STATE OF NEW YORK
DEPARTMENT OF HEALTH

REQUEST: June 2, 2017
[redacted]
AGENCY: MAP
FH #: 7545532M

In the Matter of the Appeal of [redacted]	:	**DECISION AFTER FAIR HEARING**
from a determination by the New York City Department of Social Services	:	

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 August 9, 2017, 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

MLTC Plan's appearance waived by the Office of Administrative Hearings

ISSUE

Was the MLTC Plan's determination to deny the Appellant's physician's request for prior authorization for enteral nutritional formula (Ensure) 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 77, has been in receipt of Medical Assistance through a MLTC Plan operated by Centers Plan for Healthy Living (hereinafter, the "Managed Care Plan").

2. The Appellant's physican [redacted], D.O., [redacted], requested Enteral Nutritional Formula – Orally administered enteral

nutrition (Ensure), 3 cans per day, writing in his request Appellant's "Weight loss of 5 lbs. over past 6 months".

3. On May 23, 2017, the Managed Care Plan's Initial Adverse Determination Notice, advised Appellant that coverage for Ensure would be stopped effective May 23, 2017 because "the health care service is not medically necessary. A request has been submitted on your behalf for Ensure nutritional supplementation. Your most recent weight, measured on 5/8/17 was 117 lbs. and your Body Mass Index (BMI) was 23 (normal range 18.5-24.9)."

4. On June 2, 2017, this fair hearing was requested.

APPLICABLE LAW

Social Services Law section 365-a (8) provides:

> When a non-governmental entity is authorized by the department pursuant to contract or subcontract to make prior authorization or prior approval determinations that may be required for any item of medical assistance, a recipient may challenge any action taken or failure to act in connection with a prior authorization or prior approval determination as if such determination were made by a government entity, and shall be entitled to the same medical assistance benefits and standards and to the same notice and procedural due process rights, including a right to a fair hearing and aid continuing pursuant to section twenty-two of this chapter, as if the prior authorization or prior approval determination were made by a government entity.

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.

Part 438 of 42 Code of Federal Regulations (CFR) pertains to provision of Medicaid medical care, services and supplies through Managed Care Organizations (MCOs), Prepaid Inpatient Health Plans (PIHPs), Prepaid Ambulatory Health Plans (PAHPs) and Primary Care Case Managers (PCCMs), and the requirements for contracts for services so provided. The NYS Department of Health has entered into a contract with [name of MLTC Plan].

Section 438.210 of 42 CFR Subpart D provides in part:

Section 438.210 Coverage and authorization of services.

(a) Coverage. Each contract with an MCO, PIHP, or PAHP must do the following:

(1) Identify, define, and specify the amount, duration, and scope of each service that the MCO, PIHP, or PAHP is required to offer.

(2) Require that the services identified in paragraph (a)(1) of this section be furnished in an amount, duration, and scope that is no less than the amount, duration, and scope for the same services furnished to beneficiaries under fee-for-service Medicaid, as set forth in Sec. 440.230.

(3) Provide that the MCO, PIHP, or PAHP--

(i) Must ensure that the services are sufficient in amount, duration, or scope to reasonably be expected to achieve the purpose for which the services are furnished.

(ii) May not arbitrarily deny or reduce the amount, duration, or scope of a required service solely because of diagnosis, type of illness, or condition of the beneficiary;

(iii) May place appropriate limits on a service--

(A) On the basis of criteria applied under the State plan, such as medical necessity; or

(B) For the purpose of utilization control, provided the services furnished can reasonably be expected to achieve their purpose, as required in paragraph (a)(3)(i) of this section; and

(4) Specify what constitutes ``medically necessary services'' in a manner that--

(i) Is no more restrictive than that used in the State Medicaid program as indicated in State statutes and regulations, the State Plan, and other State policy and procedures; and

(ii) Addresses the extent to which the MCO, PIHP, or PAHP is responsible for covering services related to the following:

(A) The prevention, diagnosis, and treatment of health impairments.
(B) The ability to achieve age-appropriate growth and development.
(C) The ability to attain, maintain, or regain functional capacity.

(b) Authorization of services. For the processing of requests for initial and continuing authorizations of services, each contract must require--

(1) That the MCO, PIHP, or PAHP and its subcontractors have in place, and follow, written policies and procedures.

(2) That the MCO, PIHP, or PAHP--

(i) Have in effect mechanisms to ensure consistent application of review criteria for authorization decisions; and

(ii) Consult with the requesting provider when appropriate.

(3) That any decision to deny a service authorization request or to authorize a service in an amount, duration, or scope that is less than requested, be made by a health care professional who has appropriate clinical expertise in treating the enrollee's condition or disease....

