STATE OF NEW YORK
DEPARTMENT OF HEALTH

REQUEST: March 14, 2019
[redacted]
AGENCY: MAP
FH #: 7928799R

In the Matter of the Appeal of

[redacted]

from a determination by the New York City Department of Social Services

DECISION AFTER FAIR HEARING

JURISDICTION

Pursuant to Section 22 of the New York State Social Services Law (hereinafter Social Services Law) and Part 358 of Title 18 NYCRR, (hereinafter Regulations), a fair hearing was held on May 13, 2019, in New York City, before an Administrative Law Judge. The following persons appeared at the hearing:

For the Appellant

[redacted]

For the Managed Long-Term Care Plan (MLTC Plan) Centers Plan for Healthy Living

Fair Hearing Representative

ISSUE

Was the MLTC Plan's determination to deny the Appellant's physician's request for prior authorization for enteral nutritional formula (Ensure Plus) for the Appellant correct?

FINDINGS OF FACT

An opportunity to be heard having been afforded to all interested parties and evidence having been taken and due deliberation having been had, it is hereby found that:

1. The Appellant, age 89, has been in receipt of Medical Assistance through a Medicaid MLTC Plan operated by Centers Plan for Healthy Living (hereinafter, the "Managed Care Plan").

2. The Appellant's physician requested Enteral Nutritional Formula – Orally administered enteral nutrition (Ensure Plus), 1 can three times per day.

3. On October 4, 2019, the Managed Care Plan's Initial Adverse Determination denied the Provider's request for enteral nutrition because "the health care service is not medically necessary."

4. In November 2018, the Appellant requested an internal Appeal and a fair hearing.

5. On November 26, 2018, the Managed Care Plan's Final Adverse Determination Notice denied the Appellant's request for enteral formula (Ensure Plus) because "The eligibility criteria for enteral or supplemental nutrition (Ensure Plus) as per the Medicaid Guidelines state that for someone who is orally fed includes a body mass index (BMI-a measure of one's height and weight) of less than 18.5, a medical condition that prevents one from consuming normal table foods (softened, mashed, pureed, or food broken up in a blender, significant unintentional weight loss (more than 5%) over the previous six (6) months, and serum albumin blood test (an indicator of nutritional status) to support the need for enteral nutrition."

6. The Appellant requested this fair hearing on March 14, 2019.

APPLICABLE LAW

Social Services Law section 365-a (2) states, in part, that the amount, nature and manner of providing medical assistance for needy persons shall be determined by the public welfare official with the advice of a physician and in accordance with the local medical plan, this title, and the regulations of the department.

> 2. "Standard coverage" shall mean payment of part or all of the cost of medically necessary medical, dental and remedial care, services and supplies, as authorized in this title or the regulations of the department, which are necessary to prevent, diagnose, correct or cure conditions in the person that cause acute suffering, endanger life, result in illness or infirmity, interfere with such person's capacity for normal activity, or threaten some significant handicap and which are furnished an eligible person in accordance with this title and the regulations of the department.

Section 364-j (1)(c) of the Social Services Law defines "Managed Care Program" as a program in a social services district in which Medicaid recipients enroll on a voluntary or mandatory basis to receive Medicaid services, including case management, directly or indirectly (including by referral) from a managed care provider ("Medicaid Managed Care Health Plan"), or, if applicable, from a mental health special needs plan or a comprehensive HIV special needs plan.

The United State Department of Health and Human Services (Health Care Finance Administration) has granted the State of New York a waiver under Section 1115 of the Social Security Act to permit the operation of a demonstration waiver program for Managed Care Programs in which certain eligible Medicaid recipients are subject to mandatory enrollment. An "Operational Protocol" (Protocol) has been approved by the Health Care Finance Administration

as required by the Terms and Conditions governing the demonstration waiver. Such Protocol details the day-to-day operations of the program.

The Medicaid Managed Care Model Contract delineates the terms by which Medicaid Managed Care Plans agree to cover specified healthcare services in accordance with New York State Medicaid Guidelines. Chapter 10 of the Medicaid Managed Care Model Contract states, in part:

10.1 Contractor Responsibilities

a) Contractor must provide or arrange for the provision of all services set forth in the Benefit Package for MMC Enrollees and FHPlus Enrollees subject to any exclusions or limitations imposed by Federal or State Law during the period of this Agreement. SDOH shall assure that Medicaid services covered under the Medicaid fee-for-service program but not covered in the Benefit Package are available to and accessible by MMC Enrollees.

