Clinical Policy Title:	risankizumab-rzaa
Policy Number:	RxA.728
Drug(s) Applied:	Skyrizi®
Original Policy Date:	04/18/2022
Last Review Date:	11/20/2023
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria. The provision of provider samples does not guarantee coverage under the terms of the pharmacy benefit administered by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

I. Initial Approval Criteria

A. Plaque Psoriasis (must meet all):

1. Diagnosis of moderate to severe Plaque Psoriasis (PsO) as evidenced by involvement of one of the following (a, or b,):
   a. Body surface area ≥ 3%;
   b. Hands, feet, scalp, face, or genital area;
2. Prescribed by or in consultation with a dermatologist or a rheumatologist;
3. 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]) at up to maximally indicated doses unless contraindicated or clinically significant adverse effects are experienced;
   *Exception: If one biologic DMARD that is FDA-approved for plaque psoriasis has been previously tried, then trial of a conventional systemic agent or phototherapy is not required;

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

B. Psoriatic arthritis (Must meet all):

1. Diagnosis of Psoriatic Arthritis (PsA);
2. Prescribed by or in consultation with a dermatologist or a rheumatologist;

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

C. Crohn's disease (Must meet all):

1. Diagnosis of Crohn's Disease (CD);
2. Prescribed by or in consultation with a gastroenterologist;
3. 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]) 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;
*Exception: If one biologic DMARD that is FDA-approved for crohn's disease has been previously tried, then trial of a conventional systemic agent is not required;

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, excluding manufacturer samples;

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

References

1. 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. Accessed September 16, 2022.
2. 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 September 16, 2022.
3. 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 September 16, 2022.
4. Menter A, Korman, NJ, Elmets CA, et al. American Academy of Dermatology. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 3. Guidelines of care for the management and treatment of psoriasis with topical therapies. J Am Acad Dermatol. 2009; 60:643-659. Available at: https://pubmed.ncbi.nlm.nih.gov/19217694/. Accessed September 16, 2022.
5. Gossec L, Smolen JS, Ramiro S, et al. European League Against Rheumatism (EULAR) recommendations for the management of psoriatic arthritis with pharmacological therapies: 2015 update. Ann Rheum Dis 2015; 0:1-12. Doi:10.1136/annrheumdis-2015-208337. Available at: https://pubmed.ncbi.nlm.nih.gov/26644232/. Accessed September 16, 2022.
6. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the treatment of psoriatic arthritis. American College of Rheumatology. 2019; 71(1):5-32. Doi: 10.1002/art.40726. Available at: https://pubmed.ncbi.nlm.nih.gov/30499246/. Accessed September 16, 2022.

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 Skyrizi® was created based on RxA.592.Biologic_DMARDs: 1. Dosing Information, Indication: Updated to include new indication Psoriatic arthritis (PsA). 2. Dosage Forms: Updated to include new dosage forms, Single-dose prefilled pen: 150 mg/mL and Single-dose prefilled syringe: 150 mg/mL. 3. Initial Approval Criteria, 1.A.4: Updated trial and failure criteria to include phototherapy (psoralen plus ultraviolet A light [PUVA]). 4. Initial Approval Criteria, I.B: Updated to include approval criteria for indication, Psoriatic arthritis***. 5. Appendix A: Updated to include abbreviations PUVA. 6. Appendix B, Drug Name: Updated to remove discontinued brand-name therapeutic alternative Soriatane®. 7. Appendix B, Drug Name: Updated to include brand-name therapeutic alternative of other biological DMARDs. 8. Appendix C, Contraindications: Updated to include new contraindication History of serious hypersensitivity reaction to tildrakizumab or to any of the excipients. 9. Disclaimer about contraindications "Contraindications listed reflect statements made in the manufacturer's package insert"…" was added to Appendix C. 10. References were reviewed and updated.	02/15/2022	04/18/2022

Policy was reviewed: 1. Background: Updated to include new indication Moderately to severely active Crohn's disease in adults. 2. Dosing Information, Indication: Updated to include new indication Crohn's disease. 3. Dosing Information, Dosing Regimen, Skyrizi®: Updated to include dosing information for indication Crohn's disease. 4. Dosing Information, Maximum Dose, Skyrizi®: Updated to include maximum dosing information for indication Crohn's. 5. Dosage Forms: Updated to include new dosage form: a. Single-dose prefilled cartridge: 360 mg/2.4 mL (150 mg/mL); b. Single-dose vial: 600 mg/10 mL (60 mg/mL). 6. Initial Approval Criteria, I.A.1: Updated diagnostic criteria from Diagnosis of Plaque Psoriasis (PsO) to Diagnosis of moderate to severe Plaque Psoriasis (PsO) as evidenced by involvement of one of the following (a, b, or c): a. Body surface area ≥ 3%; b. Hands, feet, scalp, face, or genital area; 7. Initial Approval Criteria, I.C: Updated to include approval criteria for indication, Crohn's disease. 8. Continued Therapy Approval Crtieria, II.A.3.b: Updated to include new maximum dose criteria 360 mg/dose subcutaneously every 8 weeks for Crohn's disease.	09/16/2022	10/19/2022

9. Appendix A: Updated to include abbreviations CD: Crohn's Disease. 10. Appendix B, Dosing Regimen, methotrexate, Humira®, Cimzia®, Stellara®: Updated to include dosing information for indication Crohn's disease. 11. Appendix B, Maximum Dose, methotrexate, Humira®, Cimzia®, Stellara®: Updated to include maximum dose information for indication Crohn's disease. 12. Appendix B, Drug Name: Updated to include therapeutic alternatives: a. azathioprine (Azasan®, Imuran®); b. Tysabri®. 13. Appendix D, Wanrings and Precautions: Updated to include new warning and precaution Hepatotoxicity in Treatment of Crohn's Disease: Drug-induced liver injury during induction has been reported. Monitor liver enzymes and bilirubin levels at baseline and, during induction, up to at least 12 weeks of treatment. Monitor thereafter according to routine patient management. 14. References were reviewed and updated.		
Policy was reviewed.	11/20/2023	11/20/2023