

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

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.

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 aminosalicilate (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: <ol style="list-style-type: none"> 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: <ol style="list-style-type: none"> 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): <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. 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	

<ul style="list-style-type: none"> 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 		
<p>Policy was reviewed:</p> <ul 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. 	<p>11/25/2024</p>	<p>12/05/2024</p>
<p>Policy reviewed.</p>	<p>12/11/2025</p>	<p>12/11/2025</p>