

Clinical Policy Title:	apremilast
Policy Number:	RxA.742
Drug(s) Applied:	Otezla®
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. Psoriatic Arthritis (must meet all):

1. Diagnosis of PsA.

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 ≥ 3 months of at least one (1) conventional systemic therapy, unless contraindicated or clinically significant adverse effects are experienced:
 - a. Methotrexate [MTX]
 - b. Cyclosporine
 - c. Acitretin
 - d. Phototherapy (psoralen plus ultraviolet A light [PUVA]);

Approval Duration

All Lines of Business (except Medicare): 12 months

C. Behçet's Disease (must meet all):

1. Diagnosis of oral ulcers in members with BD;
2. Trial and failure of at least one (1) one systemic therapy (e.g. colchicine, corticosteroids, azathioprine) at maximally indicated doses unless contraindicated or significantly adverse effects are experienced.

Approval duration

All Lines of Business (except Medicare): 12 months

II. Continued Therapy Approval

A. All Indications in Section I:

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

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.

1. Menter A, Gottlieb A, Feldman SR, et al. American Academy of Dermatology. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 1. Overview of psoriasis and guidelines of care for the treatment of psoriasis with biologics. J Am Acad Dermatol. 2008; 58:826-850. Available at: [https://www.jaad.org/article/S0190-9622\(08\)00273-9/fulltext](https://www.jaad.org/article/S0190-9622(08)00273-9/fulltext). Accessed November 25, 2024.
2. Menter A, Gottlieb A, Feldman, SR, et al. American Academy of Dermatology. Guidelines of care for the management of psoriasis and psoriatic arthritis: Section 2. Psoriatic arthritis: overview and guidelines of care for treatment with an emphasis on the biologics. J Am Acad Dermatol May 2008; 58(5): 826-50. Available at: <https://pubmed.ncbi.nlm.nih.gov/18423260/>. Accessed November 25, 2024.
3. Menter A, Korman NF, Elmetts CA, et al. American Academy of Dermatology. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 4. Guidelines of care for the management and treatment of psoriasis with traditional systemic agents. J Am Acad Dermatol. 10.1016/j.jaad.2009.03.027. Available at: <https://pubmed.ncbi.nlm.nih.gov/19493586/>. Accessed November 25, 2024.
4. Menter A, Korman, NJ, Elmetts CA, et al. American Academy of Dermatology. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 3. Guidelines of care for the management and treatment of psoriasis with topical therapies. J Am Acad Dermatol. 2009; 60:643-659. Available at: <https://pubmed.ncbi.nlm.nih.gov/19217694/>. Accessed November 25, 2024.
5. 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 2016;75(3):499-510.doi:10.1136/annrheumdis-2015-208337. Available at: <https://pubmed.ncbi.nlm.nih.gov/26644232/>. Accessed November 25, 2024.
6. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the treatment of psoriatic arthritis. American College of Rheumatology. 2019; 71(1):5-32. doi: 10.1002/art.40726. Available at: <https://pubmed.ncbi.nlm.nih.gov/30499246/>. Accessed November 25, 2024.
7. Hatemi G, Mahr A, Takeno M, et al. Improvements and correlations in oral ulcers, disease activity, and QOL in behçet’s syndrome patients treated with apremilast: a phase 3 randomized, double-blind, placebo-controlled study. Rheumatology, Volume 58, Issue Supplement_2) Available at: <https://doi.org/10.1093/rheumatology/kez062.023> . Accessed November 25, 2024.
8. Hatemi G, Christensen R, Bang D, et al. 2018 update of the EULAR recommendations for the management of Behçet’s syndrome Annals of the Rheumatic Diseases 2018;77:808-818. Available at: <https://ard.bmj.com/content/annrheumdis/early/2018/04/06/annrheumdis-2018-213225.full.pdf>. 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.Biologic_DMARDs.	01/05/2022	4/18/2022
Drug specific policy for Otezla was created based on RxA.592.Biologic_DMARDs <ol style="list-style-type: none"> 1. Dosing Information, Dosing Regimen: Updated to include renal impairment dosing information for indication PsO, PsA, BD. 2. Initial Approval Criteria I.B.3: Updated 	2/14/2022	4/18/2022

<p>trial and failure criteria to rephrase and include phototherapy (psoralen plus ultraviolet A light [PUVA]).</p> <ol style="list-style-type: none"> 3. Appendix A: Updated to include abbreviations PUVA. 4. Appendix B, Drug Name: Updated to remove discontinued brand-name therapeutic alternative Soriatane®. 5. Appendix B, Drug Name: Updated to include brand-name therapeutic alternative of other biological DMARDs. 6. Disclaimer about contraindications "Contraindications listed reflect statements made in the manufacturer's package insert..." was added to Appendix C. 7. Appendix D, General Information: Updated to include new information regarding Warnings and Precautions. 8. References were reviewed and updated. 		
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> 1. References were reviewed and updated. 	03/27/2023	04/13/2023
Policy was reviewed.	12/1/2023	12/1/2023
Policy was reviewed.	3/1/2024	3/1/2024
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> 1. Removed prescriber restrictions. 2. Updated Continued therapy approval to "Member is currently receiving medication that has been authorized.." 3. References were reviewed and updated. 	11/25/2024	12/05/2024