



Drug Class Prior Authorization Criteria
Adult Enteral Nutrition Supplement

Line of Business: Medicaid

P & T Approval Date: May 7, 2021

Effective Date: June 18, 2021

These criteria have been developed through review of medical literature, consideration of medical necessity, generally accepted medical practice standards, and approved by the IEHP Pharmacy and Therapeutics Subcommittee.

Background:

Physicians must provide medical justification for nutritional supplementation on the IEHP Prescription Prior Authorization Request Form (RX PA). For information that may be necessary for nutritional supplementation justification, please review our Nutritional Evaluation Form (NEF).

Nutritional supplements are a Medicaid covered benefit when they are used in a therapeutic regimen to prevent serious disability or death in patients with medically diagnosed conditions that preclude the full use of regular food. IEHP provides coverage for all medically necessary Medi-Cal covered enteral nutrition products, and to ensure that these services are provided in an amount no less than what is offered to beneficiaries under Medi-Cal fee-for-service.

Please see the following link for the complete list of products that are offered by Medi-Cal fee-for-service: https://files.medi-cal.ca.gov/pubsdoco/publications/masters-mtp/part2/enteral_a04p00.doc

ENSURE, JEVITY, OSMOLITE, BOOST

Covered Uses: All FDA-approved indications

Exclusion Criteria: N/A

Required Medical Information:

Must meet "1" of the following requirements:

- a. Enteral feeding tube (e.g. nasogastric, gastrostomy, jejunostomy) or transitioning from parenteral or enteral feeding tube to oral diet.
- b. For oral administration, must meet "1" of the following requirements:
 1. For members 21 years of age or older with a medical condition and adequate nutrition is not possible with dietary adjustment of regular or altered consistency (soft or pureed) foods; and Must meet "1" of the following requirements:



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- i. Involuntary weight loss of 10 percent or more within past 6 months (180 days).
 - ii. Involuntary weight loss of 7.5 percent or more within past 3 months (90 days).
 - iii. Involuntary weight loss of 5 percent or more within past month (30 days).
 - iv. Body mass index less than 18.5 kilograms per meter squared.
2. For members under 21 years of age with documented clinical signs and symptoms including status indicators of nutritional risks (stunting, wasting or underweight). Standard and modified growth charts should be used to document nutritional need and patient deficiency.
3. Severe swallowing or chewing difficulty due to “1” of the following requirements:
 - i. Cancer in the mouth, throat or esophagus.
 - ii. Injury, trauma, surgery or radiation therapy involving the head or neck.
 - iii. Chronic neurological disorders.
 - iv. Severe craniofacial anomalies.
4. Transitioning from parenteral or enteral tube feeding to an oral diet.

Age Restrictions: N/A

Prescriber Restrictions: N/A

GLUCERNA, BOOST GLUCOSE CONTROL, DIABETISOURCE AC, GLYTROL

Covered Uses: Diabetes or Hyperglycemia

Exclusion Criteria: N/A



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Required Medical

Information:

Must meet all of the following requirements:

- a. Standard coverage criteria ([see criteria for Ensure](#))
- b. ICD-10 code for the diagnosis.
- c. HbA1c (A1c) value (measured within 6 months {180 days} of the request).

Age Restrictions: N/A

Prescriber Restrictions: N/A

NEPRO, NOVASOURCE RENAL, RENALCAL, RENASTART, SUPLENA

Covered Uses: Kidney Disease (e.g. chronic kidney disease)

Exclusion Criteria: N/A

Required Medical

Information:

Must meet all of the following requirements:

- a. Standard coverage criteria ([see criteria for Ensure](#))
- b. If member is 18 years and older, must have documented of "1" of the following indicators:
 1. Blood serum potassium.
 2. BUN level greater than 20 mg per dL.
 3. Male: Urine Creatinine greater than 26 mg per kg per day; or
Female: Urine Creatinine greater than 20 mg per kg per day.
 4. Glomerular Filtration Rate (GFR) or CrCl less than 60 mL per min per 1.73 meters squared.

Age Restrictions: N/A

Prescriber Restrictions: N/A



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NUTRIHEP

Covered Uses: Liver disorder (e.g. liver fibrosis, cirrhosis)

Exclusion Criteria: N/A

Required Medical Information:

Must meet all of the following requirements:

- a. Standard coverage criteria ([see criteria for Ensure](#))
- b. Must have documented liver function test (ALT and AST) measured within 6 months (180 days) of the request.

