

<b>Clinical Policy Title:</b>	ixekizumab
<b>Policy Number:</b>	RxA.748
<b>Drug(s) Applied:</b>	Taltz®
<b>Original Policy Date:</b>	04/18/2022
<b>Last Review Date:</b>	12/05/2024
<b>Line of Business Policy Applies to:</b>	All lines of business (except Medicare)

## Criteria

### I. Initial Approval Criteria

#### A. Ankylosing Spondylitis (must meet all):

1. Diagnosis of active ankylosing spondylitis (AS) or non-radiographic axial spondyloarthritis (nr-axSpA);
2. Trial and failure of at least two (2) non-steroidal anti-inflammatory drugs (NSAIDs) each used for at least  $\geq 4$  weeks unless contraindicated or clinically significant adverse effects are experienced;
3. Member meets (a or b):
  - a. For Ankylosing Spondylitis: Trial and failure of at least one (1) of the following agents: adalimumab (Abrilada™, Hadlima™, or adalimumab-aaty), Cimzia®, Simponi Aria®, Simponi®, Enbrel®, Rinvoq®\*, Xeljanz®/XR®\*, unless contraindicated or clinically significant adverse effects are experienced;  
\*Trial of Rinvoq®, Xeljanz®/XR®\* requires inadequate response to one or more TNF inhibitors
  - b. For non-radiographic axial spondyloarthritis: Trial and failure of any one (1) of the following agents: Cimzia® or Rinvoq®\*, unless contraindicated or clinically significant adverse effects are experienced;  
\*Trial of Rinvoq® requires inadequate response to one or more TNF inhibitor.

#### Approval Duration

**All Lines of Business (except Medicare):** 12 months

#### B. Plaque Psoriasis (must meet all):

1. Diagnosis of Plaque Psoriasis (PsO);
2. Trial and failure of  $\geq 3$  months of at least one (1) conventional systemic therapy {methotrexate (MTX), cyclosporin, acitretin}, or phototherapy {psoralen plus ultraviolet A light (PUVA)} unless contraindicated or clinically significant adverse effects are experienced;  
\*Exception: If one biologic DMARD that is FDA-approved for plaque psoriasis has been previously tried, then trial of a conventional systemic agent or phototherapy is not required;
3. Trial and failure of at least one (1) of the following agents: (Abrilada™, Hadlima™, or adalimumab-aaty), Cimzia®, Enbrel®, Skyrizi®, Tremfya® or Stelara® unless contraindicated or clinically significant adverse effects are experienced.

#### Approval Duration

**All Lines of Business (except Medicare):** 12 months

#### C. Psoriatic Arthritis (must meet all):

1. Diagnosis of Psoriatic Arthritis (PsA);

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

2. Trial and failure of at least one (1) of the following agents: (Abrilada™, Hadlima™, or adalimumab-aaty), Cimzia®, Enbrel®, Stelara®, Skyrizi®, Tremfya®, Rinvoq®\*, Xeljanz®/XR\*, Simponi Aria®, Simponi® unless contraindicated or clinically significant adverse effects are experienced;  
\* Trial of Rinvoq®, Xeljanz®/XR\*, requires inadequate response to one or more TNF inhibitors

**Approval Duration**

**All Lines of Business (except Medicare):** 12 months

**II. Continued Therapy Approval**

**A. All Indications in Section I (must meet all):**

1. Member is currently receiving medication that has been authorized by RxAdvance or the member has met initial approval criteria.

**Approval Duration**

**All Lines of Business (except Medicare):** 12 months

**References**

1. Boulos P, Dougados M, MacLeod SM, et al. Pharmacological Treatment of Ankylosing Spondylitis. Drugs. 2005; 65: 2111-2127. Available at: <https://pubmed.ncbi.nlm.nih.gov/16225367/>. Accessed November 25, 2024.
2. Braun J, Davis J, Dougados M, et al. First update of the international ASAS consensus statement for the use of anti-TNF agents in patients with ankylosing spondylitis. Ann Rheum Dis. 2006; 65:316-320. Available at: <https://pubmed.ncbi.nlm.nih.gov/16096329/>. Accessed November 25, 2024.
3. Gossec L, Smolen JS, Ramiro S, et al. European League Against Rheumatism (EULAR) recommendations for the management of psoriatic arthritis with pharmacological therapies: 2015 update. Ann Rheum Dis 2015; 0:1-12. doi:10.1136/annrheumdis-2015-208337. Available at: <https://pubmed.ncbi.nlm.nih.gov/26644232/>. Accessed November 25, 2024.

Review/Revision History	Review/Revision Date	P&T Approval Date
RxA.592.Biologic_DMARDs was last reviewed and updated on 01/05/2022 and archived on 04/18/2022. For details, please refer to RxA.592.Biologics DMARDs.	02/16/2022	04/18/2022
Drug specific policy for Taltz was created based on RxA.592.Biologic DMARDs: <ol style="list-style-type: none"> <li>1. Initial Approval Criteria, 1.A: Updated indication from Axial Spondylitis to Ankylosing Spondylitis.</li> <li>2. Initial Approval Criteria, 1.A.5, 1.B.5 and 1.C.4: Updated to include new trial and failure criteria Trial and failure of at least one (1) of the following agents: Humira®, Cimzia®, Simponi Aria® or Simponi® unless contraindicated or</li> </ol>	02/16/2022	04/18/2022

<p>clinically significant adverse effects are experienced.</p> <p>3. Initial Approval Criteria, 1.B.4: Updated trial and failure criteria to include phototherapy {psoralen plus ultraviolet A light (PUVA)}.</p> <p>4. References were reviewed and updated.</p>		
<p>Policy was reviewed:</p> <p>1. Initial Approval Criteria, I.A.5.a: Updated trial and failure criteria to include drug Enbrel®, Rinvoq® and Xeljanz®/XR®.</p> <p>2. Initial Approval Criteria, I.B.5 and I.C.4: Updated trial and failure criteria to include drug Enbrel®.</p> <p>3. References were reviewed and updated.</p>	10/03/2022	10/19/2022
<p>Policy was reviewed:</p> <p>1. Initial Approval Criteria I.C.4 and I.A.5.a: Updated to add Trial of Rinvoq®, Xeljanz®/XR®* requires inadequate response to one or more TNF inhibitors.</p> <p>2. Initial Approval Criteria I.A.5.b: Updated to add Rinvoq®, as one of trial and failure drug and added that trial of Rinvoq®, requires inadequate response to one or more TNF inhibitors.</p> <p>3. References were reviewed and updated.</p>	01/03/2023	01/17/2023
<p>Policy was reviewed:</p> <p>1. Initial Approval Criteria, I.A.5.a, I.B.5 and I.C.4: Updated trial and failure criteria to include new drug Amjevita™.</p> <p>2. References were reviewed and updated.</p>	04/05/2023	04/13/2023
<p>Policy was reviewed:</p>	11/10/2023	2/28/2024

<ol style="list-style-type: none"> <li>1. Updated trial and failure criteria to include Humira biosimilar.</li> <li>2. Updated Approval duration.</li> <li>3. Removed responding positively criteria.</li> <li>4. Removed age requirements.</li> <li>5. References were reviewed and updated.</li> </ol>		
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> <li>1. Removed prescriber restrictions.</li> <li>2. Updated adalimumab biosimilars</li> <li>3. References were reviewed and updated.</li> </ol>	<p>11/25/2024</p>	<p>12/5/2024</p>