

Pharmacy Policy Bulletin

Title: Sacrosidase (Sucraid®)

Policy #: Rx.01.233

Application of pharmacy policy is determined by benefits and contracts. Benefits may vary based on product line, group, or contract. Some medications may be subject to precertification, age, quantity, or formulary restrictions (ie limits on non-preferred drugs). Individual member benefits must be verified.

This pharmacy policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety, or FDA approval may have changed. This Pharmacy Policy will be regularly updated as scientific and medical literature becomes available. This information may include new FDA-approved indications, withdrawals, or other FDA alerts. This type of information is relevant not only when considering whether this policy should be updated, but also when applying it to current requests for coverage.

Members are advised to use participating pharmacies in order to receive the highest level of benefits.

Intent:

The intent of this policy is to communicate the medical necessity criteria for Sucraid® (sacrosidase) as provided under the member's prescription drug benefit.

Description:

Congenital sucrase-isomaltase deficiency is a disorder that effects a patient's ability to digest sucrose and maltose. Congenital sucrase-isomaltase deficiency is usually identified in infancy when babies start to consume fruits, juices, and grains. These children will typically experience stomach cramps, bloating, diarrhea, and excess gas production. It can also lead to failure to gain weight, malnutrition, and failure to thrive.

Sucraid® (sacrosidase) is an enzyme replacement therapy indicated for the treatment of genetically determined sucrase deficiency, which is part of congenital sucrase-isomaltase deficiency.

Policy:

INITIAL CRITERIA: Sacrosidase (Sucraid®) is approved when there is a diagnosis of Congenital Sucrase-Isomaltase deficiency (CSID)

Initial Authorization duration: 2 years

REAUTHORIZATION CRITERIA: Sacrosidase (Sucraid®) is re-approved when there is positive clinical response to therapy.

Reauthorization duration: 2 years

Black Box Warning as shown in the drug Prescribing Information:

N/A

Guidelines:

Refer to the specific manufacturer's prescribing information for administration and dosage details and any applicable Black Box warnings.

BENEFIT APPLICATION

Subject to the terms and conditions of the applicable benefit contract, the applicable drug(s) identified in this policy is (are) covered under the prescription drug benefits of the Company's products when the medical necessity criteria listed in this pharmacy policy are met. Any services that are experimental/investigational or cosmetic are benefit contract exclusions for all products of the Company.

References:

Congenital sucrase-isomaltase deficiency. US National Library of Medicine website. Updated July 1, 2008. Available from: <https://medlineplus.gov/genetics/condition/congenital-sucrase-isomaltase-deficiency/>. Accessed January 06, 2023.

Sucraid® (sacrosidase) [package insert]. Kirkland, WA: QOL Medical, LLC; May 2022. Available from: https://www.sucraid.com/wp-content/uploads/2019/12/SucPI_R0219.pdf. Accessed January 06, 2023.

Applicable Drugs:

Inclusion of a drug in this table does not imply coverage. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

| Brand Name | Generic Name |
|------------|--------------|
| Sucraid® | Sacrosidase |

Cross References:

Rx.01.33 Off Label Use

Rx.01.221 Drugs Exceeding Claim Dollar Limit Threshold

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| Policy Version Number: | 4.00 |
| P&T Approval Date: | December 08, 2022 |
| Policy Effective Date: | April 01, 2023 |
| Next Required Review Date: | December 08, 2023 |

The Policy Bulletins on this web site were developed to assist the Company in administering the provisions of the respective benefit programs, and do not constitute a contract. If you have coverage through the Company, please refer to your specific benefit program for the terms, conditions, limitations and exclusions of your coverage. Company does not provide health care services, medical advice or treatment, or guarantee the outcome or results of any medical services/treatments. The facility and professional providers are responsible for providing medical advice and treatment. Facility and professional providers are independent contractors and are not employees or agents of the Company. If you have a specific medical condition, please consult with your doctor. The Company reserves the right at any time to change or update its Policy Bulletins.

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