Age Restrictions: N/A

Prescriber Restrictions: N/A

BENECALORIE, DUOCAL POWDER, POLYCAL POWDER

Covered Uses: All FDA-approved indications

Exclusion Criteria: N/A

Required Medical Information:

Must meet the following requirement:

- a. Must have a documented clinical evidence to support that member is unable to meet caloric nutrition need with the current use of an enteral nutrition product.

Age Restrictions: N/A

Prescriber Restrictions: N/A



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MCT OIL, LIQUIGEN MCT, DUOCAL POWDER, MICROLIPID, BETAQUIK MCT, CARBZERO, LIPISTART POWDER

Covered Uses: All FDA-approved indications

Exclusion Criteria: N/A

Required Medical Information:

Must meet "1" of the following requirements:

- a. Must have a documented diagnosis of inability to digest or absorb conventional fats.
- b. Must have a documented diagnosis of uncontrolled seizure disorder or other neurological disorder that cannot otherwise be medically managed.

Age Restrictions: N/A

Prescriber Restrictions: N/A

BENEPROTEIN, LIQUACEL, PROCEL, PROMOD LIQUID PROTEIN, PRO-STAT SUGAR FREE, PROTEINEX

Covered Uses: All FDA-approved indications

Exclusion Criteria: N/A

Required Medical Information:

Must meet the following requirement:

- a. Documentation that member is unable to meet protein requirement with current use of a high protein enteral nutrition product.

Age Restrictions: N/A

Prescriber Restrictions: N/A



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PEPTAMEN, PERATIVE, VITAL, VIVONEX RTF

Covered Uses: All FDA-approved indications

Exclusion Criteria: N/A

Required Medical Information:

Must meet ALL of the following requirements:

- a. Must meet "1" of the following requirements:
 1. Must have an intestinal malabsorption diagnosis (ICD-10-CM codes K90.0-K90.9 and K91.2); lactose intolerance alone is excluded.
 2. Must have a chronic medical diagnosis and present clinical signs and symptoms of inability to absorb nutrients or to tolerate intact protein that cannot otherwise be medically managed.
 3. Failure or clinically significant adverse effects to a standard or specialized disease-specific enteral nutrition product.
- b. Off-age products may be authorized if medical justification for off-age use is documented.

Age Restrictions: N/A

Prescriber Restrictions: N/A



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KETONEX, PHENEX, PHENYLADE, PKU

Covered Uses: Inborn errors of metabolism

Exclusion Criteria: N/A

Required Medical Information:

Must meet "1" of the following requirements:

- a. Authorization is restricted to members with a diagnosis of inborn errors of metabolism (genetic, metabolic conditions);
 1. **ICD-10 CM Codes:** Please reference the link to DHCS provider manual listed below as ICD-10 codes change/update frequently.
- b. Exception: Metabolic ketogenic formulas (e.g. KetoVie, Ketocal) can also be approved if meeting "1" of the requirements below:
 1. Documentation of seizures that is refractory to standard anti-seizure medications.
 2. Documentation of a chronic medical diagnosis where a ketogenic diet is medically necessary and failure or clinically significant adverse effects to a product in another enteral nutrition category.

Age Restrictions: N/A

Prescriber Restrictions: N/A

** Exemptions may be granted on a case-by-case basis for members who do not meet criteria but have exceptional needs.



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References:

1. For further product specific criteria, refer to DHCS policy following the steps below:

DHCS providers' manuals: http://files.medi-cal.ca.gov/pubsdoco/manuals_menu.asp

Follow link for "Pharmacy (PH)".

Follow link for "Enteral Nutrition Products (enteral)".

Follow link for "List of Enteral Nutrition Products".

2. DHCS Medi-Cal Provider Manual Part 2 – Pharmacy: Enteral Nutrition Products. Available at: https://files.medi-cal.ca.gov/pubsdoco/publications/masters-mtp/part2/enteral_a04p00.doc. Accessed April 16, 2019.

Change Control		
Date	Change	RPH
5/7/2021	<ul style="list-style-type: none">• Renew with no changes	VM
8/28/2020	<ul style="list-style-type: none">• Renew with no changes	RR
5/15/2019	<ul style="list-style-type: none">• Adjusted criteria for specialty nutrition products per DHCS provider's manual including Nepro, Nutrihep• Retired pulmonary care products per DHCS	ND
2/20/2019	<ul style="list-style-type: none">• Added background information that IEHP provides coverage for all medically necessary Medi-Cal covered enteral nutrition products, and to ensure that these services are provided in an amount no less than what is offered to beneficiaries under Medi-Cal fee-for-service.	ND
06/20/2018	<ul style="list-style-type: none">• Reformatted document	IK
05/16/2018	<ul style="list-style-type: none">• Reformatted document	HC