RxAdvance

Clinical Policy Title:	ustekinumab
Policy Number:	RxA.747
Drug(s) Applied:	Stelara®
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, 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

B. Psoriatic Arthritis (must meet all):

1. Diagnosis of PsA.

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, aminosalicylate) 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.

Approval duration

All Lines of Business (except Medicare): 12 months

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

1. Diagnosis of Crohn's Disease (CD);
2. 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,

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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.

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

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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. Accessed November 25, 2024.
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. Accessed November 25, 2024.
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 November 25, 2024.
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 November 25, 2024.
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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 Stelara was created based on RxA.592.Biologic_DMARDs	02/16/2022	04/18/2022

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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.		
Policy was reviewed: 1. Initial Approval Criteria, I.C.3: Updated age criteria from Age $\geq$ 18 years to Age $\geq$ 6 years. 2. References were reviewed and updated.	09/16/2022	10/19/2022
Policy was reviewed: 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
Policy was reviewed: 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
Policy was reviewed: 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	12/5/2024

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