Expand Medicaid Coverage of Enteral Formula

Effective date: 4/30/14

Pursuant to authority vested in the Commissioner of Health by Section 201(1)(v) of the Public Health Law and Sections 363-a and 365-a(2) (g) of the Social Services Law, Section 505.5 of Title 18 (Social Services) of the Official Compilation of Codes, Rules and Regulations of the State of New York is amended as follows, to be effective upon publication of a Notice of Adoption in the New York State Register:

Paragraph (3) of subdivision (g) of Section 505.5 of Title 18 is amended to read as follows:

(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; [and for]

(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.

REGULATORY IMPACT STATEMENT

Statutory Authority:

Social Services Law (SSL) 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. In addition, SSL section 365-a(2)(g) authorizes the Commissioner of the Department to establish standards related to enteral formula therapy and nutritional supplements for persons with a diagnosis of HIV infection, AIDS or HIV-related illness or other diseases and conditions.

Legislative Objective:

The legislative objective of this authority is to expand Medicaid coverage of enteral formula for individuals with HIV infection, AIDS or HIV-related illness or other diseases and conditions which can result in poor nutritional status.

Needs and Benefits:

Enteral nutritional formulas are ordered by practitioners and dispensed by pharmacy or durable medical equipment providers. Medicaid reimburses the cost of enteral formulas for administration via tube, or for oral nutrition when used for treatment of an inborn metabolic disorder, or to address growth and development issues in children. In 2012, the Legislature expanded Medicaid coverage of enteral formulas to persons with a diagnosis of HIV infection, AIDS or HIV-related illness (and potentially to persons with other diseases and conditions), subject to standards established by the Commissioner of the Department. The statutory change was intended to benefit underweight adults and adults who have rapid short term weight loss, who need oral enteral formula to supplement their diet.

The proposed rule would provide coverage of enteral formulas to 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.

Costs:

Costs to the State and Local Government:

The expansion of coverage of enteral formula is estimated to result in an increase in Medicaid expenditures of $3.5 million. Because the local social services districts' share of Medicaid costs is statutorily capped, it is expected that there will be no additional costs to local governments as a result of this proposed regulation.

Costs to Private Regulated Parties:

Regulated entities will not incur any costs as a result of this rule.

Costs to the Regulatory Agency:

DOH will incur an estimated cost of $20,000 to implement necessary changes to the automated phone authorization system, which processes the majority of enteral related authorizations for providers. Utilization management measures will reallocate existing staff resources equivalent to one full time employee.

Local Government Mandates:

The proposed regulation does not impose any new programs, services, duties or responsibilities upon any county, city, town, village, school district, fire district or other special district.

Paperwork:

This amendment will require practitioners and dispensers to obtain any necessary authorizations and complete the related required paperwork to the extent they provide enteral formula to individuals who qualify for coverage under the new benefit expansion.

Duplication:

This regulation does not duplicate any existing federal, state or local government regulation.

Alternatives:

The Department could expand the coverage of enteral formula to a more defined group based on age, diagnosis, or other factors. However, the proposed changes are felt to represent the most cost effective method of expanding coverage to at risk individuals not currently covered by the existing benefit limit.

Federal Standards:

This amendment does not exceed any minimum standards of the federal government for the same or similar subject areas and does not result in reimbursement by Medicaid at a higher level than established federal reimbursement for enterals.

Compliance Schedule:

It is anticipated that regulated persons would be able to comply with the rule immediately.

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REGULATORY FLEXIBILITY ANALYSIS
FOR SMALL BUSINESSES AND LOCAL GOVERNMENTS

Effect on Small Business and Local Governments:

This amendment affects 3123 pharmacies and 369 durable medical equipment providers enrolled in the Medicaid program that actively bill Medicaid for enterals. The amendment will expand the enteral benefit which will increase Medicaid utilization and billable claims for these businesses.

The expansion of coverage of enteral formula is estimated to result in an increase in Medicaid expenditures of $3.5 million. Because the local social services districts' share of Medicaid costs is statutorily capped, it is expected that there will be no additional costs to local governments as a result of this proposed regulation.

Compliance Requirements:

This amendment does not impose new reporting, record keeping or other compliance requirements on small businesses or local governments.

Professional Services:

No new professional services are required as a result of this amendment.

Compliance Costs:

There are no direct costs of compliance with this amendment.

Economic and Technological Feasibility:

The enteral benefit limit is operationalized through beneficiary information and the practitioner's fiscal order for the enteral formula. Based on this information, a dispenser is able to provide enteral formula for tube-fed individuals who cannot chew or swallow food, individuals with rare inborn metabolic disorders, children when necessary to address growth and development concerns, adults who require supplemental nutrition up to 1,000 calories per day

and are either underweight, or have a body mass index under 22 and have demonstrated an unintentional 5% weight loss within the previous 6 month period, and adults with a permanent structural limitation that prevents the chewing of food, for whom a feeding tube is medically contraindicated. Since the amendment will not change the way providers bill for services or affect the way the local districts contribute their local share of Medicaid expenses, there should be no concern about economic or technological difficulties associated with compliance of the proposed regulation.

Minimizing Adverse Impact:

No adverse impact is anticipated as the legislation amendment will expand the existing benefit limit.

Small Business and Local Government Participation:

The Department invited participation in developing coverage standards through email outreach, a webinar presentation and social media. Proposed coverage change options were presented. The stakeholder feedback received was given substantial weight when making the proposed regulation amendment. A second webinar will be scheduled to inform stakeholders of the specific changes that are being proposed. Upon adoption of the regulation, DOH will inform stakeholders of the changes in coverage and associated prior authorization modifications.

