Clinical Policy Title:	infliximab-abda
Policy Number:	RxA.744
Drug(s) Applied:	Renflexis®, Remicade®
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. 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 ≥ 3-month of at least one (1) conventional systemic therapy (e.g., azathioprine, 6-mercaptopurine [6-MP], methotrexate [MTX]) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
   b. Trial and failure of corticosteroids (e.g., prednisone, methylprednisolone, budesonide), unless contraindicated or significant adverse effects experienced.
3. Trial and failure of at least one (1) of the following agents: Inflectra® or Avsola® unless contraindicated or clinically significant adverse effects are experienced.

Approval Duration

All Lines of Business (except Medicare): 12 months

B. Ulcerative Colitis (must meet all)**:**

1. Diagnosis of Ulcerative Colitis;
2. Documentation of a Mayo Score ≥ 6;
3. Member meets one of the following (a or b):
   a. Trial and failure of ≥ 3 months of at least one conventional agent (azathioprine, 6-mercaptopurine, aminosalicylate), unless contraindicated or clinically significant adverse effects are experienced;
   b. Trial and failure of corticosteroids (e.g., prednisone, methylprednisolone, budesonide) unless contraindicated or significant adverse effects experienced;
4. Trial and failure of at least one (1) of the following agents: Inflectra® or Avsola® unless contraindicated or clinically significant adverse effects are experienced.

Approval Duration

All Lines of Business (except Medicare): 12 months

C. Rheumatoid Arthritis (must meet all)**:**

1. Diagnosis of Rheumatoid Arthritis (RA);
2. Trial and failure of ≥ 3-months of at least one conventional systemic therapy (methotrexate [MTX], sulfasalazine, leflunomide, hydroxychloroquine), unless contraindicated or clinically significant adverse effects are experienced;
3. Trial and failure of at least one (1) of the following agents: Inflectra® or Avsola® unless contraindicated

or clinically significant adverse effects are experienced.

Approval Duration

All Lines of Business (except Medicare): 12 months

D. Ankylosing Spondylitis (must meet all):

1. Diagnosis of active ankylosing spondylitis (AS);
2. Trial and failure of at least two (2) non-steroidal anti-inflammatory drugs (NSAIDs), each used for at ≥ 4 weeks unless contraindicated or clinically significant adverse effects are experienced;
3. Trial and failure of at least one (1) of the following agents: Inflectra® or Avsola® unless contraindicated or clinically significant adverse effects are experienced.

Approval duration

All Lines of Business (except Medicare): 12 months

E. Psoriatic Arthritis (must meet all)**:**

1. Diagnosis of Psoriatic Arthritis PsA;
2. Trial and failure of at least one (1) of the following agents: Inflectra® or Avsola®, unless contraindicated or clinically significant adverse effects are experienced.

Approval duration

All Lines of Business (except Medicare): 12 months

F. Plaque Psoriasis (must meet all)**:**

1. 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. Trial and failure of at least ≥ 3 month at least one (1) conventional systemic therapy (methotrexate [MTX], cyclosporin, acitretin) or phototherapy (psoralen plus ultraviolet A light [PUVA]), unless contraindicated or clinically significant adverse effects are experienced;
3. Trial and failure of at least one (1) of the following agents: Inflectra® or Avsola® unless contraindicated or clinically significant adverse effects are 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

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. 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.

4. 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.

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.Biologics_DMARDs.	01/05/2022	04/18/2022
Drug specific policy for Renflexis® was created based on RxA.592.Biologics_DMARDs: 1. Initial Approval Criteria, I.A.5, I.B.5, I.C.5, I.D.5, I.E.5, I.F:4 was updated to include Trial and failure of at least one (1) of the following agents: Inflectra® or Avsola® unless contraindicated or clinically significant adverse effects are experienced. 2. Initial Approval Criteria, I.F.4: Updated trial and failure criteria to rephrase and include phototherapy (psoralen plus ultraviolet A light [PUVA]). 3. References were reviewed and updated.	02/11/2022	04/18/2022
Policy was reviewed: 1. Initial Approval Criteria, I.B.4: Updated to include new documentation criteria, Documentation of a Mayo Score ≥ 6. 2. Initial Approval Criteria, I.F.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 3. References were reviewed and updated.	03/27/2023	04/13/2023

Policy was reviewed.	10/19/2023	10/19/2023
Policy was reviewed: 1. Removed dose and age 2. Formatting changes	1/1/2024	10/19/2023
Policy reviewed: Removed: 1. At maximally tolerated doses 2. Language of bypassinf t/f of systemic tx if on prior DMARD tx.	3/15/2024	10/19/2023
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	12/05/2024