

Medicaid Benefit Limits for Enteral Formula, Prescription Footwear, and Compression Stockings

Effective date: 3/28/12

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, 18 NYCRR Sections 505.1, 505.5, 513.0, 513.1 and 513.6 are amended, to be effective upon publication of the Notice of Adoption in the New York State Register.

Paragraph (2) of subdivision (b) of section 505.1 is amended, and a new paragraph (3) is added to read as follows:

(2) the identification card on its face:

(i) restricts an individual recipient to a single provider; or

(ii) requires prior authorization for all ambulatory medical services and supplies except emergency care [.] ; or

(3) the service exceeds benefit limitations as established by the department.

The opening language of paragraph (4) of subdivision (a) of section 505.5 is amended to read as follows:

(4) Orthopedic footwear means shoes, shoe modifications, or shoe additions which are used as follows: in the treatment of children, to correct, accommodate or prevent a physical deformity or range of motion malfunction in a diseased or injured part of the ankle or foot; in the treatment of children, to support a weak or deformed structure of the ankle or foot; as a component of a comprehensive diabetic treatment plan to treat amputation, ulceration, pre-ulcerative calluses, peripheral neuropathy with

evidence of callus formation, a foot deformity or poor circulation; or to form an integral part of an orthotic brace. Orthopedic shoes must have, at a minimum, the following features:

Subparagraph (ii) of paragraph (4) of subdivision (b) of section 505.5 is amended to read as follows:

(ii) The maximum number of refills permitted for medical/surgical supplies is found in the fee schedule for durable medical equipment, medical/surgical supplies, orthotic and prosthetic appliances and orthopedic footwear. The fee schedule for such equipment and supplies is available free of charge from the [department] Medicaid fiscal agent's website. [and is also contained in the department's Medicaid Management Information System (MMIS) provider Manual (Durable Medical Equipment, Medical and Surgical Supplies, Prosthetic and Orthotic Appliances). Copies of the manual may be obtained by writing Computer Sciences Corporation, Health and Administrative Services Division, 800 North Pearl St., Albany, NY 12204. Copies may also be obtained from the Department of Social Services, 40 North Pearl St., Albany, NY 12243. The manuals are provided free of charge to every provider of durable medical equipment, medical/surgical supplies, orthotic and prosthetic appliances and orthopedic footwear at the time of enrollment in the MA program.]

Subparagraph (vi) of paragraph (1) of subdivision (d) of section 505.5 is amended to read as follows:

(vi) [All items not listed in the department's fee schedule for durable medical equipment, medical/surgical supplies, prosthetic and orthotic appliances and orthopedic footwear require prior approval from the New York State Department of Health. The fee

schedule for such equipment and supplies is available from the department and is also contained in the department's MMIS Provider Manual (Durable Medical Equipment, Medical/Surgical Supplies, Prosthetic and Orthotic Appliances). Copies of the manual may be obtained by writing Computer Sciences Corporation, Health and Administrative Services Division, 800 North Pearl St., Albany, NY 12204. Copies may also be obtained from the Department of Social Services, 40 North Pearl St., Albany, NY 12243. The manuals are provided free of charge to every provider of durable medical equipment, medical/surgical supplies, orthotic and prosthetic appliances and orthopedic footwear at the time of enrollment in the MA program.] Reimbursement amounts for unlisted items are determined by the New York State Department of Health and must not exceed the lower of: (a) the acquisition cost to the provider plus 50 percent; or (b) the usual and customary price charged to the general public.

Subparagraph (iii) of paragraph (4) of subdivision (d) of Section 505.5 is amended to read as follows:

(iii) The fee schedule for orthotic and prosthetic appliances and devices is available free of charge from the Medicaid [department and is also contained in the department's MMIS Provider Manual (Durable Medical Equipment, Medical and Surgical Supplies, Prosthetic and Orthotic Appliances). Copies of the manual may be obtained by writing Computer Sciences Corporation, Health and Administrative Services Division, 800 North Pearl St., Albany, NY 12204. Copies may also be obtained from the Department of Social Services, 40 North Pearl St., Albany, NY 12243. The manuals are provided free of charge to every provider of durable medical equipment, medical/surgical

supplies, orthotic and prosthetic appliances and orthopedic footwear at the time of enrollment in the MA program] fiscal agent's website.

