

Clinical Policy Title:	guselkumab
Policy Number:	RxA.729
Drug(s) Applied:	Tremfya®
Original Policy Date:	04/18/2022
Last Review Date:	03/1/2024
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria. The provision of provider samples does not guarantee coverage under the terms of the pharmacy benefit administered by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

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]), unless contraindicated or clinically significant adverse effects are experienced;
3. Prescribed by or in consultation with a dermatologist or a rheumatologist;

Approval Duration

All Lines of Business (except Medicare): 12 months

B. Psoriatic Arthritis (must meet all):

1. Diagnosis of Psoriatic Arthritis (PsA);
2. Prescribed by or in consultation with a dermatologist or a rheumatologist;

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, excluding manufacturer samples;

Approval Duration

All Lines of Business (except Medicare): 12 months

References

1. 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 March 27, 2023.
2. 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.

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.

doi:10.1136/annrheumdis-2015-208337. Available at: <https://pubmed.ncbi.nlm.nih.gov/26644232/>. Accessed March 27, 2023.

3. 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 March 27, 2023.
4. Menter A, Korman NF, Elmets 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 March 27, 2023.
5. Menter A, Korman, NJ, Elmets 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 March 27, 2023.
6. 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 March 27, 2023.

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 Trefmya® was created based on RxA.592.Biologics_DMARDs: <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. Appendix A: Updated to include abbreviations PUVA: Psoralen plus ultraviolet A light. 3. Appendix B, Drug Name: Updated to remove discontinued brand-name therapeutic alternative Soriatane®. 4. Appendix B, Drug Name: Updated to include brand-name therapeutic alternative of other biological DMARDs. 5. Disclaimer about contraindications "Contraindications listed reflect statements made in the manufacturer's package insert..." was added to Appendix C. 6. References were reviewed and updated. 	02/15/2022	04/18/2022
Policy was reviewed:	03/27/2023	04/13/2023

1. References were reviewed and updated		
Policy was reviewed.	12/1/2023	12/1/2023
Policy was reviewed: 1. Removed clause of prior DMARD trial	3/1/2024	3/1/2024