Cure Period:

Chapter 524 of the Laws of 2011 requires agencies to include a "cure period" or other opportunity for ameliorative action to prevent the imposition of penalties on the party or parties subject to enforcement when developing a regulation or explain in the Regulatory Flexibility Analysis why one was not included. This regulation creates no new penalty or sanction. Hence, a cure period is not necessary.

RURAL AREA FLEXIBILITY ANALYSIS

Types and Estimated Number of Rural Areas:

Rural areas are defined as counties with a population less than 200,000 and, for counties with a population greater than 200,000, includes towns with population densities of 150 persons or less per square mile. The following 43 counties have a population less than 200,000:

Allegany	Hamilton	Schenectady
Cattaraugus	Herkimer	Schoharie
Cayuga	Jefferson	Schuyler
Chautauqua	Lewis	Seneca
Chemung	Livingston	Steuben
Chenango	Madison	Sullivan
Clinton	Montgomery	Tioga
Columbia	Ontario	Tompkins
Cortland	Orleans	Ulster
Delaware	Oswego	Warren
Essex	Otsego	Washington
Franklin	Putnam	Wayne
Fulton	Rensselaer	Wyoming
Genesee	St. Lawrence	Yates
Greene		

The following 9 counties have certain townships with population densities of 150 persons or less per square mile:

Albany	Erie	Oneida

Broome	Monroe	Onondaga
Dutchess	Niagara	Orange

This rule will apply to 3123 pharmacies and 369 durable medical equipment providers in New York State. These businesses are located in rural, as well as suburban and metropolitan areas of the State.

Compliance Requirements:

No new reporting, record keeping, or other compliance requirements are being imposed as a result of this proposal.

Professional Services:

No new additional professional services are required in order for providers in rural areas to comply with the proposed amendments.

Compliance Costs:

No initial capital costs will be imposed as a result of this rule, nor is there an annual cost of compliance.

Minimizing Adverse Impact:

The rule is not expected to have any adverse impact on public and private sector interests in rural areas.

Opportunity for Rural Area Participation:

The Department meets on a regular basis with providers groups such as the New York Medical Equipment Providers (NYMEP), who represents some rural providers. Webinar and social media sessions are accessible to providers statewide, including rural providers.

JOB IMPACT STATEMENT

Nature of Impact:

This rule will result in increased Medicaid billable claims for 3123 pharmacies and 369 durable medical equipment providers. The increase in revenue should not have an adverse impact on jobs and employment opportunities within these businesses.

Categories and Numbers Affected:

This rule, which increases Medicaid revenue for providers, should not have any adverse effect on employment opportunities.

Regions of Adverse Impact:

No region of New York State should realize adverse impact from this rule given the potential increase in Medicaid revenue for providers.

Minimizing Adverse Impact:

No adverse impact is anticipated given that this rule expands the existing benefit limit.

Self-Employment Opportunities:

The rule is expected to have minimal impact on self-employment opportunities since it expands the benefit limit and the majority of providers that will be affected by the rule are not small businesses or sole proprietorships solely dispensing enterals to Medicaid beneficiaries.

Assessment of Public Comment

Comments were received from a company that produces nutrition products and from a council that represents manufacturers of parenteral and enteral nutrition formulas, supplies, and equipment. Their recommendations for changes to the proposed regulation were identical.

The commenters suggested that the regulation should specifically provide coverage for persons with certain medical conditions that involve intestinal malabsorption, or who have reduced appetite/anorexia or dental/mouth problems. The Department has concluded that the current regulation would cover the conditions cited by the commenters, assuming the coverage criteria set forth in the proposed regulation are met. This is consistent with the authorizing statute, Social Service Law § 365-a(2)(g), which requires the Department to establish standards for coverage of enteral formula therapy and nutritional supplements for "persons with a diagnosis of HIV infection, AIDS or HIV- related illness **or *other diseases or conditions"*** (emphasis added). A modification to the existing language solely to list specific diagnoses or conditions is unnecessary. No change was made to the regulation as a result of this comment.

The commenters recommended an expanded set of criteria in those instances where a beneficiary demonstrates acute weight loss. The proposed regulation would cover individuals with a body mass index (BMI) under 22 who also demonstrate an unintentional weight loss of 5 percent or more within the previous six-month period. The commenters recommended eliminating the requirement for a BMI under 22, and providing coverage for any individuals with a chronic medical diagnosis who have a 5 percent weight loss within a one-month period, a 7.5 percent weight loss within a three-month period, or a 10 percent weight loss within a six-month period. It is the Department's position that the proposed regulation is consistent with its intent to cover enteral nutritional formula for the most medically compromised and at-risk beneficiaries

suffering acute weight loss, and that the nutritional needs of most Medicaid beneficiaries can be maintained without the use of enteral nutritional formulas through proper diet and/or nutritional modifications. No change was made to the regulation as a result of this comment.

The commenters recommended expanding coverage to patients with swallowing or chewing difficulty due to cancer of the mouth, throat, or esophagus, or due to injury or surgery involving the head and neck. However, the proposed regulation provides coverage for persons who have a permanent structural limitation that prevents the chewing of food and for whom the placement of a feeding tube is medically contraindicated. This is consistent with the Department's intent to limit coverage to individuals who will have a long-term reliance on enteral nutritional support as their sole means of nutrition. Individuals who do not have a permanent limitation preventing the chewing of food would typically be capable of eating solid foods, or other forms of solid food, such as liquefied, mashed, or pureed foods, to meet their nutritional needs. No change was made to the regulation as a result of this comment.

In addition, one commenter suggested that coverage under the proposed regulation should not be limited to underweight persons, citing a research paper on hospital malnutrition stating that overweight or obese adults who develop a severe acute illness may require nutritional intervention. However, any hospitalized Medicaid recipient is covered for nutritional support, if medically necessary, through the inpatient hospital benefit. No change was made to the regulation as a result of this comment.