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);
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) ;
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. ≥ 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]

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 ≥ 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