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Division of Medical Assistance
Botulinum Toxin Treatment:
Type A (Botox)
Type B (Myobloc)

Clinical Coverage Policy No.: 1B-1
Original Effective Date: April 1, 1991
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1.0 Description of the Product

Botulinum toxin type A (Botox) and botulinum toxin type B (Myobloc) injections are used for conditions in which neuromuscular blockade is indicated. They produce a presynaptic neuromuscular blockade by preventing the release of acetylcholine from the nerve endings. The resulting chemical denervation of muscle produces local paresis or paralysis and allows individual muscles to be weakened selectively. They have the advantage of being potent neuromuscular blocking agents with good selectivity, duration of action, with the smallest antigenicity, and fewest side effects.

In clinical conditions, such as cervical dystonia, excessive and abnormal regional muscle contraction causes torsion, spasticity, and pain. Botulinum toxin, injected in a focal fashion, produces neuromuscular blockade and paralysis. As symptoms abate, repeat injections may be required. Eventual loss of response to repeated injections may occur in some patients who have received botulinum toxin treatment. Immunoresistance may be one of the reasons for this development. As experience accumulates with other toxin types, similar resistance could be observable.

1.1 Safety and Provider Compliance

There are several botulinum toxins, currently designated A through G. Only types A and B are now FDA approved and commercially available. This policy deals *only* with botulinum toxin A (Botox) and botulinum toxin B (Myobloc). These share certain properties, and some FDA approvals, as well as certain off-label uses that are addressed in this policy. However, these two agents are *not* identical, and have differing therapeutic and adverse event profiles. Further, units and dosing are not equivalent, so they are not directly interchangeable with one another. It is expected that physicians familiar with and experienced in the use of these agents will utilize evidence-based medicine to select the appropriate drug and dose regimen for each patient, condition, and use.

2.0 Eligible Recipients

2.1 General Provisions

Medicaid recipients may have service restrictions due to their eligibility category that would make them ineligible for this service.

2.2 EPSDT Special Provision: Exception to Policy Limitations for Recipients under 21 Years of Age

42 U.S.C. § 1396d(r) [1905(r) of the Social Security Act]

Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) is a federal Medicaid requirement that requires the state Medicaid agency to cover services, products, or procedures for Medicaid recipients under 21 years of age **if** the service is **medically necessary health care** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem] identified through a screening examination** (includes any

evaluation by a physician or other licensed clinician). This means EPSDT covers most of the medical or remedial care a child needs to improve or maintain his/her health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems. Medically necessary services will be provided in the most economic mode, as long as the treatment made available is similarly efficacious to the service requested by the recipient's physician, therapist, or other licensed practitioner; the determination process does not delay the delivery of the needed service; and the determination does not limit the recipient's right to a free choice of providers.

EPSDT does not require the state Medicaid agency to provide any service, product, or procedure

- a. that is unsafe, ineffective, or experimental/investigational.
- b. that is not medical in nature or not generally recognized as an accepted method of medical practice or treatment.

Service limitations on scope, amount, duration, frequency, location of service, and/or other specific criteria described in clinical coverage policies may be exceeded or may not apply as long as the provider's documentation shows that the requested service is medically necessary "to correct or ameliorate a defect, physical or mental illness, or a condition" [health problem]; that is, provider documentation shows how the service, product, or procedure will correct or improve or maintain the recipient's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

****EPSDT and Prior Approval Requirements**

- a. If the service, product, or procedure requires prior approval, the fact that the recipient is under 21 years of age does **NOT** eliminate the requirement for prior approval.
- b. **IMPORTANT ADDITIONAL INFORMATION** about EPSDT and prior approval is found in the Basic Medicaid Billing Guide, sections 2 and 6, and on the EPSDT provider page. The Web addresses are specified below.

