UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2023 P 2179-5
Program	Prior Authorization/Medical Necessity
Medication	Sucraid (sacrosidase) oral solution
P&T Approval Date	12/2019, 1/2020, 1/2021, 1/2022, 1/2023
Effective Date	4/1/2023; Oxford only: 4/1/2023

1. Background:
Sucraid (sacrosidase) is an oral enzyme replacement therapy indicated for the treatment of genetically determined sucrase deficiency, which is part of congenital sucrase-isomaltase deficiency (CSID).

2. Coverage Criterion[a]:

A. Initial Authorization

1. **Sucraid** will be approved based on **all** of the following criteria:

   a. Diagnosis of congenital sucrase-isomaltase deficiency (CSID) as confirmed by one of the following:

      i. Biopsy of the distal duodenum or proximal jejunum demonstrating sucrase activity below the 10th percentile (< 25U).

      -OR-

      ii. All of the following:
         a) Stool pH < 6
         b) Negative lactose breath test
         c) Positive sucrose hydrogen-methane breath test (i.e., increase over 3 hours in exhaled hydrogen is >20 ppm, methane is >12 ppm, or both are >15 ppm over a previous baseline level)

   -AND-

   b. Prescribed by or in consultation with a gastroenterologist or rare disease specialist

   -AND-

   c. Will be used with a sucrose-free, low starch diet

   Authorization will be issued for 3 months.

B. Reauthorization

1. **Sucraid** will be approved based on **all of** the following criterion:

   a. Prescribed by or in consultation with a gastroenterologist or rare disease specialist

   -AND-

   b. Will be used with a sucrose-free, low starch diet

   -AND-

   c. Provider attests that the patient has achieved a clinically meaningful response while on Sucraid therapy, defined as at least a 50% reduction in all of the following:

      i. Symptoms of abdominal pain, cramps, bloating, gas, vomiting
      ii. Number of stools per day
      iii. Watery, loose stool consistency
      iv. Number of symptomatic days

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Prior Authorization/Notification may be in place.

4. References:

1. Sucraid [package insert]. Vero Beach, FL: QOL Medical, LLC; May 2022.
2. Congenital sucrase-isomaltase deficiency. U.S. Nation Library of Medicine. October 2019.
3. Puntis JW, Zamvar V. Congenital sucrase-isomaltase deficiency: diagnostic challenges and response to enzyme replacement therapy. Arch Dis Child. September 2015.
4. Robayo-Torres CC, Opekun AR, Quezada-Calvillo R, et. al.: 13C-breath test for sucrose digestion in congenital sucrase-isomaltase deficient and sacrosidase supplemented patients. J Ped Gastro Nutr. 48: 412-418. April 2009.
5. Treem WR. Clinical aspects and treatment of congenital sucrase-isomaltase deficiency. J Ped Gastro Nutr. 55 (Sup 2 Nov): S7-S13. November 2012.

Program	Prior Authorization/Medical Necessity – Sucraid
Change Control	
12/2019	New program
1/2020	Administrative; criteria clarification
1/2021	Annual review. Updated references.
1/2022	Annual review. Updated coverage criteria with current testing guidelines.
1/2023	Annual review with no changes to coverage criteria. Updated references.