10.2 Compliance with State Medicaid Plan, Applicable Laws and Regulations

a) All services provided under the Benefit Package to MMC Enrollees must comply with all the standards of the State Medicaid Plan established pursuant to Section 363-a of the SSL and shall satisfy all other applicable requirements of the SSL and PHL.

b) Benefit Package Services provided by the Contractor through its FHPlus product shall comply with all applicable requirements of the PHL and SSL.

c) Pursuant to 42 CFR 438.210, the Contractor may establish appropriate limits on a service for utilization control and/or medical necessity. The Contractor must ensure that Covered Services are provided in sufficient amount, duration and scope to reasonably be expected to achieve the purpose for which the services are furnished. The Contractor will not define medically necessary services in a manner that limits the scope of benefits provided in the SSL, the State Medicaid Plan, State regulations or the Medicaid Provider Manuals.

Section 364.2 of the Social Services Law provides in part:

The Department of Health shall be responsible for . . .

(b) establishing and maintaining standards for all non-institutional health care and services rendered pursuant to this title, . . .

Effective March 28, 2012, the Department of Health adopted amendments to 18 NYCRR 505.1, 505.5, 513.0, 513.1 and 513.6, in part concerning enteral formula, which were originally promulgated to be effective April 1, 2011.

Pursuant to the authority vested in the Department of Health and the Commissioner of Health by sections 201 and 206 of the Public Health Law and sections 363-a and 365-a (2) of the Social Services Law (SSL), Section 505.1(b)(2) of the Regulations is amended, to be effective upon filing with the Department of State, and a new paragraph (3) is added to read as follows: (3) the service exceeds benefit limitations as established by the department. A new subdivision (g) of section 505.5 of the regulations is added to read, in pertinent part, as follows: Enteral nutritional formulas are limited to coverage for tube-fed individuals who cannot chew or swallow food and must obtain nutrition through formula via tube; individuals with rare inborn metabolic disorders requiring specific medical formulas to provide essential nutrients not available through any other means, and for children under 21 when caloric and dietary nutrients from food cannot be absorbed or metabolized.

Chapter 59 of the laws of 2011 enacted a number of proposals recommended by the Medicaid Redesign Team established by the Governor to reduce costs and increase quality and efficiency in the Medicaid Program. The changes to SSL section 365-1(2)(g), that establish benefit limits for enteral formula, take effect April 1, 2011. Paragraph (t) of section 111 of Part H of Chapter 59 authorizes the Commissioner to promulgate, on an emergency basis, any regulations necessary to file these regulations on an emergency basis.

The Regulatory Impact Statement provides, in pertinent part, that section 363-a and Public Health Law section 201(1)(v) provide that the Department is the single state agency responsible for supervising the administration of the State's medical assistance ("Medicaid") program and for adopting such regulations, not inconsistent with law, as may be necessary to implement the State's Medicaid program. The legislative objective, as expressed in SSL 365-1(2)(g) is to impose benefit limitations on Medicaid coverage of enteral formula. The needs and benefits section states, in pertinent part, that Medicaid reimburses the cost of enteral formulas for administration via tube or as a liquid oral nutritional therapy when there is a documented diagnostic condition where caloric and dietary nutrients from food cannot be absorbed or metabolized. When prescribed for oral supplementation in adults who can chew and swallow their food, it is objectively difficult to assess medical necessity for the enteral formula and to prevent such reimbursement when used strictly as a convenient food supplement and not due to medical necessity to treat a clinical condition. By limiting the benefit to specific medical necessity criteria for tube-fed individuals who cannot chew or swallow food, and must obtain nutrition through formula via tube, for individuals with rare inborn metabolic disorders requiring specific medical formulas to provide essential nutrients not available through any other means, and for children when there is a documented diagnostic condition where caloric and dietary nutrients from food cannot be absorbed or metabolized, the regulation will help reduce Medicaid costs … while continuing to meet intensive medical needs of individual beneficiaries with serious medical conditions.

Title: Section 505.5 - Durable medical equipment; medical/surgical supplies; orthotic and prosthetic appliances; orthopedic footwear

(a) Definitions

(2) Medical/surgical supplies means items for medical use other than drugs, prosthetic or orthotic appliances, durable medical equipment, or orthopedic footwear which have been ordered by a practitioner in the treatment of a specific medical condition and which are usually: (i)consumable; (ii) nonreusable; (iii) disposable; (iv) for a specific rather than incidental purpose; and (v) generally have no salvageable value.

