis**: is indicated for the treatment of adult patients with active psoriatic arthritis.
   - Already tried a biologic or targeted synthetic DMARD for Psoriatic Arthritis .

3. **Ankylosing spondylitis** is indicated for the treatment of adult patients with active ankylosing spondylitis.
   - Failure, contraindication, or intolerance to ONE non-steroidal anti-inflammatory drug (NSAID) and already tried a biologic or targeted synthetic DMARD for Ankylosing Spondylitis.

4. **Non-radiographic axial Spondyloarthritis** is indicated for the treatment of adult patients with active non-radiographic axial Spondyloarthritis with objective signs of inflammation.
   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)

DOSAGE AND ADMINISTRATION

1. **Plaque psoriasis in adults**

   The recommended dose is 160 mg by subcutaneous injection (two 80 mg injections) at week 0, followed by 80 mg (one injection) at weeks 2, 4, 6, 8, 10, and 12, then maintenance dosing of 80 mg (one injection) every 4 weeks (Q4W).

   Paediatric plaque psoriasis

   - For patients **weighing greater than 50 kg**, the recommended dosage is 160 mg (two 80 mg injections) at Week 0, followed by 80 mg every 4 weeks.
   - For patients **weighing 25-50 kg**, the recommended dosage is 80 mg at Week 0, followed by 40 mg every 4 weeks.
   - For patients **weighing less than 25 kg**, the recommended dosage is 40 mg at Week 0, followed by 20 mg every 4 weeks.

2. **Psoriatic arthritis**

   The recommended dose is 160 mg by subcutaneous injection (two 80 mg injections) at week 0, followed by 80 mg (one injection) every 4 weeks thereafter. For psoriatic arthritis patients with concomitant moderate to severe plaque psoriasis, the recommended dosing regimen is the same as for plaque psoriasis.

3. **Axial Spondyloarthritis (radiographic and non-radiographic)**

   The recommended dose is 160 mg (two 80 mg injections) by subcutaneous injection at week 0, followed by 80 mg every 4 weeks.

4. **Ankylosing Spondylitis**

   The recommended dosage is 160 mg by subcutaneous injection (two 80 mg injections) at Week 0, followed by 80 mg every 4 weeks.

Discontinuation of the therapy : For all indications (plaque psoriasis in adults and children, psoriatic arthritis, axial Spondyloarthritis) consideration should be given to discontinuing treatment in patients who have shown no response after 16 to 20 weeks of treatment. Some patients with initially partial response may subsequently improve with continued treatment beyond 20 weeks.

Immunizations

Complete all age-appropriate vaccinations as recommended by current immunization guidelines prior to initiating treatment with ixekizumab.

Prior to Treatment

Evaluate patients for tuberculosis (TB) infection. Ixekizumab initiation is not recommended in patients with active TB infection. Initiate treatment of latent TB prior to initiation of ixekizumab.

Drug to Drug interactions : In plaque psoriasis studies, the safety of ixekizumab in combination with other immunomodulatory agents or phototherapy has not been evaluated. Ixekizumab was not affected by concomitant administration of oral corticosteroids, NSAIDs, sulfasalazine, or methotrexate.

Eligible clinical specialties

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

- Ixekizumab 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/2022/125521s024lbl.pdf*
2. *https://www.ema.europa.eu/en/documents/product-information/taltz-epar-product-information_en.pdf*
3. *https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/125521s032lbl.pdf*

5.2 Revision History

Date	Version No.	Change(s)
25/07/2023	V1.0	Release of V1.0
1/11/2024	V2.0	Release of V2.0