Subparagraph (i) of paragraph (5) of subdivision (d) of section 505.5 is amended to read as follows:

(i) Payment for orthopedic footwear must not exceed the lower of:

(a) [the acquisition cost to the provider plus 50%] the maximum reimbursable amount as shown in the fee schedule for durable medical equipment, medical/surgical supplies, orthotics and prosthetic appliances and orthopedic footwear; the maximum reimbursable amount will be determined for each item of footwear based on an average cost of products representative of that item; or

(b) the usual and customary price charged to the general public for the same or similar products.

Paragraph (1) of subdivision (e) of section 505.5 is amended to read as follows:

(1) [The following items] Items of durable medical equipment, medical/surgical supplies, orthotic and prosthetic appliances and devices, and orthopedic footwear are limited in their amount and frequency and may require prior authorization. Service limits and prior authorization requirements are listed in the provider manual at the Medicaid fiscal agent's website.

[ITEM

LIMIT

Cane

1 every 3 yrs.

Cane, Quad or three prong

1 every 3 yrs.

Flare heels (each)

2 pair per yr.

Cork lifts

2 pair per yr.

Steindler heel corrections

2 pair per yr.

Spenco Insert

2 pair per yr. per child

Heel wedge

2 pair per yr.

Foot, insert, removable, molded to patient model,

longitudinal arch support, each	2 per yr. per adult
Foot, insert, removable, molded to patient model, longitudinal/metatarsal support, each	2 per yr. per adult
Foot, arch support, removable, premolded, longitudinal, each	2 per yr. per adult
Foot, arch support, removable, premolded, longitudinal/metatarsal, each	2 per yr. per adult
Longitudinal arch support	1 pair per yr. per adult
Foot, arch support,	2 pair per yr. per adult
Removable mold/Levi mold	1 pair per yr. per adult
Elastic stocking/below knee medium wt.	4 pair per yr.
Elastic stocking/below knee heavy wt.	4 pair per yr.
Elastic stocking/above knee medium wt.	4 pair per yr.
Elastic stocking/above knee heavy wt.	4 pair per yr.
Elastic stocking/full length medium wt.	4 pair per yr.
Elastic stocking/full length heavy wt.	4 pair per yr.
Elastic stocking/leotards	4 pair per yr.
Elastic stocking/garter belt	4 pair per yr.
Surgical stocking/below knee	4 pair per yr.
Surgical stocking/thigh length	4 pair per yr.
Surgical stocking/full length	4 pair per yr.
Corset, Sacroiliac 2 per yr. Corset, Lumbar	2 per yr.
Handheld shower head	1 every 3 yrs.
Bed pan, fracture	1 every 3 yrs.
Urinary suspensory	1 every 5 yrs.
Emesis basin	1 every 5 yrs.
Sitz bath	1 every 5 yrs.
Urinal, female, any material	1 every 5 yrs.
Urinal, male, any material	1 every 5 yrs.
Commode pad	1 every 5 yrs.
Flotation pad	1 per yr.
Humidifier, cold air	1 every 3 yrs.
Vaporizer, room type	1 every 3 yrs.
Standard adult wheelchair	1 every 3 yrs.
Electric heating pad standard	1 every 3 yrs.
Hot fomentation heating pads	1 every 3 yrs.
Orthopedic shoes	2 pair per yr.]

A new subdivision (g) of section 505.5 is added to read as follows:

(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:

(1) Compression and surgical stockings are limited to coverage during pregnancy and for venous stasis ulcers.

(2) Orthopedic footwear is limited to coverage in the treatment of children to correct, accommodate or prevent a physical deformity or range of motion malfunction in a diseased or injured part of the ankle or foot; in the treatment of children to support a weak or deformed structure of the ankle or foot; as a component of a comprehensive diabetic treatment plan to treat amputation, ulceration, pre-ulcerative calluses, peripheral neuropathy with evidence of callus formation, a foot deformity or poor circulation; or to form an integral part of an orthotic brace.

(3) 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 age 21 when caloric and dietary nutrients from food cannot be absorbed or metabolized.

Paragraph (1) of subdivision (b) of section 513.0 is amended to read as follows:

(1) The department, as the single State agency supervising the administration of the MA program, has entered into an interagency agreement with the Department of Health whereby that department will review and approve selected medical, dental and remedial care, services and supplies prior to their being furnished. The purpose of this process is to assure that: the requested medical, dental and remedial care, services or supplies are medically necessary and appropriate for the individual recipient's medical

needs; other adequate and less expensive alternatives have been explored and, where appropriate and cost effective, are approved; the request does not exceed benefit limitations as promulgated by the department; and the medical, dental and remedial care, services or supplies to be provided conform to accepted professional standards. The department shall not allow exceptions to defined benefit limitations.

