Title 23: Division of Medicaid

Part 203: Physician Services

Chapter 2: Physician-Administered Drugs and Implantable Drug System Devices

Rule 2.1: Covered Services

A. The Division of Medicaid covers medically necessary physician-administered drugs and implantable drug system devices defined as a drug other than vaccines, diagnostic or therapeutic radiopharmaceutical, contrast imaging agent, biological or implantable drug system device covered under the Social Security Act § 1927(k)(2) that:

   1. Are administered by a medical professional in a physician's office or other outpatient clinical setting,

   2. Are incident to physician services that are separately billed to the Division of Medicaid,

   3. Qualifies for rebate in accordance with 42 USC § 1396r-8,

   4. Are Food and Drug Administration (FDA) approved or follows medically accepted indications and dosing limits supported by one (1) or more of the official compendia as designated by the Centers for Medicare and Medicaid Services (CMS), and

   5. Are not considered cosmetic, investigational, experimental or unproven.

B. The Division of Medicaid reimburses for discarded drugs or biologicals up to the dosage amount indicated on the single-use vial or package label minus the administered dose(s) if:

   1. The drug or biological is supplied in a single use vial or single–use package,

   2. The drug or biological is actually administered to the beneficiary to appropriately address his/her condition and any unused portion is discarded,

   3. The amount wasted is recorded in the beneficiary's medical record,

   4. The provider has written policy and procedures regarding single-use drugs and biologicals and bills all payers in the same manner, and

   5. The amount billed to the Division of Medicaid as a discarded drug is not administered to another beneficiary or patient.

C. The Division of Medicaid does not reimburse for discarded drugs or biologicals when:

   1. A beneficiary misses an appointment,

2. A multi-use vial or package is used,

3. The actual dose of the drug or biological administered is less than the billing unit,

4. The drug or biological is administered during an inpatient stay, or

5. The extra amount of the drug is provided to account for wastage in a syringe hub.

D. The Division of Medicaid defines an implantable drug system device as an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent or other similar or related article, including a component part, or accessory which is:

1. Recognized in the official National Formulary, the United States Pharmacopoeia or any supplement to one of these, or

2. Intended for use in the diagnosing of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease.

E. The Division of Medicaid covers the insertion and removal of a Food and Drug Administration (FDA) approved implantable drug system device if it:

1. Is medically necessary,

2. Is in compliance with its approved uses, specifications and restrictions, and

3. Meets all other applicable coverage requirements.

F. The Division of Medicaid does not cover:

1. Services related to the use of a non-covered medical device, or

2. Implantable drug system devices that are considered experimental or investigational.

Source: 42 USC § 1396r-8; Miss. Code Ann. § 43-13-121.

History: Emergency Filing eff. 03/02/2016. Revised eff. 07/01/2014.

Rule 2.3: [Refer to Miss. Admin. Code Part 203, Rule 2.1]

Rule 2.4: [Refer to Miss. Admin. Code Part 203, Rule 2.1]

Rule 2.5: [Refer to Miss. Admin. Code Part 203, Rule 2.1]

Rule 2.6: [Refer to Miss. Admin. Code Part 203, Rule 2.1]

Chapter 4: Surgery

Rule 4.13: [Refer to Miss. Admin. Code Part 203, Rule 2.1]

Rule 4.14: [Refer to Miss. Admin. Code Part 203, Rule 2.1]

Title 23: Division of Medicaid

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4. Are Food and Drug Administration (FDA) approved or follows medically accepted indications and dosing limits supported by one (1) or more of the official compendia as designated by the Centers for Medicare and Medicaid Services (CMS), and

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B. The Division of Medicaid reimburses for discarded drugs or biologicals up to the dosage amount indicated on the single-use vial or package label minus the administered dose(s) if:

1. The drug or biological is supplied in a single use vial or single–use package,

2. The drug or biological is actually administered to the beneficiary to appropriately address his/her condition and any unused portion is discarded,

3. The amount wasted is recorded in the beneficiary's medical record,

4. The provider has written policy and procedures regarding single-use drugs and biologicals and bills all payers in the same manner, and

5. The amount billed to the Division of Medicaid as a discarded drug is not administered to another beneficiary or patient.

C. The Division of Medicaid does not reimburse for discarded drugs or biologicals when:

1. A beneficiary misses an appointment,

2. A multi-use vial or package is used,

3. The actual dose of the drug or biological administered is less than the billing unit,

4. The drug or biological is administered during an inpatient stay, or

5. The extra amount of the drug is provided to account for wastage in a syringe hub.

D. The Division of Medicaid defines an implantable drug system device as an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent or other similar or related article, including a component part, or accessory which is:

1. Recognized in the official National Formulary, the United States Pharmacopoeia or any supplement to one of these, or

2. Intended for use in the diagnosing of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease.

E. The Division of Medicaid covers the insertion and removal of a Food and Drug Administration (FDA) approved implantable drug system device if it:

1. Is medically necessary,

2. Is in compliance with its approved uses, specifications and restrictions, and

3. Meets all other applicable coverage requirements.

F. The Division of Medicaid does not cover:

1. Services related to the use of a non-covered medical device, or

2. Implantable drug system devices that are considered experimental or investigational.

Source: ~~Social Security Act § 1927(k)(2);~~ 42 USC § 1396r-8; Miss. Code Ann. § 43-13-121.

