Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	March 30, 2022 September 13, 2022

Tarpeyo™ (budesonide)

LENGTH OF AUTHORIZATION: 10 months

REVIEW CRITERIA:

- Patient must be ≥ 18 years of age; **AND**
- Patient must have a diagnosis of primary immunoglobulin A nephropathy (IgAN); **AND**
- IgAN is not due to IgA vasculitis or IgAN due to viral causes, inflammatory bowel disease, autoimmune disease, cirrhosis, or IgA-dominant postinfectious glomerulonephritis; **AND**
- Patient is on a stable and maximally tolerated dose of a renin-angiotensin system (RAS) inhibitor (angiotensin converting enzyme [ACE] inhibitor or angiotensin receptor blocker [ARB]), unless contraindicated, and has been for ≥ 3 months; **AND**
- Patient continues to have proteinuria ≥ 1 g/day; **AND**
- Clinical documentation that patient is at risk of rapid disease progression; **AND**
- Patient has an estimated glomerular filtration filter (eGFR) ≥ 35 mL/min/1.73 m^2; **AND**
- Patient does not have severe hepatic impairment (Child-Pugh class C).

DOSING AND ADMINISTRATION:

- Refer to product labeling at https://www.accessdata.fda.gov/scripts/cder/daf/
- Available as 4 mg delayed release capsules