STATE OF MICHIGAN
STATE OFFICE OF ADMINISTRATIVE HEARINGS AND RULES
FOR THE DEPARTMENT OF COMMUNITY HEALTH
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IN THE MATTER OF:

Docket No. 2010-14799 PA
Case No. [redacted]

[redacted],

Appellant
_____/

DECISION AND ORDER

This matter is before the undersigned Administrative Law Judge (ALJ) pursuant to MCL 400.9 and 42 CFR 431.200 *et seq.*, following the Appellant's request for a hearing.

After due notice, a hearing was held [redacted].

The Appellant was represented by her [redacted] and her [redacted]

The Department of Community Health was represented by [redacted]. [redacted], appeared as a witness on behalf of the Department. [redacted], appeared as a witness on behalf of the Department.

ISSUE

Did the Department properly deny the Appellant's request for coverage of the nutritional supplement Re-Gen Reduced Sugar?

FINDINGS OF FACT

Based upon the competent, material and substantial evidence presented, the Administrative Law Judge finds as material fact:

1. The Appellant is a [redacted] who is a Medicaid beneficiary.

2. The Appellant is diagnosed with end stage renal disease, diabetes, liver disease. She is taking dialysis.

3. The Appellant recently underwent a double amputation of her lower limbs.

4. The Appellant suffers chronic hypo-albuminemia secondary to her ESRD and liver disease, chronic diarrhea. She has marginal calorie intake due to fluid in her belly causing intolerance to food.

5. The Appellant's medical status requires a diet that restricts sugar, sodium, potassium and phosphorus but is high in calories and protein.

6. Re-Gen is a nutritional supplement specifically designed for use by diabetic, renal patients on dialysis.

7. The Appellant is unable to consume sufficient quantities of high biologic value protein and calories to meet her nutritional needs. (Department exhibit a page 12-letter from the Appellant's doctor).

8. The Appellant has attempted use of other nutrition supplements without success, specifically, Nepro and Suplena. They exacerbated her diarrhea.

9. The Appellant had previously been given prior authorization for Re-Gen by the Department of Community Health.

10. The Appellant tolerates the requested supplement well and showed marked improvement in her albumin level. (Department exhibit A, page 12).

11. The Appellant's doctor prescribed Re-Gen and requested prior authorization for continued use of the supplement on [redacted].

12. Following review of medical documentation of the Appellant's nutritional status and needs, as prepared by her dietician, the Department denied the request for prior authorization on [redacted].

13. Thereafter, on [redacted], the Department sent a denial notice to the Appellant.

14. On [redacted], the Appellant filed a Request for Hearing with the State Office of Administrative Hearings and Rules.

CONCLUSIONS OF LAW

The Medical Assistance Program is established pursuant to Title XIX of the Social Security Act and is implemented by Title 42 of the Code of Federal Regulations (CFR). It is administered in accordance with state statute, the Social Welfare Act, the Administrative Code, and the State Plan under Title XIX of the Social Security Act Medical Assistance Program.

> The Medicaid Provider Manual addresses the need for prior authorization in the General Information for Providers Chapter at Section 8-Prior Authorization.

8.1 General Information

There may be occasions when a beneficiary requires services beyond those ordinarily covered by Medicaid or needs a service that requires prior authorization (PA). In order for Medicaid to reimburse the provider in this situation, MDCH requires that the provider obtain authorization for these services before the service is rendered. Providers should refer to their provider-specific chapter for the PA requirements.

The Medical Supplier Chapter addresses the PA requirements for medical equipment requests. It states in pertinent part:

1.7 Prior authorization

Prior authorization (PA) is required for certain items before the item is provided to the beneficiary or, in the case of custom-made DME or prosthetic/orthotic appliance, before the item is ordered. To determine if a specific service requires PA, refer to the Coverage Conditions and Requirements Section of this chapter and/or the MDCH Medical Supplier Database on the MDCH website.

PA will be required in the following situations:

- Services that exceed quantity/frequency limits or established fee screen.
- Medical need for an item beyond MDCH's Standards of Coverage.
- Use of a Not Otherwise Classified (NOC) code.
- More costly service for which a less costly alternative may exist.
- Procedures indicating PA is required on the MDCH Medical Supplier Database.