History: Emergency Filing eff. 03/02/2016. Revised eff. 07/01/2014.

Rule 2.3: ~~Botulinum Toxins A and B~~ [Refer to Miss. Admin. Code Part 203, Rule 2.1]

~~A. The Division of Medicaid covers Botulinum Toxin A and B injections when administered in accordance with Food and Drug Administration (FDA) approval or medically accepted indications and dosing limits supported by one of the following official compendia:~~

~~1. American Hospital Formulary Service Drug Information (AHFS-DI),~~

~~2. United States Pharmacopoeia-Drug Information (USP-DI) or its approved replacement~~

and/or successor publication, or

3. The DrugDEX Information System.

B. The Division of Medicaid covers Botulinum Toxin A when administered to treat the following diagnoses:

1. Facial Spasm,

2. Blepharospasm,

3. Hemifacial Spasm,

4. Cervical Dystonia,

5. Spasmodic Dysphonia,

6. Strabismus,

7. [Deleted eff. 07/01/2014]

8. Focal hand dystonia,

9. Chronic anal fissure with an unsatisfactory response to conservative treatment,

10. Esophageal achalasia in beneficiaries who have not responded to dilation therapy or who are poor surgical candidates,

11. Frey's syndrome,

12. Primary Axillary Hyperhidrosis that is inadequately managed with topical agents,

13. Spasticity to:

a) Relieve pain,

b) Assist with improving and stabilizing posture and walking,

c) Allow better range of motion,

d) Permit better response to physical therapy, and

e) Reduce severe spasms in order to provide adequate perineal and palmar hygiene,

14. [Deleted] Refer to Miss. Admin, Code Part 203, Rule 2.3.13.

15. Neurogenic detrusor over activity in beneficiaries that have an inadequate response to or are intolerant of anticholinergic medication, and

16. Chronic migraine headaches occurring greater than fifteen (15) days per month with headaches lasting four (4) hours a day or longer.

C. The Division of Medicaid covers Botulinum Toxin B to treat cervical dystonia.

D. The Division of Medicaid reimburses for one (1) injection per each functional muscle group/anatomical site regardless of the number of injections made into each group/site or the number of muscles that complies the functional group.

E. The Division of Medicaid does not cover Botulinum toxin treatment for:

1. Cosmetic reasons,

2. Investigational use,

3. Experimental purposes, or

4. Continued use if two (2) consecutive treatments utilizing an appropriate or maximum dose failed to produce a satisfactory clinical response.

F. Documentation must be maintained in the beneficiary's medical record including, but not limited to:

1. Support for the medical necessity of the Botulinum Toxin injections and any prior treatments that were unsuccessful,

2. A covered diagnosis,

3. Type, dilution, strength and dosage of the injection and frequency of administration,

4. Amount of drug wastage,

5. Support for the medical necessity of electromyography procedures, if performed,

6. Clinical effectiveness of all injections, and

7. A complete description of the functional muscle group/anatomical site(s) injected.

Source: Miss. Code Ann. § 43-13-121.

History: Revised and added Miss. Admin. Code Part 203, Rule 2.3.A, B.15, B.16. and deleted Rule 2.3.B.7. eff. 07/01/2014.

Rule 2.4: ~~Xolair~~ [Refer to Miss. Admin. Code Part 203, Rule 2.1]

~~A. The Division of Medicaid covers Xolair when all of the following indications are determined and proper documentation submitted for medical review:~~

~~1. Patient must be greater than twelve (12) years of age with at least a one (1) year diagnosis of moderate to severe persistent asthma as defined by the National Heart, Lung and Blood Institute.~~

~~2. Patient must have a positive skin test or in vitro reactivity to a perennial aeroallergen, such as an allergy to dust mites, mold, animal dander or cockroaches, and have symptoms that are inadequately controlled with inhaled corticosteroids.~~

~~3. Treatment is prescribed and administered by a board-certified pulmonologist or allergist/immunologist in that physician's office.~~

~~4. IgE level is thirty (30) IU/ml to seven hundred (700) IU/ml.~~

~~5. Allergy-related/asthma-related emergency department visits more than twice a year in the past year or hospitalization for treatment in the past two (2) years.~~

~~6. Documented compliance and treatment regimen of a combination of medium dose inhaled corticosteroid and long-acting beta-2 agonists and/or leukotriene receptor agonists administered for three (3) months without symptom improvement. Xolair (Omalizumab) is only covered as a second line drug treatment after the first line treatments have failed.~~

~~7. Inadequate asthma control with course of systemic corticosteroids and/or high dose inhaled corticosteroids required for daily control.~~

~~8. Impairment in activities of daily living, such as work, school attendance, exercise or sleep.~~

~~9. Patient is nonsmoking and if not, actively receiving smoking cessation treatment.~~

~~B. Xolair is non-covered in the following situations:~~

~~1. Treatment of acute exacerbation of asthma or status asthmaticus.~~

~~2. Administration to patients with an IgE less than thirty (30) IU/ml or greater than seven hundred (700) IU/ml.~~

~~3. Administered as a first line treatment with no documentation that treatment of continual use with first line corticosteroids and beta-2 agonist has failed.~~

~~C. