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| Clinical Policy Title: | infliximab-axxq |
| Policy Number: | RxA.731 |
| Drug(s) Applied: | Avsola® |
| Original Policy Date: | 04/18/2022 |
| Last Review Date: | 12/11/2025 |
| 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);
2. 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).

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

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]

Approval Duration

All Lines of Business (except Medicare): 12 months

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.

D. Psoriatic Arthritis (must meet all):

1. Diagnosis of Psoriatic Arthritis (PsA).

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

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 ≥ 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

Approval duration

All Lines of Business (except Medicare): 12 months

II. Continued Therapy Approval

A. All Indications in Section I (must meet all):

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

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 November 25, 2024.
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 November 25, 2024.
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 November 25, 2024.
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 November 25, 2024.

| Review/Revision History | Review/Revision Date | P&T Approval Date |
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| Policy established. | 02/15/2022 | 04/18/2022 |
| Policy was reviewed: <ol style="list-style-type: none"> 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): <ol style="list-style-type: none"> 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 |
| Policy was reviewed: <ol style="list-style-type: none"> 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 | 12/05/2024 |
| Policy was reviewed. | 12/11/2025 | 12/11/2025 |