

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

Background

Tarpeyo™ is a corticosteroid indicated to reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression, generally a urine protein-to-creatinine ratio (UPCR) ≥ 1.5 g/g.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
budesonide (Tarpeyo™)	Proteinuria in adults with primary immunoglobulin A nephropathy	16 mg administered orally once daily, in the morning at least 1 hour before a meal.	16 mg / day.

Dosage Forms

- Delayed release capsules: 4 mg.

Clinical Policy

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. Immunoglobulin A nephropathy (must meet all):

1. Diagnosis of proteinuria in adults with primary immunoglobulin A nephropathy (Berger's disease);
2. Member is ≥ 18 years of age;
3. Documentation of biopsy-verified IgAN;
4. Member is currently receiving a stable dose of an RAS inhibitor (ACE inhibitor or ARB) at a maximally tolerated dose;
5. Member has UPCR (≥ 1.5);
6. Member has eGFR ≥ 35 mL/min/1.73 m²;
7. Patient is not currently receiving dialysis or has undergone kidney transplant;
8. Dose does not exceed 16 mg orally once daily.

Approval Duration

Commercial: 9 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.

Medicaid: 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.

Approval Duration

Commercial: 9 months

Medicaid: 9 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key

RAS: renin-angiotensin system

ACE: angiotensin converting enzyme

UPCR: urine protein creatinine ratio

IgAN: immunoglobulin A nephropathy

ARB: angiotensin receptor blockers

eGFR: estimated glomerular filtration rate

APPENDIX B: Therapeutic Alternatives

Not applicable.

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
 - Tarpeyo™ is contraindicated in patients with hypersensitivity to budesonide or any of the ingredients of Tarpeyo™. Serious hypersensitivity reactions, including anaphylaxis have occurred with other budesonide formulations.

*Contraindications listed reflect direct statements made in the manufacturer's package insert; for additional uses, warnings, and precautions, please refer to clinical guidelines.

- Boxed Warning(s):
 - None reported.

APPENDIX D: General Information

- Avoid use in patients with active or quiescent tuberculosis infection, untreated fungal, bacterial, systemic viral or parasitic infections, or ocular herpes simplex. May affect vaccine efficacy.

References

1. Tarpeyo™ Prescribing Information. Stockholm, Sweden: Calliditas Therapeutics AB; December 2021. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/215935s000lbl.pdf. Accessed February 22, 2022.
2. Budesonide, Lexi-Drug. Lexicomp. Wolters Kluwer Health, Inc. Riverwoods, IL. Available at: <http://online.lexi.com>. Accessed February 22, 2022.
3. Clinical Pharmacology [database online] powered by ClinicalKey. Tampa, FL: Elsevier, 2021. Available at: <http://www.clinicalkey.com>. Accessed February 22, 2022.
4. IPD Analytics Rx Brief_Tarpeyo™ for IgA Nephropathy 2.2022. Available at: <https://secure.ipdanalytics.com/User/Pharma/RxStrategy/Search?q=Tarpeyo>. Accessed February 22, 2022.

Review/Revision History

Review/Revision Date

P&T Approval Date

Policy established.	2/9/2022	04/18/2022
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