Clinical Policy Title:	budesonide
Policy Number:	RxA.725
Drug(s) Applied:	Tarpeyo®
Original Policy Date:	04/18/2022
Last Review Date:	06/17/2026
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Immunoglobulin A Nephropathy (IgAN) (must meet all):

1. Diagnosis of primary immunoglobulin A nephropathy at risk for rapid progression;
2. Medication is prescribed in combination with a RAS inhibitor (e.g., ACE inhibitor or ARB);
3. Member has eGFR ≥ 30 mL/min/1.73 m2 and UPCR ≥ 0.5 g/g
4. Documentation of a trial of one systemic corticosteroid (e.g., methylprednisolone, prednisone), unless contraindicated or clinically significant adverse effects are experienced

Approval Duration

All Lines of Business (except Medicare): 9 months

II. Continued Therapy Approval

A. Immunoglobulin A nephropathy (must meet all):

1. Reauthorization not authorized. Length of therapy restricted to one time 9-month supply.

References

1. Kidney Disease: Improving Global Outcomes (KDIGO) Glomerular Diseases Work Group. KDIGO 2021 Clinical Practice Guideline for the Management of Glomerular Diseases. Kidney Int. 2021 Oct;100(4S):S1-S276. Available at: https://kdigo.org/wpcontent/uploads/2017/02/KDIGO-Glomerular-Diseases-Guideline-2021-English.pdf. Accessed August 28, 2024.
2. ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). Identifier NCT03643965, Efficacy and Safety of Nefecon in Patients With Primary IgA (Immunoglobulin A) Nephropathy (Nefigard); 2023 July 18. Available at: https://clinicaltrials.gov/ct2/show/NCT03643965. Accessed August 28, 2024.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	02/09/2022	04/18/2022
Policy was reviewed: 1. Initial Approval Criteria, I.A.2: Updated to include new prescriber criteria Prescribed by or in consultation with a nephrologist. 2. Initial Approval Criteria, I.A.5: Updated to include new combination therapy	04/05/2023	04/13/2023

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.

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criteria Tarpeyo® is prescribed in combination with a RAS inhibitor. 3. Initial Approval Criteria, I.A.7: Updated from Member has eGFR ≥ 35 mL/min/1.73 m^2 to Member has eGFR between or equal to 35 and 90 mL/min/1.73 m^2. 4. Initial Approval Criteria, I.A.10: Updated to include new trial and failure criteria Trial and failure of two alternative systemic corticosteroids (e.g., methylprednisolone, prednisone), each used for at least 2 months, unless contraindicated or clinically significant adverse effects are experienced. 5. References were reviewed and updated.		
Policy was reviewed.	10/19/2023	10/19/2023
Policy was reviewed: 1. Removed age restrictions. 2. Removed prescriber restrictions. 3. Removed dose restrictions. 4. Updated approval duration verbiage. 5. References were reviewed and updated.	08/28/2024	09/13/2024
Policy was reviewed: 1. Removed biopsy requirement 2. Changed corticosteroid requirement from two to one.	8/7/2025	N/A
Policy reviewed: 1. Changed UPCR to 0.5 per guidelines 2. Added documentation for corticosteroid trial and failure	6/17/2026	6/25/2026

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