

Ixekizumab

Adjudication Guideline

Rule Category:
Pharmaceutical

Ref: No:
2023-PH-23

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

Table of Contents

1.	Abstract	3
1.1	For Members.....	3
1.2	For Medical Professionals.....	3
2.	Scope	3
3.	Adjudication Policy.....	3
3.1	Eligibility / Coverage Criteria.....	3
3.2	Requirements for Coverage	5
3.3	Non-Coverage.....	5
3.4	Payment and Coding Rules	5
4.	Denial codes	5
5.	Appendices	5
5.1	References	5
5.2	Revision History	5

1. Abstract

1.1 For Members

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

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 ^{1,2}

- 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% ^{2,6}.
 - 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 ⁶.
- 3. Ankylosing spondylitis** is indicated for the treatment of adult patients with active ankylosing spondylitis ⁶.
 - 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 ⁶:
 - 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 ^{1,2}

1. Plaque psoriasis in adults ^{1,2}

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 ¹

- 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 ^{1,2}

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) ^{1,2}

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 ¹

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 ²: 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 ^{1,2}

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

Prior to Treatment ^{1,2}

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 ²: 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 specialties
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

5.2 Revision History

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

Disclaimer

By accessing these Daman Adjudication Guidelines, you acknowledge that you have read and understood the terms of use set out in the disclaimer below:

The information contained in this Adjudication Guideline is intended to outline the procedures of adjudication of medical claims as applied by the National Health Insurance Company – Daman PJSC (hereinafter "Daman"). The Adjudication Guideline is not intended to be comprehensive, should not be used as treatment guidelines and should only be used for the purpose of reference or guidance for adjudication procedures and shall not be construed as conclusive. Daman in no way interferes with the treatment of patient and will not bear any responsibility for treatment decisions interpreted through Daman Adjudication Guideline. Treatment of patient is and remains at all times the sole responsibility of the treating Healthcare Provider. This Adjudication Guideline does not grant any rights or impose obligations on Daman. The Adjudication Guideline and all of the information it contains are provided "as is" without warranties of any kind, whether express or implied which are hereby expressly disclaimed.

Under no circumstances will Daman be liable to any person or business entity for any direct, indirect, special, incidental, consequential, or other damages arising out of any use of, access to, or inability to use or access to, or reliance on this Adjudication Guideline including but without limitation to, any loss of profits, business interruption, or loss of programs or information, even if Daman has been specifically advised of the possibility of such damages. Daman also disclaims all liability for any material contained in other websites linked to Daman website.

This Adjudication Guideline is subject to the laws, decrees, circulars and regulations of Abu Dhabi and UAE. Any information provided herein is general and is not intended to replace or supersede any laws or regulations related to the Adjudication Guideline as enforced in the UAE issued by any governmental entity or regulatory authority, or any other written document governing the relationship between Daman and its contracting parties.

This Adjudication Guideline is developed by Daman and is the property of Daman and may not be copied, reproduced, distributed or displayed by any third party without Daman's express written consent. This Adjudication Guideline incorporates the Current Procedural Terminology (CPT®), which is a registered trademark of the American Medical Association ("AMA") and the CPT codes and descriptions belong to the AMA. Daman reserves the right to modify, alter, amend or obsolete the Adjudication Guideline at any time by providing one month prior notice.