A new subdivision (h) of section 513.1 is added to read as follows:

(h) Benefit limits means specified Medicaid coverage limits which cannot be exceeded by obtaining prior approval or authorizations and for which no exceptions are allowed.

Paragraph (1) of subdivision (a) of section 513.6 is amended to read as follows:

(1) the specific statutory and regulatory standards and benefit limits governing the furnishing of the requested care, services, or supplies;

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.

Legislative Objective:

The legislative objective, expressed through SSL section 365-a(2)(g), is to impose benefit limitations on Medicaid coverage of enteral formula, prescription footwear, and compression stockings.

Needs and Benefits:

Enteral formula. Enterals 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 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. In the Medicare program enterals are covered for tube-fed individuals only.

Medicaid has attempted to put controls into place such as Card Swipe Prior Authorization and Automated Telephone Prior Authorization. Medicaid has also continued to monitor (through reporting systems) and correct provider prescribing and dispensing activity. In 2004, the enteral pricing methodology was changed, resulting in a 10-20 percent reduction in fees. Despite these measures, total yearly Medicaid utilization and expenditures for enteral nutrition have risen from less than \$11 million per year in 1997 to over \$70 million using the current coverage guidelines and procedures.

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 by \$15.4 million state and local share annually while continuing to meet intensive medical needs of individual beneficiaries with serious medical conditions.

Orthopedic footwear. Orthopedic footwear is ordered by practitioners and dispensed by durable medical equipment providers. Medicaid currently reimburses the cost of footwear for treatment of any physical deformity, range of motion malfunction, or foot or ankle weakness. A significant portion of utilization under the current benefit is for individuals whose needs can be met with off the shelf footwear. When prescribed for these less serious purposes, it is objectively difficult to assess medical necessity for the footwear and to prevent such reimbursement. Medicare reimburses footwear only for

treatment of diabetes complications. Additionally, footwear is currently manually priced at invoice cost plus 50 percent, resulting in paper claims.

By limiting the benefit based on medical necessity criteria and adopting the new reimbursement methodology, the regulation will reduce Medicaid costs by \$7.35 million state and local share in State Fiscal Year 2011-12 while continuing to meet intensive medical needs of individual beneficiaries with serious medical conditions.

Compression stockings. Compression stockings are ordered by practitioners and dispensed by pharmacy or durable medical equipment providers. Medicaid currently reimburses the costs of stockings for treatment of clinically significant medical conditions such as open wounds, and complications in pregnancy. Medicaid also currently reimburses the cost of stockings that have been prescribed for relatively less serious purposes such as circulatory improvement and wound prevention. When prescribed for these less serious purposes, it is objectively difficult to assess medical necessity for the stockings and to prevent their reimbursement when used strictly for comfort or convenience instead of medically necessary treatment for a clinical condition. Medicare reimburses for stockings only for treatment of open wounds.

By limiting the benefit based on diagnoses of pregnancy or open wounds, the regulation will help reduce Medicaid costs while continuing to meet intensive medical needs of individual beneficiaries with serious medical conditions.

In addition to the changes described above, the regulation amends sections 513.0, 513.1 and 513.6 to clarify that the new benefit limitations are not subject to exception through prior approval. Also, the regulation updates outdated language in section 505.5

regarding how durable medical equipment providers could obtain a hard copy of the Medicaid Provider Manual; such Manual is currently made available to providers online.

COSTS:

Costs for the Implementation of, and Continuing Compliance with the Regulation to the Regulated Entity:

This amendment will not increase costs to the regulated parties. It will reduce revenues to the extent providers are furnishing enteral formula, prescription footwear, or compression stockings beyond the scope of the benefit limit.

Costs to State and Local Government:

This amendment will not increase costs to the State or local governments. Savings to the Medicaid Program will be achieved by establishing these benefit limits.

Costs to the Department of Health:

There will be no additional costs to the Department.

Local Government Mandates:

This amendment will not impose any program, service, duty, additional cost, or responsibility on any county, city, town, village, school district, fire district, or other special district.

Paperwork:

This amendment will not impose any additional paperwork for providers of enteral formula, prescription footwear, or compression stockings.

Duplication:

There are no duplicative or conflicting rules identified.

Alternatives:

The benefit limits on enteral formula, prescription footwear, and compression stockings are mandated by section 365-a(2)(g) of the SSL. No alternatives were considered.

