Generic Name: Sacrosidase oral solution

Therapeutic Class or Brand Name: Sucraid

Applicable Drugs: N/A

Preferred: N/A

Non-preferred: N/A

Date of Origin: 6/2/2025

Date Last Reviewed / Revised: N/A

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through VII are met)

I. Documented diagnosis of Congenital Sucrase-Isomaltase Deficiency (CSID) established by meeting one of the following A or B:

   A. Patient has undergone endoscopic biopsy of the small bowel and disaccharidase levels are consistent with CSID as evidenced by ALL of the following (i through iv):

      i. Decreased (usually absent) sucrase level (normal reference: > 25 U/g protein)

      ii. Decreased or normal isomaltase (palatinase) level (normal reference: > 5 U/g protein)

      iii. Decreased maltase level (normal reference: > 100 U/g protein)

      iv. Decreased or normal lactase level (normal reference: > 15 U/g protein)

   B. Patient history of molecular genetic testing demonstrating homozygous or compound heterozygous pathogenic or likely pathogenic sucrase isomaltase gene variant.

II. Documented symptoms consistent with congenital sucrose-isomaltase deficiency (e.g., diarrhea, bloating, abdominal cramping, vomiting) prior to initiation.

III. Sucraid (Sacrosidase) will be used concomitantly with a low-starch diet.

IV. Minimum age requirement: 5 months old.

V. Treatment must be prescribed by or in consultation with a gastroenterologist, geneticist, metabolic disorder sub-specialist, or physician who specializes in the treatment of congenital diarrheal disorders.

VI. Request is for a medication with the appropriate FDA labeling, or its use is supported by current clinical practice guidelines.

VII. Refer to the plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have documented treatment failure or contraindication to the preferred product(s).

EXCLUSION CRITERIA

- Hypersensitivity to yeast, yeast products, glycerin (glycerol), or papain.

Other Criteria

- N/A

Quantity / Days Supply Restrictions

- Sacrosidase oral solution 8500 units/mL:
  - Patients weighing ≤15 kg: 8,500 units (1 mL) per meal or snack
  - Patients weighing >15 kg: 17,000 units (2 mL) per meal or snack

Approval Length

- **Authorization:** 6 months
- **Re-Authorization:** 1 year. An updated letter of medical necessity or progress notes showing positive clinical response, as evidenced by a reduction in symptoms, number of stools per day, or number of symptomatic days and patient continues to follow a low-starch diet.

Appendix

N/A

References

1. Sucraid [Prescribing Information], Vero Beach, FL; QOL Medical, LLC.; 2024. Accessed April 21, 2025.

   https://www.sucraidprescribinginformation.com/

2. Treem WR, McAdams L, Stanford L, Kastoff G, Justinich C, Hyams J. Sacrosidase therapy for congenital sucrase-isomaltase deficiency. J Pediatr Gastroenterol Nutr. 1999;28(2):137-142. doi:10.1097/00005176-199902000-00008. Accessed April 21, 2025.

   https://pubmed.ncbi.nlm.nih.gov/9932843/

3. Danialifar TF, Chumpitazi BP, Mehta DI, Di Lorenzo C. Genetic and acquired sucrase-isomaltase deficiency: A clinical review. J Pediatr Gastroenterol Nutr. 2024;78(4):774-782. doi:10.1002/jpn3.12151. Accessed April 21, 2025.

   https://pubmed.ncbi.nlm.nih.gov/38327254/

4. Treem WR. Clinical aspects and treatment of congenital sucrase-isomaltase deficiency. J Pediatr Gastroenterol Nutr. 2012;55 Suppl 2:S7-S13. doi:10.1097/01.mpg.0000421401.57633.90. Accessed April 21, 2025.

   https://pubmed.ncbi.nlm.nih.gov/23103658/

Historical Tracking of Changes Made to Policy

DISCLAIMER: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.