

<b>Policy Name:</b>	<b>Oral Budesonide Products</b>	<b>Policy #:</b>	<b>2028P</b>
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## Purpose of the Policy

The purpose of this policy is to define coverage criteria for the oral budesonide products including brand Uceris, generic, budesonide oral extended release tablets and Tarpeyo.

## Statement of the Policy

Health Alliance Medical Plans and Health Alliance Northwest will approve the use of brand Uceris, generic budesonide oral extended release tablets or Tarpeyo delayed release capsules under the specialty pharmacy benefit when the following criteria have been met.

- Note: Health Alliance does not require prior authorization for Uceris rectal foam or budesonide extended release capsules.

## Criteria

- 1. Coverage Criteria for Ulcerative Colitis (Uceris/Budesonide extended release tablets)**
  - 1.1 Prescribed by or in consultation with a gastroenterologist (stomach doctor)
  - 1.2 Age 18 years or older
  - 1.3 Diagnosis of ulcerative colitis with the intent of treatment to induce remission
  - 1.4 Trial and failure of at least one topical mesalamine product (Rowasa, Canasa, Mesalamine enemas) used concurrently with an oral aminosalicylate (sulfasalazine, olsalazine, mesalamine, or balsalazide), OR symptoms require rapid improvement (greater than 4 stools/day, severe impairment to daily life)
  - 1.5 Approval Period: 8 weeks of therapy within 6 months
- 2. Coverage Criteria for Primary Immunoglobulin A Nephropathy (Tarpeyo)**
  - 2.1 Diagnosis of primary immunoglobulin A nephropathy (IgAN) confirmed by biopsy
  - 2.2 Age 18 years or older
  - 2.3 Prescribed by or in consultation with a nephrologist
  - 2.4 Urine protein-to-creatinine ratio (UPCR)  $\geq 1.5$  g/g or proteinuria  $\geq 2$  g/day
  - 2.5 eGFR  $\geq 35$  mL/min/1.73 m<sup>2</sup>
  - 2.6 Patient is stable on RAS inhibitor (ACE-I or ARB) at maximally tolerated dose unless contraindicated
  - 2.7 Patient is not currently receiving dialysis or has undergone kidney transplant
  - 2.8 Approval Period: 9 months (Therapy duration limited per package insert)
- 3. Exclusion Criteria**
  - 3.1 Uceris is not covered for severe ulcerative colitis defined as more than 6 bloody stools per day and signs of systemic involvement (fever, tachycardia, anemia)
  - 3.2 Uceris is not covered for the diagnosis of collagenous and lymphocytic colitis
    - Budesonide 3mg ER (Entocort) capsules are available without prior authorization and can be used to treat collagenous and lymphocytic colitis. The 3mg strength of budesonide ER can provide the initial 9mg recommended dosage as well as allow for taper.
  - 3.3 Tarpeyo is not covered if patient is currently receiving dialysis or has undergone kidney transplant.

## CPT Codes

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## HCPCS Codes

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## References

1. Uceris (budesonide tablet, extended release) [prescribing information]. Bridgewater, NJ: Valeant Pharmaceuticals; April 2020.
2. Tarpeyo (budesonide) [prescribing information]. Stockholm Sweden: Colliditas Therapeutics AB; December 2021.
3. Rubin DT, Ananthakrishnan AN, Siegel CA, et al. ACG Clinical Guideline: Ulcerative Colitis in Adults. *Am J Gastroenterol* 2019; 114:384-413.
4. Feuerstein JD, Isaacs KL, Schneider Y, et al. AGA Clinical Practice Guidelines on the Management of Moderate to Severe Ulcerative Colitis. *Gastroenterology* 2020; 158:1450.
5. Kidney Disease: Improving Global Outcomes (KDIGO) Glomerular Diseases Work Group. KDIGO 2021 clinical practice guideline for the management of glomerular diseases. *Kidney Int.* 2021;100(4S):S1-S276.

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### DISCLAIMER

This Medical Policy has been developed as a guide for determining medical necessity. The process of medical necessity review also entails review of the most recent literature and physician review. Medical Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the most appropriate care. Health Alliance encourages input from providers when developing and implementing medical policies. Benefit determinations are based on applicable contract language in the member's Policy/ Subscription Certificate/ SummaryPlan Description. This Medical Policy does not guarantee coverage. There may be a delay between the revision of this policy and the posting on the web. Please contact the Health Alliance Customer Service Department at 1-800-851-3379 for verification of coverage.