

Clinical Policy Title:	certolizumab pegol
Policy Number:	RxA.732
Drug(s) Applied:	Cimzia®
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) or non-radiographic axial spondyloarthritis (nr-axSpA);
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 Crohn's Disease (CD);
2. Member meets one of the following (a or b):
 - a. Trial and failure of a ≥ 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 moderate-to-severe PsO;
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

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.

E. Rheumatoid Arthritis (must meet all):

1. Diagnosis of Rheumatoid Arthritis (RA);
2. Trial and failure of a ≥ 3 months of at least one 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. Polyarticular Juvenile Idiopathic Arthritis (must meet all):

1. Diagnosis of active Polyarticular Juvenile Idiopathic Arthritis;
2. Trial and failure of a ≥ 6 weeks of the following conventional therapies at maximally tolerated doses: leflunomide or methotrexate, 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. 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 December 03, 2024.
2. Braun J, Davis J, Dougados M, et al. First update of the international ASAS consensus statement for the use of anti-TNF agents in patients with ankylosing spondylitis. *Ann Rheum Dis*. 2006; 65:316-320. Available at: <https://pubmed.ncbi.nlm.nih.gov/16096329/>. Accessed December 03, 2024.
3. Braun J, van den Berg R, Baraliako X, et al. 2010 Update of the ASAS/EULAR recommendations for the management of ankylosing spondylitis. *Ann Rheum Dis* 2011; 70:896-904. Available at: <https://pubmed.ncbi.nlm.nih.gov/21540199/>. Accessed December 03, 2024.
4. Menter A, Gottlieb A, Feldman SR, et al. American Academy of Dermatology. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 1. Overview of psoriasis and guidelines of care for the treatment of psoriasis with biologics. *J Am Acad Dermatol*. 2008; 58:826-850. Available at: [https://www.jaad.org/article/S0190-9622\(08\)00273-9/fulltext](https://www.jaad.org/article/S0190-9622(08)00273-9/fulltext). Accessed December 03, 2024.
5. Menter A, Gottlieb A, Feldman, SR, et al. American Academy of Dermatology. Guidelines of care for the management of psoriasis and psoriatic arthritis: Section 2. Psoriatic arthritis: overview and guidelines of care for treatment with an emphasis on the biologics. *J Am Acad Dermatol* May 2008; 58(5): 826-50. Available at: <https://pubmed.ncbi.nlm.nih.gov/18423260/>. Accessed December 03, 2024.
6. Menter A, Korman NF, Elmets CA, et al. American Academy of Dermatology. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 4. Guidelines of care for the management and treatment of psoriasis with traditional systemic agents. *J Am Acad Dermatol*. 10.1016/j.jaad.2009.03.027. Available at: <https://pubmed.ncbi.nlm.nih.gov/19493586/>. Accessed December 03, 2024.

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10. Zochling J, van der Heijde D, Burgos-Vargas, R, et al. ASAS/EULAR recommendations for the management of ankylosing spondylitis. Ann Rheum Dis. 2006; 65:442-452. Available at: <https://pubmed.ncbi.nlm.nih.gov/16126791/>. Accessed December 03, 2024.
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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.Biologic_DMARDs	01/05/2022	04/18/2022
Drug specific policy for Otezla was created based on RxA.592.Biologic_DMARDs <ol style="list-style-type: none"> 1. Initial Approval Criteria, I.B.4: Updated to remove Medical justification supports inability to use immunomodulators (see Appendix D). 2. Initial Approval Criteria, I.C.4: Updated trial and failure criteria to rephrase and include phototherapy (psoralen plus ultraviolet A light [PUVA]). 3. References were reviewed and updated. 	02/10/2022	04/18/2022
Policy was reviewed:	03/27/2023	04/13/2023

<ol style="list-style-type: none"> 1. Initial Approval Criteria, I.A.5, I.B.5, I.D.4 and I.E.5: Updated dosing criteria from Dose does not exceed 400 mg every 4 weeks to Dose does not exceed 400 mg at weeks 0, 2, and 4, followed by maintenance dose of 400 mg every 4 weeks. 2. Initial Approval Criteria, I.C.1: Updated diagnosis criteria from Diagnosis of PsO to Diagnosis of moderate-to-severe PsO as evidenced by involvement of one of the following (a or b): <ol style="list-style-type: none"> a. ≥ 3% of total body surface area; b. Hands, feet, scalp, face, or genital area 3. Initial Approval Criteria, I.E.5: Updated dosing criteria from Dose does not exceed 400 mg every 4 weeks to Dose does not exceed 400 mg every 2 weeks. 4. Continued Therapy Approval. II.A.3: Updated dosing criteria from If request is for a dose increase, new dose does not exceed 400 mg every 4 weeks to If request is for a dose increase, new dose does not exceed (a or b): <ol style="list-style-type: none"> a. For CD, RA, PsA, AS, nr-axSpA: 400 mg every 4 weeks; b. For PsO: 400 mg every 2 weeks 5. References were reviewed and updated. 		
Policy was reviewed.	10/19/2023	10/19/2023
Policy was reviewed: <ol style="list-style-type: none"> 1. Removed age criteria. 2. Removed dosing criteria. 3. Removed reauthorization requirement for positive response to therapy. 4. References were reviewed and updated. 	12/12/2023	1/1/2024
Policy reviewed: <ol style="list-style-type: none"> 1. Removed “At up to maximally tolerated doses” 	3/15/2024	1/1/2024
Policy was reviewed: <ol style="list-style-type: none"> 1. Removed prescriber restrictions. 2. Updated to add new indication, Polyarticular Juvenile Idiopathic Arthritis. 	12/03/2024	12/05/2024

3. Updated Continued therapy approval to “Member is currently receiving medication that has been authorized..” 4. References were reviewed and updated.		
Policy reviewed.	12/11/2025	12/11/2025