Subject: Enteral nutrition (tube feeding) and oral nutritional formulas

Applicability: Missouri and Kansas membership

Purpose: To clarify the management of nutritional formulas

Policy:

Statement of coverage decision: Coverage of enteral and oral supplement nutritional formulas is provided when criteria is met. Nutritional products are provided after coverage by the WIC program is determined to be insufficient to meet needs. This may be either additional amount when the member is eligible for WIC or the entire product when the member is no longer covered under the WIC program. This policy does not address metabolic formulas, which are covered as directed by state regulations.

Criteria for coverage: An annual nutritional consultation with a registered dietician, primary care provider, or specialist is recommended to develop weight gain strategies and diet modifications to meet caloric needs. This should be clearly documented in the evaluation or progress notes submitted with the prior authorization request. Additionally, to qualify for enteral/supplemental formula or special foods, <u>one</u> of the following (items 1-5) must be met:

1. For sole source of nutritional support, all items must be met:

- There is medical documentation of the inability to tolerate standard oral nutrition that would be appropriate for his/her age group.
- A permanent tube feeding mechanism is in place OR there is medical documentation of complete dependence on the nutritional formula by oral route.
- Nutritional formula must be commercially available and be considered a complete nutrition source. A valid HCPC code is required.
- WIC coverage unavailable or inadequate to meet needs for growth.
 - If the child is younger than 5 years of age, there must be a statement from WIC on the amount and type of formula or supplements provided per month.
 - WIC is considered unavailable if child is ≥5 years of age. Misuse or lost vouchers or abuse of the WIC service that causes an interruption in WIC coverage would not be considered a valid reason to provide supplement.
 - Nutritional need is the amount of formula to establish or maintain an appropriate weight for age and gender.

2. For oral supplementation required for inadequate weight gain:

- First determine if inadequate weight gain is present by one of the following being met (A prior history of poor growth is adequate for children with a medical condition compatible with poor growth but currently maintaining appropriate growth while receiving oral supplementation):
 - Weight below the 3rd percentile for gestation corrected age and sex on more than one occasion, typically over 3 months or more.
 - Special growth charts for selected genetic syndromes should be used when indicated and available (eg, for children with Down syndrome, Turner syndrome).
 - Growth charts are located at the Centers for Disease Control web site, in the section for National Center for Health Statistics (NCHS): http://www.cdc.gov/nchs/

- Weight for length or height <10th percentile.
- In those children who are considered overweight (BMI 85th to 94th percentile) or obese (≥95th percentile) where weight loss is desired (**), An undesired rate of weight loss that causes the weight curve to decrease by two or more major percentile lines major lines are 97th, 90th, 75th, 50th, 25th, 10th, and 3rd)
- A rate of daily weight gain less than that expected for age. The expected weight gain for infants and toddlers is:
 - 26 to 31 g/day for those 0 to 3 months
 - 17 to 18 g/day for those 3 to 6 months
 - 12 to 13 g/day for those 6 to 9 months
 - 9 to 13 g/day for those 9 to 12 months
 - 7 to 9 g/day for those 1 to 3 years
- Then, if inadequate weight gain is present, <u>all of</u> the following must be met:
 - Documentation of inadequate weight gain (failure to thrive) despite medical oversight for at least 3 months.
 - For an infant or toddler who has not gained weight well in the past but who is on supplement currently and gaining weight, the past history can be used to meet this criteria. This would be seen most often in premature infants or those who have had significant surgeries or medical issues early in life.
 - For an older child, it may be unintended weight loss when the weight is disproportionately low compared to the height.
 - Compliance with or intolerance of attempts to increase caloric intake.
 - Nutritional formula must be commercially available and be considered a complete nutrition source. A valid HCPC code is required.
 - Normal daily nutrition is not considered supplemental.
 - Diagnosis of a medical condition that is compatible with inadequate weight gain; such as but not limited to anatomical or functional problems of the gastrointestinal tract that impair digestion or absorption, neurological disorders that impair swallowing or chewing, intolerance or allergy to standard-milk-based or soy-based formula (see below), treatment with medications that have anti-nutrient or catabolic properties (e.g. anti-tumor treatments, stimulants, etc.), increased caloric needs due to excessive burns, infections, trauma, or other illness that impairs caloric intake or retention
 - WIC coverage unavailable due to child's age or inadequate to meet needs for growth.

3. For oral supplementation required for food allergies, all of the following must be met:

- Member should have a documented food allergy identified through appropriate evaluation by an allergist, or in some cases, the PCP. If there is a clinical history suggestive of milk/soy allergy that may require substitution with the use of a nutritional formula, and appropriate evaluation has not been done, request should be reviewed by the medical director, and if needed, coordination of a referral to an allergy specialist by case management.
- An annual nutritional consult with a registered dietician, primary care provider, or specialist confirms that standard food or milk cannot meet nutritional needs and is recommended to develop weight gain strategies and diet modifications to meet caloric needs. Soymilk would be considered a standard food.
- WIC coverage has been determined.
- Dietary modification must be supported by peer reviewed medical literature.
- The supplement is a commercially prepared oral nutrition formula with a valid HCPC code and is the most cost-effective means of providing adequate nutrition for the diagnosed allergy.