Basic Medicaid Billing Guide: <http://www.ncdhhs.gov/dma/medbillcaguide.htm>

EPSDT provider page: <http://www.ncdhhs.gov/dma/EPSTDTprovider.htm>

3.0 When the Product Is Covered

IMPORTANT NOTE: EPSDT allows a recipient less than 21 years of age to receive services in excess of the limitations or restrictions below and without meeting the specific criteria in this section when such services are **medically necessary health care services** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem]; that is, documentation shows how the service, product, or procedure will correct or improve or maintain the recipient's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

EPSDT DOES NOT ELIMINATE THE REQUIREMENT FOR PRIOR APPROVAL IF PRIOR APPROVAL IS REQUIRED. For additional information about EPSDT and prior approval requirements, see **Section 2.0** of this policy.

3.1 General Criteria

Medicaid covers botulinum toxins when the treatment is medically necessary and

- a. the treatment is individualized, specific, and consistent with symptoms or confirmed diagnosis of the illness or injury under treatment, and not in excess of the recipient's needs;
- b. the treatment can be safely furnished, and no equally effective and more conservative or less costly treatment is available statewide; and
- c. the treatment is furnished in a manner not primarily intended for the convenience of the recipient, the recipient's caretaker or the provider.

3.2 Specific Criteria: Botulinum Toxins Types A and B

- a. There must be no contraindications to botulinum toxin injection, including infection at the proposed injection site
- b. There must be no hypersensitivity to any ingredient in the formulation.

3.3 Coverage of Botulinum Toxin Type A (Botox)

Clinical judgment determines whether to use *CPT procedure code 64614, chemodenervation of muscle(s); extremity(s) and/or trunk muscles*, or *64640, destruction by neurolytic agent; other peripheral nerve or branch*.

Medicaid covers botulinum toxin type A (Botox) for the following conditions:

- a. Chronic anal fissure refractory to conservative treatment
- b. Esophageal achalasia patients in whom surgical treatment is not indicated
- c. Blepharospasm
- d. Spasmodic torticollis, secondary to cervical dystonia
- e. Hereditary spastic paraplegia
- f. Multiple sclerosis for patients with spasticity
- g. Neuromyelitis optica for patients with spasticity secondary to spinal cord involvement
- h. Other demyelinating diseases of central nervous system with secondary spasticity
- i. Spastic hemiplegia and hemiparesis affecting dominant side
- j. Spastic hemiplegia and hemiparesis affecting non-dominant side
- k. Quadriplegia, including conditions covered by ICD-9-CM codes 344.00 through 344.5
- l. Infantile cerebral palsy, specified or unspecified, including congenital diplegia; congenital hemiplegia; and quadriplegic, monoplegic, and infantile hemiplegia
- m. Disorders of eye movement (strabismus) including conditions covered by ICD-9 codes 378.00 through 378.9
- n. Laryngeal spasm
- o. Achalasia and cardiospasm
- p. Gustatory hyperhidrosis (Frey's syndrome)
- q. Hemifacial spasms
- r. Primary focal hyperhidrosis due to axillary hyperhidrosis (see **Section 3.3.1** below)

- s. Disturbance of salivary secretion (sialorrhea)(see **Section 3.3.2** below)
- t. Schilder's disease

3.3.1 Primary Axillary Hyperhidrosis

For the purposes of this policy, primary axillary hyperhidrosis is defined as a condition involving focal, visible, and severe sweating that has lasted for at least 6 months, has no apparent cause, and has at least two of the following characteristics:

- a. Sweating is bilateral and relatively symmetric
- b. Sweating impairs daily activity
- c. Episodes occur at least once per week
- d. The age of onset was less than 25 years
- e. There is a positive family history
- f. Focal sweating stops during sleep

Treatment of severe axillary hyperhidrosis with Botox is considered medically reasonable and necessary only when both of the following criteria are met:

- a. The patient has documented medical complications due to hyperhidrosis, (skin maceration with secondary skin infections, significant constant disruption of professional life, etc.); and
- b. There is medical record documentation that the patient has either failed a 6-month trial of conservative management, including the use of topical aluminum chloride or extra-strength antiperspirants, or could not tolerate these agents.

3.3.2 Sialorrhea

N.C. Medicaid covers Botox treatment of sialorrhea when

- a. there is documented disability from sialorrhea due to conditions such as motor neuron disease or Parkinson's disease; or
- b. there is documented failure to respond to a reasonable trial of traditional therapies (such as anticholinergics, speech therapy, or surgical therapy) or a contraindication to the traditional therapy.