Federal Standards:

The proposed regulations do not exceed any minimum federal standards.

Compliance Schedule:

Social services districts and fiscal intermediaries should be able to comply with the proposed regulations when they become effective.

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REGULATORY FLEXIBILITY ANALYSIS FOR SMALL BUSINESSES AND LOCAL GOVERNMENTS

Effect of Rule:

This amendment affects the 3,123 pharmacies and 369 durable medical equipment providers enrolled in the Medicaid program who actively bill Medicaid for enteral formula. The amendment will limit the enteral benefit, which will reduce Medicaid utilization and billable claims to these businesses, some of which are small. The Department is anticipating a \$15.40 million reduction in enteral expenditures in State Fiscal Year (SFY) 2011-12 and thereafter.

This amendment affects the 955 durable medical equipment providers enrolled in the Medicaid program who actively bill Medicaid for footwear. The amendment will limit the footwear benefit, which will reduce Medicaid utilization and billable claims to these businesses, some of which are small. The Department is anticipating a \$7.35 million reduction in footwear expenditures in SFY 2011-12 and \$16 million annually thereafter.

This amendment affects the 1196 pharmacies and 441 durable medical equipment providers enrolled in the Medicaid program who actively bill Medicaid for stockings. The amendment will limit the stocking benefit, which will reduce Medicaid utilization and billable claims to these businesses, some of which are small. The Department is anticipating a \$1.07 million reduction in stocking expenditures in SFY 2011-12 and thereafter.

The fifty-eight local social services districts share in the costs of services provided to eligible beneficiaries who receive Medicaid through their districts.

Compliance Requirements:

This amendment does not impose new reporting, recordkeeping 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. However, affected providers will realize reduced Medicaid billings for enteral formula, prescription footwear, and compression stockings. Local social service districts will experience decreased costs in their share of medical expenses for these items as a result of overall decreases in utilization.

Economic and Technological Feasibility:

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 for enteral formula, prescription footwear, or compression stockings. Therefore, there should be no technological difficulties associated with compliance with the proposed regulation.

Minimizing Adverse Impact:

SSL section 365-a(2)(g) requires a benefit limit on the coverage of enteral formula, prescription footwear, and compression stockings. These limits will affect providers by reducing payable Medicaid claims for such items. This impact cannot be avoided given the statutory mandate.

Small Business and Local Government Participation:

Local government officials have consistently urged the Department to implement Medicaid cost savings programs. The Department also meets on a regular basis with provider groups such as the New York Medical Equipment Providers (NYMEP). NYMEP has been informed of the proposed changes and has indicated its concerns regarding adequate notice to beneficiaries and practitioners on the revised benefits. Upon promulgating the regulation, the Department will inform the industry of the changes and assist as necessary with the transition to the new benefit limits.

RURAL AREA FLEXIBILITY ANALYSIS

Types and Estimated Number of Rural Areas:

The benefit limit on enteral formula will apply to 3123 pharmacies and 369 durable medical equipment providers in New York State. The benefit limit on prescription footwear will apply to 955 durable medical equipment providers in New York State. The benefit limit on compression stockings will apply to 1196 pharmacies and 441 durable medical equipment providers in New York State. These businesses are located in rural, as well as suburban and metropolitan areas of the State.

Reporting, Recordkeeping and Other Compliance Requirements and Professional Services:

No new reporting, recordkeeping or other compliance requirements and professional services are needed in a rural area to comply with the proposed rule.

Costs:

There are no direct costs associated with compliance. However, affected providers will realize reduced Medicaid billable claims for enteral formula, prescription footwear, and compression stockings.

Minimizing Adverse Impact:

The Department considered the approaches in Section 202-bb(2)(b) of the State Administrative Procedure Act and found them to be inappropriate given the legislative objective.

Rural Area Participation:

The Department meets on a regular basis with provider groups such as the New York Medical Equipment Providers (NYMEP), who represents some rural providers, to

discuss reimbursement issues. NYMEP has indicated its concerns regarding adequate notice to beneficiaries and practitioners on the revised benefits. Upon promulgating the regulation, the Department will inform the industry of the changes and assist as necessary with the transition to the new benefit limits.

JOB IMPACT STATEMENT

Nature of Impact:

This rule will result in decreased Medicaid billable claims for providers of enteral formula, prescription footwear, and compression stockings. This decreased revenue will not likely have an adverse impact on jobs and employment opportunities within these businesses as they offer a wide variety of services which are reimbursed by Medicaid.