(g) Benefit limitations. The department shall establish defined benefit limits for certain Medicaid services as part of its Medicaid State Plan. The department shall not allow exceptions to defined benefit limitations. The department has established defined benefit limits on the following services:
(3) Enteral nutritional formulas are limited to coverage for:
(i) tube-fed individuals who cannot chew or swallow food and must obtain nutrition through formula via tube; (ii) individuals with rare inborn metabolic disorders requiring specific medical formulas to provide essential nutrients not available through any other means; (iii) children under age 21 when caloric and dietary nutrients from food cannot be absorbed or metabolized; and (iv) persons with a diagnosis of HIV infection, AIDS, or HIV-related illness, or other disease or condition, who are oral-fed and who: (a) require supplemental nutrition, demonstrate documented compliance with an appropriate medical and nutritional plan of care, and have a body mass index under 18.5 as defined by the Centers for Disease Control, up to 1,000 calories per day; or (b) require supplemental nutrition, demonstrate documented compliance with an appropriate medical and nutritional plan of care, and have a body mass index under 22 as defined by the Centers for Disease Control and a documented, unintentional weight loss of 5 percent or more within the previous 6 month period, up to 1,000 calories per day; or (c) require total nutritional support, have a permanent structural limitation that prevents the chewing of food, and the placement of a feeding tube is medically contraindicated.

From the Department's DME provider manual dated April 2014:

ENTERAL NUTRITIONAL FORMULA
Benefit Coverage Criteria is limited to:

- Beneficiaries who are **fed via** nasogastric, gastrostomy or jejunostomy **tube.**
- Beneficiaries with **inborn metabolic disorders**.
- **Children up to 21 years of age,** who require liquid oral nutritional therapy when there is a documented diagnostic condition where caloric and dietary nutrients from food cannot be absorbed or metabolized.
- Adults with a diagnosis of HIV infection, AIDS, or HIV-related illness, or other disease or condition, who are oral-fed, **and who**;
    - require supplemental nutrition, demonstrate documented compliance with an appropriate medical and nutritional plan of care, and have a body mass index (BMI) under 18.5 as defined by the Centers for Disease Control, up to 1,000 calories per day; **or**
    - require supplemental nutrition, demonstrate documented compliance with an appropriate medical and nutritional plan of care, have a body mass index (BMI) under 22 as defined by the Centers for Disease Control, and a documented, unintentional weight loss of 5 percent or

more within the previous 6-month period, up to 1,000 calories per day; **or**

- require total oral nutritional support, have a permanent structural limitation that prevents the chewing of food, and placement of a feeding tube is medically contraindicated. Page 32 of 176

Documentation Requirements:

- The therapy must be an integral component of a documented medical treatment plan and ordered in writing by an authorized practitioner. It is the responsibility of the practitioner to maintain documentation in the beneficiary's record regarding the medical necessity for enteral nutritional formula.
- The physician or other appropriate health care practitioner has documented the beneficiary's nutritional depletion.
- Medical necessity for enteral nutritional formula must be substantiated by documented physical findings and/or laboratory data (e.g., changes in skin or bones, significant loss of lean body mass, abnormal serum/urine albumin, protein, iron or calcium levels, or physiological disorders resulting from surgery, etc.)
- Documentation for beneficiaries who qualify for enteral formula benefit must include an established diagnostic condition and the pathological process causing malnutrition and one or more of the following items:
  (a)Clinical findings related to the malnutrition such as a recent involuntary weight loss or a child with no weight or height increase for six months.
  (b)Laboratory evidence of low serum proteins (i.e., serum albumin less than 3 gms/dl; anemia or leukopenia less than 1200/cmm);
  (c)Failure to increase body weight with usual solid or oral liquid food intake.

Additional Information:

●Non-standard infant formulas are reimbursable by Medicaid under the appropriate enteral therapy code.

●The calculation for pricing enteral formula is as follows: Number of calories per can divided by 100 equals the number of caloric units per can.

●Enteral formula requires voice interactive prior authorization, as indicated by the "*****" next to the code description. The prescriber must write the prior authorization number on the fiscal order and the dispenser completes the authorization process by calling (866) 211-1736. For requests that exceed 2,000 calories per day for qualifying beneficiaries, a prior approval request may be submitted with medical justification.

●The New York State Medicaid Program does not cover enteral nutritional therapy as a convenient food substitute.

- Standard milk-based infant formulas are not reimbursable by Medicaid.

The Department's 2014 Pharmacy Provider Manual advises in relevant part:

ENTERAL NUTRITIONAL FORMULA
Benefit Coverage Criteria is limited to:
• Beneficiaries who are **fed via** nasogastric, gastrostomy or jejunostomy **tube.**

• Beneficiaries with **inborn metabolic disorders**.
• **Children up to 21 years of age,** who require liquid oral nutritional therapy when there is a documented diagnostic condition where caloric and dietary nutrients from food cannot be absorbed or metabolized.
• Adults with a diagnosis of HIV infection, AIDS, or HIV-related illness, or other disease or condition, who are oral-fed, **and who**;

- require supplemental nutrition, demonstrate documented compliance with an appropriate medical and nutritional plan of care, and have a body mass index (BMI) under 18.5 as defined by the Centers for Disease Control, up to 1,000 calories per day; **or**
- require supplemental nutrition, demonstrate documented compliance with an appropriate medical and nutritional plan of care, have a body mass index (BMI) under 22 as defined by the Centers for Disease Control, and a documented, unintentional weight loss of 5 percent or more within the previous 6-month period, up to 1,000 calories per day; **or**
- require total oral nutritional support, have a permanent structural limitation that prevents the chewing of food, and placement of a feeding tube is medically contraindicated.