3.4 Coverage of Botulinum Toxin Type B (Myobloc)

3.4.1 Spasmodic Torticollis and Cervical Dystonia

Medicaid covers botulinum toxin type B (Myobloc) for the FDA-approved treatment of spasmodic torticollis, secondary to cervical dystonia to reduce the severity of abnormal head position and neck pain associated with cervical dystonia. The recipient's medical record must document findings consistent with spasmodic torticollis.

Note: The choice of selecting botulinum toxin type A or B as the preferred initial agent for cervical dystonia treatment is based on the clinical judgment of the managing provider.

3.4.2 Sialorrhea

Medicaid covers botulinum toxin type B (Myobloc) for the treatment of sialorrhea as detailed in **Section 3.3.2**.

3.5 Electromyography

Medicaid covers electromyography when it is medically necessary to determine the proper injection site(s). See **Attachment A** for billing information.

4.0 When the Product Is Not Covered

IMPORTANT NOTE: EPSDT allows a recipient less than 21 years of age to receive services in excess of the limitations or restrictions below and without meeting the specific criteria in this section when such services are **medically necessary health care services** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem]; that is, documentation shows how the service, product, or procedure will correct or improve or maintain the recipient's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

EPSDT DOES NOT ELIMINATE THE REQUIREMENT FOR PRIOR APPROVAL IF PRIOR APPROVAL IS REQUIRED. For additional information about EPSDT and prior approval requirements, see **Section 2.0** of this policy.

4.1 General Criteria

Botulinum toxin treatment is not covered when

- a. the recipient does not meet the eligibility requirements listed in **Section 2.0**;
- b. the recipient does not meet the medical necessity criteria listed in **Section 3.0**;
- c. the procedure unnecessarily duplicates another provider's procedure; **or**
- d. the procedure is experimental, investigational, or part of a clinical trial.

4.2 Specific Criteria

Use of botulinum toxin type A or B to treat disorders or conditions other than those listed in **Section 3.0** is not covered.

- a. Any botulinum toxin treatment of other spastic conditions not listed in **Section 3.0**, including the treatment of smooth muscle spasm, anal spasm, irritable colon, or biliary dyskinesia, is considered to be cosmetic, investigational, unsafe, and ineffective; and is not accepted as the standard of practice within the medical community.
- b. Treatment of headaches, craniofacial wrinkles, and neurogenic bladder is not covered.

5.0 Requirements for and Limitations on Coverage

IMPORTANT NOTE: EPSDT allows a recipient less than 21 years of age to receive services in excess of the limitations or restrictions below and without meeting the specific criteria in this section when such services are **medically necessary health care services** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem]; that is, documentation shows

how the service, product, or procedure will correct or improve or maintain the recipient's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

EPSDT DOES NOT ELIMINATE THE REQUIREMENT FOR PRIOR APPROVAL IF PRIOR APPROVAL IS REQUIRED. For additional information about EPSDT and prior approval requirements, see **Section 2.0** of this policy.

5.1 FDA Guidelines for Administration of Botulinum Toxins

Before considering botulinum toxin treatment, it should be established that the patient has been unresponsive to conventional methods of treatments such as medication, physical therapy, and other appropriate methods used to control and/or treat spastic conditions.

The patient who has a spastic or excessive muscular contraction condition is usually started with a low dose of botulinum toxin. Other spastic or muscular contraction conditions, such as eye muscle disorders (e.g., blepharospasm) may require lesser amounts of botulinum toxin. For larger muscle groups, it is generally agreed that once a maximum dosage per site has been reached and there is no response, the treatment is discontinued. With response, the effect of the injections generally lasts for three months, at which time the patient may need repeat injections to control the spastic or excessive muscular condition. It is usually considered not medically necessary to give botulinum toxin injections for spastic or excess muscular contraction conditions more frequently than every 90 days, unless acceptable justification is documented for more frequent use in the initial therapy.

Treatments may be continued unless any two treatments in a row, utilizing an appropriate or maximum dose of botulinum toxin, failed to produce satisfactory clinical response. Providers must also document the response to these injections after every third session.

