UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 2179-7
Program	Prior Authorization/Medical Necessity
Medication	Sucraid (sacrosidase) oral solution
P&T Approval Date	12/2019, 1/2020, 1/2021, 1/2022, 1/2023, 1/2024, 4/2024
Effective Date	7/1/2024

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 Criteria:

A. Initial Authorization

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

   a. Diagnosis of congenital sucrase-isomaltase deficiency (CSID)

   -AND-

   b. Diagnosis has been confirmed by **one** of the following:

      (1) Endoscopic biopsy of the small bowel indicating **all** of the following:

         (a) Normal small bowel morphology
         (b) Absent or markedly reduced sucrase activity
         (c) Isomaltase activity varying from 0 to full activity
         (d) Reduced maltase activity
         (e) **One** of the following:

            i. Normal lactase activity
            ii. **Both** of the following:

               - Reduced lactase
               - Sucrase:lactase ratio of < 1.0

      -OR-

      (2) Molecular genetic testing of the sucrase-isomaltase (SI) gene indicating a pathogenic isomaltase gene variant

      -OR-

      (3) Carbon-13 sucrose breath test (^{13}C SBT) indicating a cumulative [^{13}C] CO_2 exhalation over 90 minutes below 10th percentile (i.e., < 3.9% for men and < 5.2% for women)

-AND-

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

-AND-

d. 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. Documentation of positive clinical response Sucraid therapy [e.g., reduced symptoms (e.g., abdominal pain, bloating, gas, vomiting), reduced number of stools per day, reduced number of symptomatic days]

   -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 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 2023.
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. Treem WR. Clinical aspects and treatment of congenital sucrase-isomaltase deficiency. J Ped Gastro Nutr. 55 (Sup 2 Nov): S7-S13. November 2012.
5. Treem WR, McAdams L, Stanford L, Kastoff G, Justinich C, Hyams J. Sacrosidase therapy for congenital sucrase-isomaltase deficiency. J Pediatr Gastroenterol Nutr. 1999 Feb;28(2):137-42. doi: 10.1097/00005176-199902000-00008. PMID: 9932843.

6. Robayo-Torres CC, Opekun AR, Quezada-Calvillo R, Villa X, Smith EO, Navarrete M, Baker SS, Nichols BL. 13C-breath tests for sucrose digestion in congenital sucrase isomaltase-deficient and sacrosidase-supplemented patients. J Pediatr Gastroenterol Nutr. 2009 Apr;48(4):412-8. doi: 10.1097/mpg.0b013e318180cd09. PMID: 19330928; PMCID: PMC3955999.

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.
1/2024	Annual review. Updated confirmation of diagnosis requirements for initial authorization. Simplified reauthorization criteria. Updated references.
4/2024	Added carbon-13 sucrose breath test as an acceptable confirmatory diagnostic test. Updated references.