

Clinical Policy Title:	tildrakizumab-asmn
Policy Number:	RxA.736
Drug(s) Applied:	Ilumya®
Original Policy Date:	04/18/2022
Last Review Date:	12/05/2024
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Plaque Psoriasis (must meet all):

1. Diagnosis of Plaque Psoriasis (PsO);
2. Trial and failure of ≥ 3 months of at least one (1) conventional systemic therapy (methotrexate [MTX], cyclosporin, acitretin) or phototherapy (psoralen plus ultraviolet A light [PUVA]) at up to maximally indicated doses 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. Member meets both (a and b):
 - a. Trial and failure of at least three (3) first line agents: adalimumab (Abrilada, Hadlima or adalimumab-aaty), Cimzia®, Enbrel®, Skyrizi®, Tremfya® or Stelara® unless contraindicated or clinically significant adverse effects are experienced;
 - b. Trial and failure of Taltz® unless contraindicated or clinically significant adverse effects are experienced.

Approval Duration

All Lines of Business (except Medicare): 12 months

II. Continued Therapy Approval

A. Plaque Psoriasis (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

Not Applicable

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.Biologic_DMARDs	01/05/2022	04/18/2022
Drug specific policy for Ilumya® was created based on	02/09/2022	04/18/2022

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.

<p>RxA.592.Biologics_DMARDs:</p> <ol style="list-style-type: none"> 1. Initial Approval Criteria, 1.A.4: Updated trial and failure criteria to rephrase and include phototherapy (psoralen plus ultraviolet A light [PUVA]). 2. Initial Approval Criteria, I.A.5 updated to remove Failure of two of the following, each used for ≥ 3 months, unless contraindicated or clinically significant adverse effects are experienced: Cimzia®, Humira®, Inflectra®, Otezla®, Renflexis™, Skyrizi™, Stelara®, Taltz®. 3. Initial Approval Criteria, I.A.5. Updated to include Member meets both (a and b): <ol style="list-style-type: none"> a. Trial and failure of at least three (3) first line agents: Humira®, Cimzia®, Skyrizi®, Tremfya® or Stelara® unless contraindicated or clinically significant adverse effects are experienced; *Exception: If a total of two TNF inhibitors (Humira®, Cimzia®, Enbrel®) has previously been tried and failed, trial of a third TNF inhibitor is not required. b. Trial and failure of Taltz® unless contraindicated or clinically significant adverse effects are experienced. 		
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> 1. Initial Approval Criteria, I.A.5.a: Updated trial and failure criteria to include drug Enbrel®. 2. Initial Approval Criteria, I.A.5.a: Updated to remove exception trial and failure criteria "Exception: If a total of two TNF inhibitors (Humira®, Cimzia®, Enbrel®) has previously been tried and failed, trial of a third TNF inhibitor is not required". 	10/03/2022	10/19/2022
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> 1. Initial Approval Criteria, I.A.5.a: Updated trial and failure criteria to include new drug Amjevita™. 	04/05/2023	04/13/2023
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> 1. Updated trial and failure criteria to include Humira biosimilar. 2. Updated Approval duration. 3. Removed responding positively criteria. 	11/10/2023	10/19/2023
<p>Policy reviewed:</p> <ol style="list-style-type: none"> 1. Removed dose 	2/1/2024	NA
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> 1. Removed prescriber restrictions. 2. Updated adalimumab biosimilars. 	11/25/2024	12/05/2024

3. Updated Continued therapy approval to “Member is currently receiving medication that has been authorized..”		
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