5.1.1 Dosage Limitations for Botulinum Toxin Type A (Botox)

The cumulative dosage should not exceed 600 units in 90 days.

5.1.2 Limitations for Botulinum Toxin Type B (Myobloc)

The cumulative dosage should not exceed 10,000 units in 12 weeks (84 days).

5.2 Unit Limitations

Medicaid covers one injection of Botox or Myobloc for each site, regardless of the number of injections made into the site. A site is defined as including muscles of a single contiguous body part (a single limb, eyelid, face, neck, etc.).

6.0 Providers Eligible to Bill for Botulinum Toxin Treatment

Providers who meet Medicaid's qualifications for participation and are currently enrolled with the N.C. Medicaid program are eligible to bill for botulinum toxin treatment when it is within the scope of their practice.

7.0 Additional Requirements

7.1 Federal and State Requirements

All providers must comply with all applicable state and federal laws and regulations.

7.2 Medical Record Documentation

Documentation in the recipient's medical record should include all of the following elements:

- a. Support for the medical necessity of the botulinum toxin injection
- b. A covered diagnosis
- c. A statement that traditional methods of treatments have been unsuccessful
- d. Dosage and frequency of the injections
- e. Support for the medical necessity of electromyography procedures, if used
- f. Support of the clinical effectiveness of the injections
- g. Specific site(s) injected

7.3 Records Retention

As a condition of participation, providers are required to keep records necessary to disclose the extent of services rendered to recipients and billed to the N.C. Medicaid program [Social Security Act 1902(a)(27) and 42 CFR 431.107]. Records must be retained for a period of at least five years from the date of service, unless a longer retention period is required by applicable federal or state law, regulations, or agreements (10A NCAC 22F.0107).

Copies of records must be furnished upon request.

The Health Insurance Portability and Accountability Act (HIPAA) does not prohibit the release of records to Medicaid (45 CFR 164.502).

8.0 Policy Implementation/Revision Information

Effective Date: April 1, 1991

Revision Information:

Date	Section Revised	Change
03/01/2007	Throughout policy	Coverage criteria and diagnoses for botulinum toxin type A (Botox) were clarified.
03/01/2007	Throughout policy	Coverage of botulinum toxin type B (Myobloc) was implemented as a covered treatment when provided in accordance with the criteria and guidelines in the policy.
5/1/2007	Sections 2 through 5	EPSDT information was revised to clarify exceptions to policy limitations for recipients under 21 years of age
11/1/2008	Section 1.1	Added section about safety and compliance.
11/1/2008	Section 2.2	Added citation for EPSDT information.

Date	Section Revised	Change
11/1/2008	Throughout	Updated standard language to match revised policy template; revised general English usage for greater clarity.
11/1/2008	Section 3.2	Separated the specific requirements (no contraindications, no hypersensitivity) from the general criteria for coverage; renumbered subsequent sections.
11/1/2008	Section 3.3	Added a paragraph deferring to clinical judgment; added the diagnoses of quadriplegia, Schilder's disease, and sialorrhea; moved Congenital diplegia—Infantile hemiplegia to be included in infantile cerebral palsy and added detail in that line.
11/1/2008	Sections 3.3.1 and 3.3.2	Assigned subheadings for primary axillary hyperhidrosis and sialorrhea (3.3.1 and 3.3.2, respectively).
11/1/2008	Section 3.4.1	Added heading for spasmodic torticollis and cervical dystonia; combined two sentences into one.
11/1/2008	Section 3.4.2	Added the diagnosis of sialorrhea.
11/1/2008	Section 4.2	Moved restriction on type B to introductory sentence of Specific Criteria; removed sialorrhea from the non-covered list (Specific Criteria will become Section 4.2 if this is approved).
11/1/2008	Section 7.0	Added heading (now 7.2) for medical record documentation; added standard sections on federal & state requirements and records retention.
11/1/2008	Attachment A	Added additional diagnosis and procedure codes for quadriplegia, Schilder's disease, sialorrhea, spasticity, and infantile cerebral palsy; added or updated code descriptions per 2008 guides; added CPT code 46505; added table headings; revised billing guidelines; deleted some CPT procedure codes for electromyography (92265, 95860, 95861, 95867, 95868, 95869, 95870)

Attachment A: Claims-Related Information

Reimbursement requires compliance with all Medicaid guidelines, including obtaining appropriate referrals for recipients enrolled in the Medicaid managed care programs.