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1.5 MEDICAL NECESSITY

Services are covered if they are the most cost-effective treatment available and meet the Standards of Coverage stated in the Coverage Conditions and Requirements Section of this chapter. A service is determined to be medically necessary if prescribed by a physician and it is:

- Within applicable federal and state laws, rules, regulations, and MDCH promulgated policies.
- Medically appropriate and necessary to treat a specific medical diagnosis or medical condition, or functional need.
- Within accepted medical standards; practice guidelines related to type, frequency, and duration of treatment; and within scope of current medical practice.
- Inappropriate to use a nonmedical item.
- The most cost effective treatment available.

1.10 NONCOVERED ITEMS

Items that are not covered by Medicaid include, but are not limited to:

- Adaptive equipment (e.g., rocker knife, swivel spoon, etc.)
- Air conditioner
- Air purifier
- **Enteral formula to accommodate psychological or behavioral conditions, food preferences, allergies, loss of appetite, or noncompliance with a specialized diet**
- Environmental Control Units
- Equipment not used or not used properly by the beneficiary
- Equipment for social or recreational purposes
- Exam tables/massage tables
- Exercise equipment (e.g., tricycles, exercise bikes, weights, mat/mat tables, etc.)
- Generators
- Hand/body wash
- Heating pads
- Home modifications
- Hot tubs
- House/room humidifier
- Ice packs
- Items for a beneficiary who is non-compliant with a physician's plan of care (or) items ordered for the purpose of solving problems related to noncompliance (e.g., insulin pump)

- Items used solely for the purpose of restraining the beneficiary for behavioral or other reasons
- Lift chairs, reclining chairs, vibrating chairs
- More than one pair of shoes on the same date of service
- New equipment when current equipment can be modified to accommodate growth
- Nutritional formula representing only a liquid form of food
- Nutritional puddings/bars
- Over-the-counter shoe inserts
- Peri-wash
- Portable oxygen, when oxygen is ordered to be used at night only
- Power tilt-in-space or reclining wheelchairs for a long-term care resident because there is limited staffing
- Pressure gradient garments for maternity-related edema
- Prosthetic appliances for a beneficiary with a potential functional level of K0
- Regular or dietetic foods (e.g., Slimfast, Carnation instant breakfast, etc.)
- Room dehumidifiers
- School Items (e.g., computers, writing aids, book holder, mouse emulator, etc.)
- Second units for school use
- Second wheelchair for beneficiary preference or convenience
- Sensory Devices (e.g., games, toys, etc.)
- Sports drinks/juices
- Stair lifts
- Standard infant/toddler formula
- Therapy modalities (bolsters, physio-rolls, therapy balls, jett mobile)
- Thickeners for foods or liquids (e.g., Thick – it)
- Toothettes
- Transcutaneous Nerve Stimulator when prescribed for headaches, visceral abdominal pain, pelvic pain, or temporal mandibular joint (TMJ) pain
- Ultrasonic osteogenesis stimulators
- UV lighting for Seasonal Affective Disorder
- Vacu-brush toothbrushes

- Weight loss or "light" products
- Wheelchair lifts or ramps for home or vehicle (all types)
- Wheelchair accessories (e.g., horns, lights, bags, special colors, etc.)
- Wigs for hair loss

For specific procedure codes that are not covered, refer to the MDCH Medical Supplier Database on the MDCH website or the Coverage Conditions and Requirements Section of this chapter. (emphasis added by ALJ)

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2.13.A Enteral Nutition (Administered Orally)

Standards of Coverage

Enteral nutition (administered orally) may be covered for beneficiaries under the age of 21 when:

- A chronic medical condition exists in nutritional deficiencies and a three month trial is required to prevent gastric placement.
- Supplemental to regular diet or meal replacement is required, and the beneficiary's weight-to-height ratio has fallen below the fifth percentile on standard growth grids.
- Physician documentation details low percentage increase in growth pattern or trend directly related to the nutritional intake and associated diagnosis/medical condition.

