

MEDICATION COVERAGE POLICY

PHARMACY AND THERAPEUTICS ADVISORY COMMITTEE

POLICY:	Nutrition in CKD	P&T DATE:	5/9/2017
THERAPEUTIC CLASS:	Gastrointestinal Disorders	REVIEW HISTORY:	2/16, 11/15, 9/15, 9/14,
LOB AFFECTED:	MCL	(MONTH/YEAR)	12/07

This policy has been developed through review of medical literature, consideration of medical necessity, generally accepted medical practice standards, and approved by the HPSJ Pharmacy and Therapeutic Advisory Committee.

☒ OVERVIEW

This medication coverage policy is supplemental to the PH-19 Nutritional Supplements for Medical Conditions HPSJ Policy.

In summation, PH-19 states the following regarding oral or enteral nutrition supplements:

- Enteral nutrition supplements or replacements are only covered through the Medi-Cal pharmacy benefit when used as a medically necessary therapeutic regimen to prevent serious disability or death in patients with medically diagnosed conditions that preclude the use of regular food.
- Nutritional supplements are not medically necessary when the criteria are not met or if use of the supplements are based on convenience or preference of the member or provider.
- Infant formula for normal healthy infants is a specifically excluded benefit under the Medi-Cal, California Children's Services (CCS), or Genetically Handicapped Persons Program, those who are eligible under WIC will be referred to WIC.

****Note:** *This coverage policy strictly reviews the nutritional agents used specifically for the treatment or management of nutrition in chronic kidney disease (CKD) patients. For all other cases where nutritional supplementation is needed, please refer to Policy – Nutritional Supplements for Medical Conditions.*

☒ MEDICAL NECESSITY CRITERIA

All requests for nutritional supplementation will be evaluated by a HPSJ Pharmacist. The Medical Director is ultimately responsible for all determinations.

- The following medical necessity criteria will be used:
 - Enteral nutrition supplements covered must be intended for the specific management of a disease or condition for which distinctive nutritional requirements based on scientific principles are established by medical evaluation.
- If medical necessity criteria are met, the supplement will be approved.

☒ REQUIRED DOCUMENTATION FOR PRIOR AUTHORIZATION AND REAUTHORIZATION

- ☒ All pertinent patient information including:
 - Age, height, weight, growth charts for infants and children, medical diagnosis, reason(s) for requesting nutritional supplementation, previous nutritional programs attempted, percent of daily caloric intake obtained without supplementation, other food sources, dietary/nutrition consultant information, and supporting lab documentation (e.g. albumin level, total lymphocyte count failure-to-thrive workup, etc.).
- ☒ Patients referred by their PCP for long-term nutritional supplementation will require an evaluation by a specialist (e.g. endocrinologist, gastroenterologist, or qualified nutritionist).

- ⊕ Reauthorization will be required every 6 months or as appropriate based on condition.
- ⊕ A denial letter from Medicare, WIC program, or CCS is required (if applicable).

Table 1: Available Formulary Nutritional Supplementation Agents for High Nutrient Requirement Disease States (Current as of 5/2017)

Enteral/Oral Product	Serving Size	Unit	Protein (g) per Serving	Calories (kcal) per Serving	Avg Daily Servings	Avg Daily Protein	Restrictions
FIBERSOURCE HN LIQUID	250	mL	13.5	300	6	80	PA
JEVITY 1 CAL LIQUID	237	mL	10.4	250	5	55	PA
JEVITY 1.2 CAL LIQUID	237	mL	13.2	285	6	76	PA
JEVITY 1.5 CAL LIQUID	237	mL	15.1	355	5	70	PA
NEPRO CARB STEADY LIQUID	237	mL	19.1	425	3	57	PA
NUTREN 1.0 LIQUID	250	mL	10	250	5	51	PA
NUTREN 1.5 LIQUID	250	mL	17	375	6	101	PA
NUTREN 2.0 LIQUID	250	mL	20	500	4	71	PA

Avg = Average, PA = Prior Authorization required

Clinical Justification:

Patients who meet medical necessity criteria for oral or enteral nutritional supplementation can choose from the above formulary agents in Table 1 as they are available in either cans or enteral packages, vary in grams of protein, and vary in calories per serving to meet the needs of different daily protein and calorie requirements. Also, these agents consist of the majority of nutritional products utilized by HPSJ members in the year 2016, making them the most likely to be easily accessible and readily available to all members.