A. Claim Type

Professional (CMS-1500/837P transaction)

B. Diagnosis Codes

Providers must bill the ICD-9-CM diagnosis codes(s) to the highest level of specificity that supports medical necessity.

a. Botulinum Toxin Type A

ICD-9-CM Diagnosis Code	Description
333.81	Blepharospasm
333.83	Spasmodic torticollis (secondary to cervical dystonia)
334.1	Hereditary spastic paraplegia
340	Multiple sclerosis (with secondary code to indicate spasticity)
341.0	Neuromyelitis optica (with secondary code to indicate spasticity)
341.1	Schilder's disease
341.8	Other demyelinating diseases of central nervous system(with secondary code to indicate spasticity)
341.9	Demyelinating disease of central nervous system, unspecified
342.11	Spastic hemiplegia and hemiparesis affecting dominant side
342.12	Spastic hemiplegia and hemiparesis affecting non-dominant side
343.0	Infantile cerebral palsy; diplegic
343.1	Infantile cerebral palsy; hemiplegic
343.2	Infantile cerebral palsy;quadriplegic
343.3	Infantile cerebral palsy; monoplegic
343.4	Infantile cerebral palsy; infantile hemiplegia
343.8	Other specified infantile cerebral palsy
343.9	Infantile cerebral palsy, unspecified
344.00	Quadriplegia unspecified
344.01	Quadriplegia C1–C4 complete
344.02	Quadriplegia C1–C4 incomplete
344.03	Quadriplegia C5–C7 complete
344.04	Quadriplegia C5–C7 incomplete
344.09	Other quadriplegia and quadripareisis
351.8	Hemifacial spasms
378.00 through 378.9	Disorders of eye movement (strabismus)
478.75	Laryngeal spasm
527.7	Disturbance of salivary secretion

ICD-9-CM Diagnosis Code	Description
530.0	Achalasia and cardiospasm
565.0	Anal fissure
705.21	Primary focal hyperhidrosis
705.22	Gustatory hyperhidrosis (Frey's Syndrome)
723.5	Torticollis unspecified

b. Botulinum Toxin Type B

ICD-9-CM Diagnosis Code	Description
333.83	Spasmodic torticollis
527.7	Sialorrhea

C. Procedure Code(s)

a. HCPCS Procedure Codes

HCPCS Code	Description
J0585	Botulinum toxin type A, per unit
J0587	Botulinum toxin type B, per 100 units

b. CPT Codes for Botulinum Toxin Type A

CPT Code	Description
31513	Laryngoscopy, indirect; with vocal cord injection
31570	Laryngoscopy, direct, with injection into vocal cord(s), therapeutic
31571	Laryngoscopy, direct, with injection into vocal cord(s), therapeutic; with operating microscope or telescope
46505	Chemodenervation of internal anal sphincter
64612	Chemodenervation of muscle(s); muscle(s) innervated by facial nerve (e.g., for blepharospasm, hemifacial spasm)
64613	Chemodenervation of muscle(s); neck muscle(s) (e.g., for spasmodic torticollis, spasmodic dysphonia)
64614	Chemodenervation of muscle(s); extremity(s) and/or trunk muscle(s) (e.g., for dystonia, cerebral palsy, multiple sclerosis)
64640	Destruction by neurolytic agent; other peripheral nerve or branch
64650	Chemodenervation of eccrine glands; both axillae
67345	Chemodenervation of extraocular muscle

c. CPT Codes for Botulinum Toxin Type B

CPT Code	Description
64612	Chemodenervation of muscle(s); muscle(s) innervated by facial nerve (e.g., for blepharospasm, hemifacial spasm)
64613	Chemodenervation of muscle(s); neck muscle(s) (e.g., for spasmodic torticollis, spasmodic dysphonia)

D. Coding Guidelines

a. Botulinum Toxin Type A (Botox)