Categories and Numbers Affected:

This rule, which decreases Medicaid revenue, will not likely affect employment opportunities within providers who provide enteral formula, prescription footwear, and compression stockings.

The dispensing of enteral formula and compression stockings requires store clerk level staff, not licensed professionals.

The dispensing of prescription footwear requires staff certification from a national orthotic and prosthetic accreditation and training body. Support staff require no special training.

Regions of Adverse Impact:

This rule will affect all regions within the State and businesses out of New York State that are enrolled in the Medicaid Program to provide enteral formula, prescription footwear, and compression stockings.

Minimizing Adverse Impact:

SSL section 365-a(2)(g) requires a benefit limit on the coverage of enteral formula, prescription footwear, and compression stockings. These limits will affect providers by reducing payable Medicaid claims for such items. This impact cannot be avoided given the statutory mandate.

Self-Employment Opportunities:

The rule is expected to have minimal impact on self-employment opportunities since the majority of providers that will be affected by the rule are not small businesses or sole proprietorships whose sole business is dispensing enteral formula, prescription footwear, or compression stockings.

ASSESSMENT OF PUBLIC COMMENT

Public comment was received from 16 commentators: the Cystic Fibrosis Center at SUNY-Upstate, SAPS Drug Wholesale, Inc., Abbott Nutrition, a manufacturer of enteral nutritional formulas, Alzheimer's Association, Dialysis Patient Citizens, Northeast Kidney Foundation, Dr. Brett Abrams, a dietician, a registered nurse, a social worker, God's Love We Deliver, New York State Dietetic Association, Self Help, and three citizens.

Several commenters objected to coverage of enteral nutritional formulas for adults being limited to tube feeding and to treatment of inborn metabolic disorders. Various commenters urged that Medicaid also cover nutritional supplements for children with chronic kidney disease and for individuals with HIV/AIDS, cancer, diabetes, Alzheimer's disease, autism, or renal disease. One commenter requested coverage of prescription footwear for persons with leg length disparities. No changes were made to the proposed regulation as a result of these comments, since the Department lacks the authority to provide for such coverage by regulation, given the specific limitations imposed by SSL section 365-a(2)(g). However, the Department notes that SSL section 365-a(2)(g) in no way limits the ability of individuals under age 21 to receive early and periodic screening, diagnosis and treatment (EPSDT) services otherwise available pursuant to section 365-a(3).

Other comments expressed the opinion that the enteral formula limitations would harm other patient populations with a legitimate medical need for these nutritional supplements, and place a financial burden on persons who no longer have enteral formula covered by Medicaid. These comments were essentially criticisms of the legislative

change to SSL section 365-a(2)(g); they were not comments on specific language in the proposed regulation, nor did they suggest that the proposed regulation failed to conform to the statutory requirements. Therefore, no changes were made to the proposed regulation as a result of these comments.

One commenter posited a diminishment in health status of persons who no longer have enteral formula covered by Medicaid, and estimated an additional cost of \$8 million annually from a resulting rise in hospital admissions. The commenter submitted a cost analysis based primarily on assumptions drawn from a 2006 study published in The American Journal of Medicine entitled “A Randomized Double-blind, Placebo-controlled Trial of Nutritional Supplementation During Acute Illness”. The study compared the hospital readmission rates of elderly persons who received oral medical nutrition during hospitalization and for the following six months, and those who did not. From the information submitted by the commenter, the Department could not conclude that the cited study established that the proposed regulation would result in increased Medicaid costs, let alone allow statistically reliable cost estimates to be developed. The Department concluded that the commenter’s assertion, that unintended consequences of the proposed regulation would result in higher costs to the Medicaid program, is speculative.

One commenter, a community services organization, argued that the limitations on coverage of enteral formula, compression stockings, and prescription footwear violate federal requirements relating to the amount, duration, and scope of services provided under the Medicaid program, and that, at a minimum, the proposed regulation must provide a prior approval mechanism by which these services and supplies would be

covered for persons with other medical conditions who established a medical need for them. The Department disagrees with the commenter's interpretation of the federal Medicaid requirements in question, and considers it inconsistent with the flexibility granted states to decide the extent to which they will cover optional Medicaid services. In any event, as indicated above, the Department cannot, by regulation, provide coverage of these services in contravention of the limitations imposed by the State Legislature in SSL section 365-a(2)(g). Therefore, no changes were made to the proposed regulation as a result of this comment.