Documentation Requirements
• The therapy must be an integral component of a documented medical treatment plan and ordered in writing by an authorized practitioner. It is the responsibility of the practitioner to maintain documentation in the beneficiary's record regarding the medical necessity for enteral nutritional formula.
• The physician or other appropriate health care practitioner has documented the beneficiary's nutritional depletion.
• Medical necessity for enteral nutritional formula must be substantiated by documented physical findings and/or laboratory data (e.g., changes in skin or bones, significant loss of lean body mass, abnormal serum/urine albumin, protein, iron or calcium levels, or physiological disorders resulting from surgery, etc.)
• Documentation for beneficiaries who qualify for enteral formula benefit must include an established diagnostic condition and the pathological process causing malnutrition and one or more of the following items:
(a) Clinical findings related to the malnutrition such as a recent involuntary weight loss or a child with no weight or height increase for six months.
(b) Laboratory evidence of low serum proteins (i.e., serum albumin less than 3 gms/dl; anemia or leukopenia less than 1200/cmm);
(c) Failure to increase body weight with usual solid or oral liquid food intake.
Additional Information:
●Non-standard infant formulas are reimbursable by Medicaid under the appropriate enteral therapy code.
●The calculation for pricing enteral formula is as follows: Number of calories per can divided by 100 equals the number of caloric units per can.
●Enteral formula requires voice interactive prior authorization, as indicated by the "*****" next to the code description. The prescriber must write the prior authorization number on the fiscal order and the dispenser completes the authorization process by calling (866) 211-1736. For requests that exceed 2,000 calories per day for qualifying beneficiaries, a prior approval request may be submitted with medical justification.

●The New York State Medicaid Program does not cover enteral nutritional therapy as a convenient food substitute.
●Standard milk-based infant formulas are not reimbursable by Medicaid.

Section 360-7.5(a) of the Regulations provides how the Medical Assistance Program pays for medical care. Generally, the Program will pay for covered services which are necessary in amount, duration and scope to providers who are enrolled in the Medical Assistance program, at the Medical Assistance rate or fee which is in effect at the time the services were provided. Such Regulations also provide that, in instances where an erroneous eligibility determination is reversed by a social services district discovering an error, a fair hearing decision, or a court order or where the district did not determine eligibility within required time periods, and where the erroneous determination or delay caused the recipient or his/her representative to pay for medically-necessary services which would otherwise have been paid for by the Medical Assistance Program, payment may be made directly to the recipient or the recipient's Representative.

Section 358-5.9 of the Regulations provide in part:

> (a) At a fair hearing concerning the denial of an application for or the adequacy of public assistance, medical assistance, HEAP, [SNAP] benefits or services, the appellant must establish that the agency's denial of assistance or benefits was not correct or that the appellant is eligible for a greater amount of assistance or benefits.

DISCUSSION

On November 26, 2018, the Managed Care Plan's Final Adverse Determination Notice denied the provider's request for prior authorization for enteral formula (Ensure Plus) because "The eligibility criteria for enteral or supplemental nutrition (Ensure Plus) as per the Medicaid Guidelines state that for someone who is orally fed includes a body mass index (BMI-a measure of one's height and weight) of less than 18.5, a medical condition that prevents one from consuming normal table foods (softened, mashed, pureed, or food broken up in a blender, significant unintentional weight loss (more than 5%) over the previous six (6) months, and serum albumin blood test (an indicator of nutritional status) to support the need for enteral nutrition."

The present hearing was originally requested to review the Plan's October 4, 2018 determination to deny prior approval, which the November 26, 2018 internal appeal determination upheld.

The evidence has been considered. Although the Appellant's condition is sympathetic, her need for enteral nutrition fails to satisfy the criteria for approval as set forth in New York State Medicaid Guidelines, namely that she is not under the age of 21 requiring nutrition for growth and development, she is not tube-fed, has not been diagnosed with a rare inborn metabolic disorder, nor does her need stem from a diagnosed disease, illness or condition which has caused her to lose an excessive amount of weight. She also is not reported to be HIV

positive. Since Appellant is not in any of the categories permitted to receive enteral nutrition under revised Medicaid rules, the Managed Care Plan's determination must be sustained.

DECISION

The Managed Care Plan's determination to deny the Appellant's physician's request for prior authorization for enteral nutritional formula (Ensure Plus) for the Appellant was correct.

DATED: Albany, New York
07/05/2019

NEW YORK STATE
DEPARTMENT OF HEALTH

By

Commissioner's Designee