PRIOR AUTHORIZATION CRITERIA

BRAND NAME*
(generic)

SUCRAID
(sacrosidase)

Status: CVS Caremark Criteria
Type: Initial Prior Authorization with Quantity Limit ***Ref # 3369-C***

** Drugs that are listed in the target drug box include both brand and generic and all dosage forms and strengths unless otherwise stated. OTC products are not included unless otherwise stated.*

FDA-APPROVED INDICATIONS
Sucraid is indicated as oral replacement therapy of the genetically determined sucrase deficiency, which is part of congenital sucrase-isomaltase deficiency.

COVERAGE CRITERIA
The requested drug will be covered with prior authorization when the following criteria are met:

- The patient has a diagnosis of congenital sucrase-isomaltase deficiency

AND

- The diagnosis of congenital sucrase-isomaltase deficiency was confirmed by small bowel biopsy
  OR
- The diagnosis of congenital sucrase-isomaltase deficiency was confirmed by genetic testing
  OR
- The diagnosis of congenital sucrase-isomaltase deficiency was confirmed by sucrose hydrogen breath test

Quantity Limits apply.

RATIONALE
The intent of the criteria is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. Sucraid is indicated as oral replacement therapy of the genetically determined sucrase deficiency, which is part of congenital sucrase-isomaltase deficiency (CSID). The definitive test for diagnosis of CSID is the measurement of intestinal disaccharidases following small bowel biopsy.[1] Genetic testing may be indicated in some cases. Other tests may include sucrose hydrogen breath tests[4,5] Therefore, coverage will be considered for patients who have congenital sucrose-isomaltase deficiency that was confirmed by small bowel biopsy, genetic testing, or sucrose hydrogen breath test.

The recommended dosage of Sucraid is 1 mL per meal or snack for patients weighing up to 15 kg, and 2 mL per meal or snack for patients weighing over 15 kg. Sucraid is supplied in 4 ounce, 118 mL, bottles.[1] Therefore, to accommodate for up to 3 meals and 3 snacks per day at the highest dosage, a quantity limit of 3 bottles, 354 mL, per month will apply to patients who meet the prior authorization criteria.

REFERENCES

1. Sucraid [package insert]. Vero Beach, FL: QOL Medical, LLC; September 2018.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Hudson, OH: Wolters Kluwer Clinical Drug Information, Inc. http://online.lexi.com/. Accessed August 2020.
3. Micromedex (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. http://www.micromedexsolutions.com/. Accessed August 2020.
4. National Organization for Rare Disorders (NORD). Congenital Sucrase-Isomaltase Deficiency. 2005. Available at https://rarediseases.org. Accessed August 2020.

5. Genetic and Rare Diseases Information Center. Congenital sucrose-isomaltase deficiency. 2020. Available at https://rarediseases.info.nih.gov. Accessed August 2020.

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)
Reviewed: Medical Affairs (CHART) 10/24/2019, 01/23/2020, 09/24/2020, 12/31/2020
External Review: 12/2019, 04/2020, 12/2020

CRITERIA FOR APPROVAL

1	Does the patient have a diagnosis of congenital sucrase-isomaltase deficiency? [If no, then no further questions.]	Yes	No
2	Was the diagnosis of congenital sucrase-isomaltase deficiency confirmed by small bowel biopsy? [If yes, then skip to question 5.]	Yes	No
3	Was the diagnosis of congenital sucrase-isomaltase deficiency confirmed by genetic testing? [If yes, then skip to question 5.]	Yes	No
4	Was the diagnosis of congenital sucrase-isomaltase deficiency confirmed by sucrose hydrogen breath test? [If no, then no further questions.]	Yes	No
5	Does the patient require an amount for coadministration with more than three meals and three snacks per day with the requested drug? [RPh Note: If yes, then deny and enter a partial approval of 3 bottles (354 mL)/25 days or 9 bottles (1062 mL)/75 days of the requested drug.]	Yes	No

Mapping Instructions			
	Yes	**No**	**DENIAL REASONS – DO NOT USE FOR MEDICARE PART D**
1.	Go to 2	Deny	You do not meet the requirements of your plan. Your plan covers this drug when you have congenital sucrase-isomaltase deficiency. Your request has been denied based on the information we have. [Short Description: No approvable diagnosis]
2.	Go to 5	Go to 3	
3.	Go to 5	Go to 4	
4.	Go to 5	Deny	You do not meet the requirements of your plan. Your plan covers this drug when your diagnosis was confirmed by one of the following: - small bowel biopsy - genetic testing - sucrose hydrogen breath test Your request has been denied based on the information we have. [Short Description: No confirmation of diagnosis]

5.	Deny	Approve, 12 months, 3 bottles (354 mL)/25 days* or 9 bottles (1062 mL)/75 days*	You have requested more than the maximum quantity allowed by your plan. Current plan approved criteria cover up to 3 bottles (354 mL)/month of the requested drug and strength. You have been approved for the maximum quantity that your plan covers for a duration of 12 months. Your request for additional quantities of the requested drug and strength has been denied. [Short Description: Over max quantity]

**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.*