The following CPT procedure codes are to be reported with the respective listed covered ICD-9-CM diagnosis codes when billing for botulinum toxin type A (Botox):

CPT Code	Description	ICD-9-CM Diagnosis Code	Description
31513	Laryngoscopy, indirect; with vocal cord injection	478.75	Laryngeal spasm
31570	Laryngoscopy, direct, with injection into vocal cord(s), therapeutic	478.75	Laryngeal spasm
31571	Laryngoscopy, direct, with injection into vocal cord(s), therapeutic; with operating microscope or telescope	478.75	Laryngeal spasm
46505	Chemodeneration of internal anal sphincter	565.0	Anal fissure
64612	Chemodeneration of muscle(s); muscle(s) innervated by facial nerve (e.g., for blepharospasm, hemifacial spasm)	333.81	Blepharospasm
		351.8	Hemifacial spasm nerve
		527.7	Sialorrhea
64613	Chemodeneration of muscle(s); neck muscle(s) (e.g., for spasmodic torticollis, spasmodic dysphonia)	333.83 344.00 through 344.09	Spasmodic torticollis Quadriplegia
64614 (continues)	Chemodeneration of muscles; extremity(s) and/or trunk muscle(s) (e.g., for dystonia, cerebral palsy, multiple sclerosis) (continues)	334.1	Hereditary spastic paraplegia
		340	Multiple sclerosis
		341.0	Neuromyelitis optica
		341.1	Schilder's disease
		341.8	Other demyelinating diseases of central nervous system
		341.9	Demyelinating disease of central nervous system, unspecified
		342.11	Spastic hemiplegia (dominant)
342.12	Spastic hemiplegia (non-dominant)		

CPT Code	Description	ICD-9-CM Diagnosis Code	Description
64614 (continued)	Chemodenervation of muscles; extremity(s) and/or trunk muscle(s) (e.g., for dystonia, cerebral palsy, multiple sclerosis) (continued)	343.0 through 343.9	Infantile cerebral palsy
		344.00 through 344.09	Quadriplegia
		530.0	Achalasia and cardiospasm
		705.21	Primary focal hyperhidrosis
64640	Destruction by neurolytic agent; other peripheral nerve or branch	343.0 through 343.9	Infantile cerebral palsy
		565.0	Anal fissure
		705.21	Primary focal hyperhidrosis
64650	Chemodenervation of eccrine glands; both axillae	705.21	Primary focal hyperhidrosis
67345	Chemodenervation of extraocular muscle	378.00 through 378.90	Strabismus

b. Electromyography for Guidance

Only one electromyography code may be reported for each injection site. The following procedure codes for EMG guidance may be billed if appropriate.

CPT Code	Description
95873	Electrical stimulation for guidance in conjunction with chemodenervation
95874	Needle electromyography for guidance in conjunction with chemodenervation (List separately in addition to code for primary procedure)

c. Botulinum Toxin Type B (Myobloc)

The following procedure codes are to be reported with the corresponding ICD-9-CM diagnosis codes when billing for botulinum toxin type B (Myobloc).

CPT Code	Description	ICD-9-CM Diagnosis Code	Description
64612	Chemodenervation of muscle(s); muscle(s) innervated by facial nerve (e.g., for blepharospasm, hemifacial spasm)	527.7	Sialorrhea

CPT Code	Description	ICD-9-CM Diagnosis Code	Description
64613	Chemodeneration of muscle(s); neck muscle(s) (e.g., for spasmodic torticollis, spasmodic dysphonia)	333.83	Spasmodic torticollis

E. Modifiers

Providers are required to follow applicable modifier guidelines.

F. Billing Units

1. Botulinum Toxin Type A: 1 billing unit = 1 unit
2. Botulinum Toxin Type B: 1 billing unit = 100 units
3. Medicaid covers an administration fee when billed with the injection (J0585 or J0587) on the same day of service with the J0585 or J0587 code.

Note: An administration fee is not covered on the same day of service as an evaluation and management code for recipients age 21 and over.

G. Place of Service

Outpatient office settings

H. Co-payments

Medicaid recipients aged 21 and older may be subject to co-payments for office visits.

I. Reimbursement

Providers must bill their usual and customary charges.