Clinical Policy Title:	infliximab-dyyb
Policy Number:	RxA.737
Drug(s) Applied:	Inflectra®
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. 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.

Approval Duration

All Lines of Business (except Medicare): 12 months

B. Crohn's Disease (must meet all)**:**

1. Diagnosis of moderate to severe Crohn's Disease (CD);
2. Member meets one of the following (a or b):
   a. Trial and failure of ≥ 3 months of at least one (1) conventional systemic therapy (e.g., azathioprine, 6-mercaptopurine [6-MP], methotrexate [MTX]) , 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.

Approval Duration

All Lines of Business (except Medicare): 12 months

C. Plaque Psoriasis (must meet all):

1. Diagnosis of chronic-severe Plaque Psoriasis (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 of 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.

Approval Duration

All Lines of Business (except Medicare): 12 months

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 moderate to severe Rheumatoid Arthritis (RA);
2. Trial and failure of ≥ 3 months of at least one (1) conventional systemic therapy (methotrexate [MTX], sulfasalazine, leflunomide, hydroxychloroquine), unless contraindicated or clinically significant adverse effects are experienced.

Approval Duration
All Lines of Business (except Medicare): 12 months

F. Ulcerative Colitis (must meet all)**:**
1. Diagnosis of moderate to severe Ulcerative Colitis (UC);
2. Member meets one of the following (a or b):
   a. Trial and failure of ≥ 3 months of at least one (1) conventional therapy (azathioprine, 6-mercaptopurine, or an aminosalicylate (e.g., sulfasalazine, mesalamine)) , 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.

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. 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.
5. Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. *J Am Acad Dermatol*. 2019;80(4):1029-1072. Available at https://pubmed.ncbi.nlm.nih.gov/30772098/. Accessed November 25, 2024.

Review/Revision History	Review/Revision Date	P&T Approval Date
RxA.592.Bilogic_DMARDs was last reviewed and	01/05/2022	04/18/2022

updated on 01/05/2022 and archived on 04/18/2022. For details, please refer to RxA.592.Bilogics_DMARDs.		
Drug specific policy for Inflectra® was created based on RxA.592.Bilogics_DMARDs: 1. Initial Approval Criteria, 1.C.4: Updated trial and failure criteria to rephrase and include phototherapy (psoralen plus ultraviolet A light [PUVA]). 2. References were reviewed and updated.	02/10/2022	4/18/2022
Policy was reviewed: 1. Initial Approval Criteria, I.C.1: Updated diagnostic criteria from Diagnosis of Plaque Psoriasis (PsO) to Diagnosis of chronic-severe Plaque Psoriasis (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
Policy was reviewed: 1. I.A.4: Removed at up to maximally indicated doses 2. I.A.5: Removed dosing 3. I.B.1. Specified moderate to severe per FDA approved indications (Micromedex) 4. I.B.4a: Removed at up to maximally indicated doses 5. I.B.4b: Removed exception of using a DMARD 6. I.B.5. Removed dosing 7. I.C.4: Removed at up to maximally indicated doses. Removed exception of using a DMARD. 8. I.C.5. Removed dosing 9. I.D.4: Removed dosing 10. I.E.1. Specified moderate to severe per FDA approved indications (Micromedex) 11. I.E.4: Removed at up to maximally indicated doses. Removed exception of using a DMARD.	04/02/2024	

12. I.E.5. Removed dosing 13. I.F.1. Specified moderate to severe per FDA approved indications (Micromedex) 14. I.F.5: Edited criteria to include use of conventional therapy or corticosteroid. Removed exception of using a DMARD. 15. I.E.6. Removed dosing 16. II.A. Revised continuation of therapy criteria. Removed dosing and positive response to therapy. 17. Removed age under all indications		
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