

# Initial Prior Authorization with Quantity Limit Sucraid

## Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Sucraid	sacrosidase

## Indications

### FDA-approved Indications

Sucraid (sacrosidase) Oral Solution is indicated for the treatment of sucrase deficiency, which is part of congenital sucrase-isomaltase deficiency (CSID), in adult and pediatric patients 5 months of age and older.

## Coverage Criteria

### Congenital Sucrase-Isomaltase Deficiency (CSID)

Authorization may be granted when the patient has a diagnosis of congenital sucrase-isomaltase deficiency (CSID) when ONE of the following criteria is met:

- The diagnosis of CSID was confirmed by small bowel biopsy.
- The diagnosis of CSID was confirmed by genetic testing.

- The diagnosis of CSID was confirmed by sucrose hydrogen breath test.

## Quantity Limits Apply

### Quantity Limit

Please Note: Since manufacturer package sizes may vary, it is the discretion of the dispensing pharmacy to fill quantities per package size up to these quantity limits. In such cases the filling limit and day supply may be less than what is indicated.

The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing OR the duration of 21 days is used for a 25-day fill period and 63 days is used for a 75-day fill period to allow time for refill processing.

Drug	1 Month Limit	3 Month Limit
Sucraid Multiple-Dose Bottle (Each bottle contains 4 oz [118 mL total])	354 mL / 25 days	1,062 mL / 75 days
Sucraid Single-Use Container (Each carton contains 150 single-use containers of 2 mL each [300 mL total])	300 mL / 21 days	900 mL / 63 days

## Duration of Approval (DOA)

- 3369-C: DOA: 12 months

## References

1. Sucraid [package insert]. Vero Beach, FL: QOL Medical, LLC; August 2024.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2024. <https://online.lexi.com>. Accessed September 9, 2024.
3. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 09/09/2024).
4. National Organization for Rare Disorders (NORD). Congenital Sucrase-Isomaltase Deficiency. 2005. Available at <https://rarediseases.org/rare-diseases/disaccharide-intolerance-i/>. Accessed September 9, 2024.

# Document History

Written by: UM Development (DS)

Date Written: 10/2019

Revised: 01/2020 (no clinical changes), 09/2020 (added sucrose hydrogen breath test to confirm dx, updated title), 09/2021 (no clinical changes); (VLS) 06/2022 (added 2mL single-dose package), 09/2022 (no clinical changes); (SS) 09/2023 (no clinical changes); (MRS) 09/2024 (no clinical changes)

Reviewed: Medical Affairs (CHART) 10/24/2019, 01/23/2020, 09/24/2020, 12/31/2020, 09/30/2021, 09/22/2022, 09/28/2023, 09/26/2024

External Review: 12/2019, 04/2020, 12/2020, 12/2021, (FYI) 08/2022, 12/2022, 12/2023, 12/2024

## **CRITERIA FOR APPROVAL**

- |   |  |     |    |
|---|--|-----|----|
| 1 | Does the patient have a diagnosis of congenital sucrase-isomaltase deficiency (CSID)?<br>[If Yes, then go to 2. If No, then no further questions.]                           | Yes | No |
| 2 | Was the diagnosis of congenital sucrase-isomaltase deficiency (CSID) confirmed by small bowel biopsy?<br>[If Yes, then go to 5. If No, then go to 3.]                        | Yes | No |
| 3 | Was the diagnosis of congenital sucrase-isomaltase deficiency (CSID) confirmed by genetic testing?<br>[If Yes, then go to 5. If No, then go to 4.]                           | Yes | No |
| 4 | Was the diagnosis of congenital sucrase-isomaltase deficiency (CSID) confirmed by sucrose hydrogen breath test?<br>[If Yes, then go to 5. If No, then no further questions.] | Yes | No |
| 5 | Does the patient require an amount of the requested drug for coadministration with more than three meals and three snacks per day?<br>[No further questions]                 | Yes | No |

RPh Note: If yes, then deny and enter a partial approval per Quantity Limit Chart.

Mapping Instructions			
	Yes	No	DENIAL REASONS

Reference number(s)
3369-C

<b>1.</b>	Go to 2	Deny	<p>Your plan only covers this drug when it is used for certain health conditions. Covered use is for congenital sucrase-isomaltase deficiency (CSID). Your plan does not cover this drug for your health condition that your doctor told us you have. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review.</p> <p>[Short Description: Diagnosis]</p>
<b>2.</b>	Go to 5	Go to 3	
<b>3.</b>	Go to 5	Go to 4	
<b>4.</b>	Go to 5	Deny	<p>Your plan only covers this drug when your condition was confirmed by one of the following: A) Small bowel biopsy, B) Genetic testing, or C) Sucrose hydrogen breath test. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review.</p> <p>[Short Description: No confirmation of diagnosis]</p>
<b>5.</b>	[Please select appropriate denial close option. For the denial verbiage, only include the requested drug. Remove all other drugs]	[PA approved for 12 months. See Quantity Limit Chart.]. Approve, 12 Months	<p>We have denied your request because it is for more than the amount your plan covers (quantity limit). We reviewed the information we had. We have partially approved your request for this drug up to the amount your plan covers (354 mL of the Multiple-Dose Bottle per month OR 300 mL of the Single-Use Containers per 25 days). Your request for more drug has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review.</p> <p>[Short Description: Quantity, Exceeds max limit, Partial denial]</p>

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