

<b>Clinical Policy Title:</b>	guselkumab
<b>Policy Number:</b>	RxA.729
<b>Drug(s) Applied:</b>	Tremfya®
<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. 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.

#### Approval Duration

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

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

1. Diagnosis of Psoriatic Arthritis (PsA).

#### Approval Duration

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

#### C. Ulcerative Colitis (must meet all):

1. Diagnosis of moderately to severely active ulcerative colitis;
2. Member does not have combination use of biological disease-modifying antirheumatic drugs or JAK inhibitors;
3. Trial and failure to one of the following conventional therapies, unless contraindicated or clinically significant adverse effects are experienced: 6-mercaptopurine, aminosalicylate (eg, mesalamine, olsalazine, sulfasalazine), azathioprine, or corticosteroids (eg, prednisone)

#### 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

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. 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 December 03, 2024.
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. doi:10.1136/annrheumdis-2015-208337. Available at: <https://pubmed.ncbi.nlm.nih.gov/26644232/>. Accessed December 03, 2024.
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 December 03, 2024.
4. 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 December 03, 2024.
5. 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 December 03, 2024.
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 December 03, 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	04/18/2022
Drug specific policy for Trefmya® was created based on RxA.592.Biologics_DMARDs: <ol style="list-style-type: none"> <li>1. Initial Approval Criteria, 1.A.4: Updated trial and failure criteria to rephrase and include phototherapy (psoralen plus ultraviolet A light [PUVA]).</li> <li>2. Appendix A: Updated to include abbreviations PUVA: Psoralen plus ultraviolet A light.</li> <li>3. Appendix B, Drug Name: Updated to remove discontinued brand-name therapeutic alternative Soriatane®.</li> <li>4. Appendix B, Drug Name: Updated to include brand-name therapeutic alternative of other biological DMARDs.</li> <li>5. Disclaimer about contraindications "Contraindications listed reflect statements made in the manufacturer's</li> </ol>	02/15/2022	04/18/2022

package insert..." was added to Appendix C. 6. References were reviewed and updated.		
Policy was reviewed: 1. References were reviewed and updated	03/27/2023	04/13/2023
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
Policy was reviewed: 1. Removed prescriber restrictions. 2. Updated to add new indication, Ulcerative Colitis. 3. Updated Continued therapy approval to "Member is currently receiving medication that has been authorized.." 4. References were reviewed and updated.	12/03/2024	12/5/2024