Section 438.236 of 42 CFR Subpart D provides in part:

Section 438.236 Practice guidelines.

(a) Basic rule: The State must ensure, through its contracts, that each MCO and, when applicable, each PIHP and PAHP meets the requirements of this section.

(b) Adoption of practice guidelines. Each MCO and, when applicable, each PIHP and PAHP adopts practice guidelines that meet the following requirements:

(1) Are based on valid and reliable clinical evidence or a consensus of health care professionals in the particular field.

(2) Consider the needs of the MCO's, PIHP's, or PAHP's enrollees.

(3) Are adopted in consultation with contracting health care professionals.

(4) Are reviewed and updated periodically as appropriate.

(c) Dissemination of guidelines. Each MCO, PIHP, and PAHP disseminates the guidelines to all affected providers and, upon request, to enrollees and potential enrollees.

(d) Application of guidelines. Decisions for utilization management, enrollee education, coverage of services, and other areas to which the guidelines apply are consistent with the guidelines.

Section 438.402 of 42 CFR Subpart F provides in part:

(a) The grievance system. Each MCO [Managed Care Organization] and PIHP [Prepaid Inpatient Health Plan] must have a system in place for enrollees that includes a grievance process, an appeal process, and access to the State's fair hearing system...

Section 4403-f of the Public Health Law pertains to Managed Long Term Care Plans.

Article 49 of the Public Health Law pertains to Utilization Review and External Appeal.

Article V.A. of the Managed Long Term Care Partial Capitation Model Contract provides in part:

A. Provision of Benefits

1. The Contractor shall provide covered services set forth in Appendix G in accordance with the coverage and authorization requirements of 42 CFR 438.210; comply with professionally recognized standards of health care and implement practice guidelines consistent with 42 CFR 438.236; and comply with the requirements of 42 CFR 438.114 regarding emergency and post-stabilization services to the extent that services required to treat an emergency medical condition are within the scope of covered services in Appendix G.

2. Benefit package services provided by the Contractor under this Contract shall comply with all standards of the State Medicaid Plan established pursuant to SSL §363-a and shall satisfy all applicable requirements of the PHL and SSL. Non-covered services for which the Enrollee is eligible under the Medicaid Program will be paid by the Department on a fee-for-service basis directly to the provider of service. The parties acknowledge and accept that the Department has the right to make modifications to the benefit package services (set forth in Appendix G) with advance notice to the Contractor of at least sixty (60) days. Such modifications may include expansions of and/or restrictions to such benefit package services, the addition of new benefit package services, and/or the elimination of benefit package services. Such modifications will be made only as necessary to implement statewide Medicaid program initiatives, including Medicaid Redesign initiatives.

Appendix G of the Model Contract provides that the capitation for a partial capitation Managed Long-Term Care Plan includes Durable Medical Equipment ("DME"), including Medical//Surgical Supplies, Enteral and Parenteral Formula#, and Hearing Aid Batteries, Prosthetics, Orthotics and Orthopedic Footwear. (Compression and support stockings are limited to coverage only for pregnancy or treatment of venous stasis ulcers).

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 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 May 23, 2017, the Managed Care Plan's Initial Adverse Determination Notice denied the physician's April 17, 2017 request for prior authorization for enteral formula (Ensure) because:

"the health care service is not medically necessary.

A request has been submitted on your behalf for Ensure nutritional supplementation. Your most recent weight, measured on 5/8/17 was 117 lbs. and your Body Mass Index (BMI) was 23 (normal range 18.5-24.9).

Generally, Medicaid guidelines for the use of nutritional supplementation (such as Ensure) is limited to: people who are fed via nasogastric, jejunostomy or gastrostomy tube; for the treatment of inborn errors of metabolism; and adults with a diagnosis of HIV infection, AIDS, or HIV-related illness, or other disease or condition, who are orally-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 (BMI) under 18.5, 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; 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. The clinical information provided shows that your BMI is above the range normally considered for nutritional supplementation. The request for Ensure supplementation must therefore, be denied."

At the hearing, the Managed Care Plan submitted records it had obtained from Appellant's physician's office to establish that the Appellant had the following BMI's:

12/08/16 BMI 22.6
03/07/17 BMI 23.6
05/08/17 BMI 23

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."

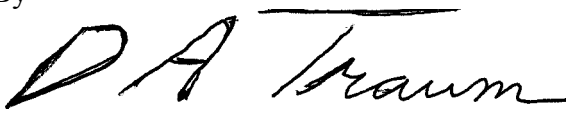
DECISION

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

DATED: Albany, New York
09/26/2017

NEW YORK STATE
DEPARTMENT OF HEALTH

By



Commissioner's Designee