

Clinical Policy Title:	ustekinumab
Policy Number:	RxA.747
Drug(s) Applied:	Stelara®
Original Policy Date:	04/18/2022
Last Review Date:	3/1/2024
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, unless contraindicated or clinically significant adverse effects are experienced:
 - a. Methotrexate [MTX]
 - b. Cyclosporine
 - c. Acitretin
 - d. Phototherapy (psoralen plus ultraviolet A light [PUVA]);
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 PsA;
2. Prescribed by or in consultation with a dermatologist or rheumatologist;

Approval Duration

All Lines of Business (except Medicare): 12 months

C. Ulcerative Colitis (must meet all):

1. Diagnosis of UC;
2. Member meets one of the following (a or b):
 - a. Trial and failure of ≥ 3 months of at least one (1) conventional agent (azathioprine, 6-mercaptopurine, aminosalicilate) unless contraindicated or clinically significant adverse effects are experienced;
 - b. Trial and failure of corticosteroid treatment (e.g., prednisone, methylprednisolone, budesonide) unless contraindicated or significant adverse effects experienced;
3. Prescribed by or in consultation with a gastroenterologist;

Approval duration

All Lines of Business (except Medicare): 12 months

D. Crohn's Disease (must meet all):

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. Diagnosis of Crohn’s Disease (CD);
3. Member meets one of the following (a or b):
 - a. Trial and failure of a ≥ 3 months of at least one (1) conventional systemic therapy (e.g., azathioprine, 6-mercaptopurine [6-MP], methotrexate [MTX]), unless contraindicated or clinically significant adverse effects are experienced;
 - b. Trial and failure of corticosteroid treatment (e.g., prednisone, methylprednisolone, budesonide), unless contraindicated or significant adverse effects experienced;
4. Prescribed by or in consultation with a gastroenterologist;

Approval Duration

All Lines of Business (except Medicare): 12 months

II. Continued Therapy Approval

A. All Indications:

1. Member is currently receiving or has been treated with this medication within the past 90 days, excluding manufacturer samples.

Approval Duration

All Lines of Business (except Medicare): 12 months

References

1. Lichtenstein GR, Loftus Jr. EV, Isaacs KI, Regueiro MD, Gerson LB, and Sands BE. ACG clinical guideline: management of Crohn’s disease in adults. Am J Gastroenterol. 2018; 113:481-517. Available at: <https://pubmed.ncbi.nlm.nih.gov/29610508/>. Accessed November 16, 2023.
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 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 16, 2023.
3. Gottlieb A, Korman NJ, Gordon KB, et al. 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. Journal of the American Academy of Dermatology. 2008;58(5):851-864. Available at: [https://www.jaad.org/article/S0190-9622\(08\)00274-0/fulltext](https://www.jaad.org/article/S0190-9622(08)00274-0/fulltext). Accessed November 16, 2023.
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 November 16, 2023.
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 November 16, 2023.
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://ard.bmj.com/content/79/6/700.1>. Accessed November 16, 2023.

Review/Revision History	Review/Revision Date	P&T Approval Date
RxA.592.Biologic_DMARDs was last reviewed and updated	01/05/2022	04/18/2022

on 01/05/2022 and archived on 04/18/2022. For details, please refer to RxA.592.Biologic_DMARDs.		
<p>Drug specific policy for Stelara was created based on RxA.592.Biologic_DMARDs</p> <ol style="list-style-type: none"> 1. Initial Approval Criteria, I.A.4: Updated to remove Medical justification supports inability to use immunomodulators (see Appendix D). 2. Initial Approval Criteria, 1.B.4: Updated trial and failure criteria to rephrase and include phototherapy (psoralen plus ultraviolet A light [PUVA]). 3. References were reviewed and updated. 	02/16/2022	04/18/2022
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> 1. Initial Approval Criteria, I.C.3: Updated age criteria from Age ≥ 18 years to Age ≥ 6 years. 2. References were reviewed and updated. 	09/16/2022	10/19/2022
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> 1. Removed prior age criteria. 2. Removed prior dosing criteria. 3. Updated approval duration. 4. Removed reauthorization requirement for positive response to therapy. 5. References were reviewed and updated. 	11/16/2023	01/01/2024
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> 1. 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; 	3/1/2024	3/1/2024