For CHSCS coverage, a nutritionist or appropriate subspecialist must indicate that long-term enteral supplementation is required to eliminate serious impact on growth and development.

For beneficiaries age 21 and over:

- The beneficiary must have a medical condition that requires the unique composition of the formulae nutrients that the beneficiary is unable to obtain from food

- The nutritional composition of the formulae represents an integral part of treatment of the specified diagnosis/medical condition.
- The beneficiary has experienced significant weight loss.

Documentation

Documentation must be less than 30 days old and include:

- Specific diagnosis/medical condition related to the beneficiary's inability to take or eat food
- Duration of need
- Amount of calories needed per day
- Current height and weight, as well as change over time. (for beneficiaries under 21, weight-to-height ratio)
- Specific prescription identifying levels of individual nutrient(s) that is required in increased or restricted amounts.
- List of economic alternatives that have been tried
- Current laboratory values for albumin or total protein (for beneficiaries age 21 and over only).

For continued use beyond 3-6 months, the CHSCS Program requires a report from a nutritionist or appropriate pediatric subspecialist.

PA Requirements
PA is required for all enteral formulae for oral administration.

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This ALJ reviewed the evidence of record to determine whether the Standards of Coverage were met with the documentation submitted. The testimony of the doctor and nurse were also considered very carefully. It is clear the Appellant had medical complications that result in a decreased tolerance for food, including her fluid storage and diarrhea. This ALJ was moved by the compelling testimony provided by the doctor and has concern for the Appellant's medical condition. The Department of Community Health, however, has enacted a very strict policy pertaining to approval for supplements such as Re-Gen. Not only do the standards of coverage have to be met, but once the standards of coverage are satisfied, it must not be excluded from coverage under non-covered items.

When reviewing the documentation and testimony in evidence, this ALJ could not find medical evidence the Appellant has suffered weight loss. It could be that it was inadvertently omitted. It could be because the Appellant had not suffered weight loss at the time of the request. This ALJ suspects the reason there is no documentation of weight loss could be in part due to the fact that the supplement had been approved previously by the Department, thus at that time renewal, she had not suffered any weight loss because the supplement was having the desired effect. For this reason, this ALJ does not know how the Department reconciles the requirement of showing weight loss for a continuing approval of a product that is working. The fact the policy requires a showing for weight loss is not something this ALJ has the authority to disregard regardless of the reason. In any event, no documentation of weight loss was found by this ALJ.

The other requirements for standards of coverage appear to be met. Certainly the Appellant has a medical condition that requires the unique composition of the formulae nutrients that the beneficiary is unable to obtain from food according to her doctor. The doctor's credible testimony establishes she is not tolerant of a sufficient amount to meet her nutritional requirements due to the combination of her medical conditions that result in fluid build up and diarrhea. This was found credible by this ALJ. The nutritional supplement represents an integral part of treatment of the specified diagnosis/medical condition as it is increase protein intake and raise albumin levels. The evidence establishes it has done this.

Ultimately, without the showing of weight loss, this ALJ is forced to sustain the Department's denial. Based upon the standards of coverage for the supplement requested, the above findings of fact and conclusions of law, I find the Department's denial of coverage for the Duo-Cal was supported by its own policy.

IT IS THEREFORE ORDERED that:

The Department's decision is AFFIRMED.

Jennifer Isiogu
Administrative Law Judge
for Janet Olszewski, Director
Michigan Department of Community Health

cc: [redacted]

Date Mailed: 3/25/2010

***** NOTICE *****

The State Office of Administrative Hearings and Rules may order a rehearing on either its own motion or at the request of a party within 30 days of the mailing date of this Decision and Order. The State Office of Administrative Hearings and Rules will not order a rehearing on the Department's motion where the final decision or rehearing cannot be implemented within 90 days of the filing of the original request. The Appellant may appeal the Decision and Order to Circuit Court within 60 days of the mailing date of the Decision and Order or, if a timely request for rehearing was made, within 60 days of the mailing date of the rehearing decision.