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Scope: Medicaid

## SPECIALTY GUIDELINE MANAGEMENT

### Sucraid (sacrosidase)

#### POLICY

##### I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

##### FDA-Approved Indication

Treatment of congenital sucrose-isomaltase deficiency.

All other indications are considered experimental/investigational and are not a covered benefit.

##### II. CRITERIA FOR INITIAL APPROVAL

##### **Congenital sucrose-isomaltase deficiency (CSID)**

Authorization of 3 months may be granted for treatment of CSID for members who are at least 5 months of age or older when all of the following criteria are met:

1. Sucraid is prescribed by a gastroenterologist, endocrinologist, or genetic specialist; **AND**
2. Member's current weight is provided (for the purpose of dose calculations); **AND**
3. Dose does not exceed FDA approved labeling; **AND**
4. Patient has a diagnosis of congenital sucrose-isomaltase deficiency documented by:
  - a. Small bowel biopsy; **OR**
  - b. Genetic testing; **OR**
  - c. Sucrose hydrogen breath test

##### III. CONTINUATION OF THERAPY

Authorization of 6 months may be granted for all members (including new members) who meet all initial authorization criteria and achieve or maintain positive clinical response with Sucraid as defined as at least 50% reduction in symptoms (e.g: abdominal pain, cramps, bloating, gas, vomiting, diarrhea, number of stools per day, and number of symptomatic days)

##### IV. QUANTITY LIMIT

Coverage is available for a quantity sufficient to allow for FDA-approved dosing:

> 15kg: 2mL with each meal or snack

≤15kg: 1mL with each meal or snack