

Clinical Pharmacy Program Guidelines for Sucraid

Program	Prior Authorization
Medication	Sucraid (sacrosidase) oral solution
Markets in Scope	Arizona, California, Colorado, Hawaii, Maryland, New Jersey, Nevada, New York, New York EPP, Pennsylvania CHIP, Rhode Island, South Carolina
Issue Date	12/2019
Pharmacy and Therapeutics Approval Date	1/2021
Effective Date	3/2021

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:

<p>A. <u>Initial Authorization</u></p> <p>1. Sucraid will be approved based on <u>all</u> of the following criteria:</p> <p style="padding-left: 40px;">a. Diagnosis of congenital sucrase-isomaltase deficiency (CSID) as confirmed by <u>one</u> of the following:</p> <p style="padding-left: 80px;">(1) Duodenal biopsy showing low sucrose activity and normal amounts of other disaccharides</p> <p style="text-align: center; padding-left: 40px;">-OR-</p> <p style="padding-left: 80px;">(2) <u>All</u> of the following:</p> <p style="padding-left: 120px;">(a) Stool pH < 6</p> <p style="padding-left: 120px;">(b) Negative lactose breath test</p> <p style="padding-left: 120px;">(c) Increase in breath hydrogen > 10 ppm when challenged with sucrose after fasting</p> <p style="text-align: center; padding-left: 40px;">-AND-</p>
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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:

- (1) Symptoms of abdominal pain, cramps, bloating, gas, vomiting
- (2) Number of stools per day
- (3) Watery, loose stool consistency
- (4) Number of symptomatic days

Authorization will be issued for 12 months.

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.
- Supply limits may be in place.

4. References:

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1. Sucraid [package insert]. Vero Beach, FL: QOL Medical, LLC.; September 2018.
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 –Sucraid
Change Control	
Date	Change
12/2019	New program
1/2020	Specified increase in breath hydrogen when challenged with sucrose is “after fasting” to align with package insert Clinical Studies section.
1/2021	Annual review. Updated reference.