RAdvance

Clinical Policy Title:	infliximab-axxq
Policy Number:	RxA.731
Drug(s) Applied:	Avsola®
Original Policy Date:	04/18/2022
Last Review Date:	2/1/2024
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

- A. Ankylosing Spondylitis (must meet all):
 - 1. Diagnosis of active ankylosing spondylitis (AS);
 - Trial and failure of ≥ 1 month trial, unless contraindicated or clinically significant adverse effects are experienced, of at least two (2) non-steroidal anti-inflammatory drugs (NSAIDs);
 - 3. Prescribed by or in consultation with a rheumatologist;

Approval Duration

All Lines of Business (except Medicare): 12 months

- B. Crohn's Disease (must meet all):
 - 1. Diagnosis of Crohn's disease (CD) or fistulizing Crohn's disease;
 - 2. Trial and failure of ≥ 3 months, unless contraindicated or clinically significant adverse effects are experienced, of one (1) of the following:
 - a. 6-mercaptopurine
 - b. Azathioprine
 - c. Corticosteroids
 - d. Methotrexate
 - 3. Prescribed by or in consultation with a gastroenterologist;

Approval Duration

All Lines of Business (except Medicare): 12 months

C. Plaque Psoriasis (must meet all):

- 1. Diagnosis of chronic-severe PsO as evidenced by involvement of one of the following (a or b):
 - a. \geq 3% of total body surface area;
 - b. Hands, feet, scalp, face, or genital area.
- 2. Trial and failure of ≥ 3 months, unless contraindicated or clinically significant adverse effects are experienced, of one (1) of the following:
 - a. Methotrexate
 - b. Cyclosporine
 - c. Acitretin
 - d. psoralen plus ultraviolet A light [PUVA]

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.

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Revised 10/2023



3. Prescribed by or in consultation with a dermatologist or a rheumatologist; **Approval Duration**

All Lines of Business (except Medicare): 12 months

- **D. Psoriatic Arthritis** (must meet all):
 - 1. Diagnosis of Psoriatic Arthritis (PsA);
 - 2. Prescribed by or in consultation with a dermatologist or rheumatologist;

Approval Duration

All Lines of Business (except Medicare): 12 months

- E. Rheumatoid Arthritis (must meet all):
 - 1. Diagnosis of Rheumatoid Arthritis (RA);
 - 2. Trial and failure of ≥ 3 months, unless contraindicated or clinically significant adverse effects are experienced, of one (1) of the following:
 - a. Methotrexate
 - b. Sulfasalazine
 - c. Leflunomide
 - d. Hydroxychloroquine
 - 3. Prescribed by or in consultation with a rheumatologist;

Approval Duration

All Lines of Business (except Medicare): 12 months

F. Ulcerative Colitis (must meet all):

- 1. Diagnosis of Ulcerative Colitis (UC);
- 2. Documentation of a Mayo Score \geq 6;
- 3. Trial and failure of ≥ 3 months, unless contraindicated or clinically significant adverse effects are experienced, of one (1) of the following:
 - a. Azathioprine
 - b. Mercaptopurine
 - c. Aminosalicylate (e.g., mesalamine, olsalazine, sulfasalazine)
 - d. Corticosteroids
- 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 in Section I (must meet all):
 - 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. Aletaha D, Neogi T, Silman AJ, et al. 2010 Rheumatoid Arthritis Classification Criteria. Arthritis and Rheumatism September 2010;62(9):2569-2581. Available at: https://pubmed.ncbi.nlm.nih.gov/20872595/. Accessed March 27, 2023.
- 2. Boulos P, Dougados M, MacLeod SM, et al. Pharmacological Treatment of Ankylosing Spondylitis. Drugs. 2005; 65: 2111-2127. Available at: https://pubmed.ncbi.nlm.nih.gov/16225367/. Accessed March 27, 2023.
- 3. Bernell O, Lapidus A, Hellers G. Risk Factors for Surgery and Postoperative Recurrence in Crohn's Disease. Annals of Surgery. 2000; 231(1): 38-45. Available at: https://pubmed.ncbi.nlm.nih.gov/10636100/. Accessed March 27, 2023.
- 4. Sandborn WJ. Crohn's Disease Evaluation and Treatment: Clinical Decision Tool. Gastroenterology 2014; 147: 702-705. Available at: https://pubmed.ncbi.nlm.nih.gov/25046160/. Accessed March 27, 2023.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	02/15/2022	04/18/2022
 Policy was reviewed: 1. Initial Approval Criteria, I.C.1: Updated diagnosis criteria from Diagnosis of PsO to Diagnosis of chronic-severe PsO as evidenced by involvement of one of the following (a or b): a. ≥ 10% of total body surface area; b. Hands, feet, scalp, face, or genital area 2. Initial Approval Criteria, I.F.4: Updated to include new documentation criteria, Documentation of a Mayo Score ≥ 6. 3. References were reviewed and updated. 	03/27/2023	04/13/2023
Policy was reviewed.	10/19/2023	10/19/2023