4. <u>For oral supplementation and/or special foods for PKU or other metabolic condition, all of the</u> <u>following must be met:</u>

- Member must have a documented metabolic condition.
- WIC coverage unavailable.
- An annual nutritional consult with a registered dietician is recommended for all patients with PKU or other metabolic conditions. If this is not in place, the PCN Care Navigator should assist in coordinating this for the member.
- The supplement or food is commercially prepared, has a valid HCPC code, and is the most cost-effective means of providing adequate nutrition for the metabolic condition.

5. For oral supplementation for chronic life-long conditions:

- One of the following conditions must be present:
 - Cystic Fibrosis
 - Chronic Renal Insufficiency
 - o Crohn's Disease
 - Short Bowel Syndrome
 - Malabsorption Disorders
 - Developmental Conditions (i.e. autism)
 - Neurological Conditions (i.e. cerebral palsy)
- Formula will be approved for members who have maintained an appropriate weight for at least 6 months as outlined by their PCP, specialist or registered dietician. During this time, nutritional therapy should be in place, and the amount of formula volume should be expected to decrease over time while the weight is maintained. Some patients may require ongoing supplementation to maintain an appropriate weight.

Authorization period:

- **Initial:** 3 months for both types of support. When authorized, verify amount after WIC amount, and that requested amount matches the medical record daily intake.
 - In circumstances where the family has not yet connected with WIC, an approval for 1 month's time can be entered to support the patients nutritional needs in the interim
- **Extended:** Supplemental nutrition should be reviewed every 3 months for continued need when there is no life-long chronic disease condition. Supplemental nutrition for a life-long chronic disease should be authorized every 6 months. Complete nutrition should be authorized every 6 months, unless medical plan indicates a transition to other nutritional options.

Discontinuation of authorization: Adequate nutrition can be sustained by traditional diet for age.

Reasons for non-coverage:

- Medical necessity not demonstrated for nutritional supplement.
- Elemental formula supplement for children who do not meet food allergy criteria noted above. This would include Attention Deficit/Hyperactivityt Disorder, Autism Spectrum Disorder, and asthma, for example.
- Member or family unhappy with WIC choice of formula or food supplements.
- Misuse or lost vouchers, or abuse of the WIC service that causes an interruption in WIC coverage
- Adult oral supplements
- Requested supplement does not have a HCPC code.

Application of guideline:

Clinical staff utilization of this guideline will take into account the clinical situation and consider the following individual factors for each case under review:

- Age
- Co-morbidities
- Complications
- Progress of treatment
- Psychosocial circumstances
- Environmental factors

Definitions:

- Enteral nutrition: tube feeding using the gastrointestinal tract, via a nasogastric, gastric or jejunal tube.
- **Oral Supplement:** additional intake to increase the caloric consumption for someone who has an inadequate intake of age-appropriate food to meet his/her metabolic needs but is able to take oral nutrition.
- **Sole source nutrition:** total dependence on a nutritional formula feeding to provide all nutrition. Infants are by nature dependent on formula (or breast milk) as sole nutrition for the first several months of life. This term is designed for children and adults who would otherwise normally meet their nutritional needs with a standard diet for age but cannot for whatever reason.
- WIC: Women, Infants and Children nutritional program. Coverage is available for low-income families; all Medicaid recipients automatically qualify. Food or formula support is provided to pregnant women and children up to the age of 5. WIC provides a large number of specialty formulas. Vouchers are done for commonly available formulas; direct shipment is done for others. The web site for each state WIC agency contains a comprehensive list of formulas and food supplements and other resources. It is the expected source of formula for infants, and nutritional support for young children. WIC is required to provide the appropriate formula for a covered child's needs. Preference for a particular brand is not required. Each state has a contracted vendor for infant formulas and adheres to that list.

Medical background: Children are vulnerable to long-term consequences of malnutrition. The WIC program has been instrumental in providing appropriate nutrition but cannot meet the needs of all population groups. Therefore, Medicaid provides coverage for both sole source and supplemental nutrition to members with documented needs when WIC is unable to provide the nutritional support.

Children with weight gain issues and failure to thrive can be successfully managed with nutritional counseling and modification of mealtime habits and types of food provided. Nutritional consultation can play a key role in helping caregivers provide nutritious meals using standard food options. Use of liquid food supplements can sometimes be perceived as an easier way for caregivers to provide good nutrition. Nutritionists can assist families in understanding food choices, and also recommend the amount of supplementation needed for growth and development.

There are common trials of diet modification for behavioral disorders. Most are unsubstantiated in the peer reviewed medical literature despite anecdotal reports of success. Specifically, casein-free and/or gluten free diets for children with Autism Spectrum Disorder are noted in the lay literature to be potentially successful. These restrictive diets can be managed with appropriate balance of standard food but are difficult to maintain.

There is no evidence of benefit in the peer-reviewed literature, however. Thus, although parents may choose to use these dietary modifications, we would not provide coverage for elemental formulas for children with these diagnoses.

The food and formula guide for Missouri for 202021 can be found at:

https://health.mo.gov/living/families/wic/pdf/retailer-ffrg-jan2021.pdf

The food and formula guide for Kansas for 2021 can be found at:

http://www.kansaswic.org/download/Formula_Manufacturers_Products_rev.pdf

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WIC web site for Missouri: http://health.mo.gov/living/families/wic/.

WIC website for Kansas: http://www.kansaswic.org/

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Policy drafted by: PCN Clinical Services Committee **Policy approved by:** Doug Blowey, MD, PCN Medical Director

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Disclaimer: Any coverage determination requires medical necessity, coverage by the member's benefit plan, and eligibility. The sole purpose of this document is to address medical necessity.