Triage:

- **Other forms of insurance coverage: Medicare Part B, CCS, etc.**
- **New therapy or continuation of therapy**
- **Pertinent documentation submitted as listed above**

⊕ EVALUATION CRITERIA FOR APPROVAL/EXCEPTION CONSIDERATION

Below are the coverage criteria and required information for each agent. These coverage criteria have been reviewed approved by the HPSJ Pharmacy & Therapeutics (P&T) Advisory Committee. For conditions not covered under this Coverage Policy, HPSJ will make the determination based on Medical Necessity as described in HSPJ Medical Review Guidelines (UM06).

Nutritional Supplements for High Nutrient Requirement Disease States

Fibersource, Jevity, Nepro, Nutren

☐ Coverage Criteria:

- **Chronic Kidney Disease:** – Reserved for ESRD patients diagnosed with malnutrition that cannot meet nutritional needs through a standard diet and able to meet the criteria of use for medical necessity.
- Patients with protein-energy wasting, meeting at least 1 of the following criteria:
 - Serum albumin < 3.8 g/dL (3-month rolling average)
 - BMI < 18.5 kg/m²
 - Unintentional weight loss (≥ 5% over 1 month; ≥7.5% over 3 mos.; or ≥ 10% over 6 mos.)

AND

 - Clinical record showing patient has failed oral nutritional supplements OR documentation of use of an enteral feeding tube.

☐ Limits:

- Maximum of 6 months (initial use).

- Continuation of therapy only after demonstrated benefit of enteral/parenteral nutrition for at least 3-rolling months. Maximum of 1 year.
- ❑ **Required Information for Approval:**
 - Documentation of high nutrient requiring disease state
 - Diagnosis of malnutrition that cannot meet needs through a standard diet
 - Meets medical necessity criteria as stated above and as stated in PH-19
 - Clinical record of failing oral nutritional supplements OR documentation of an enteral feeding tube
 - Meets protein-energy wasting criteria (1 of the following):
 - Serum albumin < 3.8 g/dL (3-month rolling average)
 - BMI < 18.5 kg/m²
 - Unintentional weight loss (≥ 5% over 1 month; ≥7.5% over 3 mos.; or ≥ 10% over 6 mos.)
- ❑ **Notes:**
 - **Above criteria will also be used when considering other high nutrient requirement disease states.**
 - **All intradialytic parenteral nutrition (IDPN) are NON-FORMULARY** – Reserved for patients who have documented diagnosis of a GI disorder (e.g. gastroparesis, malabsorption) OR cannot be maintained on enteral feedings (patient can meet ≥ 50% of nutritional needs orally and has not been able to increase oral intake with supplements, whereupon enteral nutrition consists of < 50% of the total dietary intake).

☒ REFERENCES

1. Title 22 CCR 51313.33(e)(2)

☒ REVIEW & EDIT HISTORY

Document Changes	Reference	Date	P&T Chairman
Creation of Policy	UM 59 – Nutritional Supplements.pdf	12/2007	Allen Shek, PharmD, BCPS
Update to Policy	UM 59 - Therapeutic Enteral Formula for Medical Conditions in Infants and Children.docx	9/2014	Jonathan Szkotak, PharmD, BCACP
Update to Policy	PH19 - Nutritional Supplements for Medical Conditions 09-2015.docx	9/2015	Jonathan Szkotak, PharmD, BCACP
Update to Policy	Drug Class Review - Nutrition in ESRD 2015-11.docx	11/2015	Johnathan Yeh, PharmD
Update to Policy	PH-19 – Nutritional Supplements for Medical Conditions 2-2016.docx	2/2016	Johnathan Yeh, PharmD
Creation of Policy	HPSJ Coverage Policy - Gastrointestinal Disorders - Nutrition 2017-05	5/2017	Johnathan Yeh, PharmD

Note: All changes are approved by the HPSJ P&T Committee before incorporation into the utilization policy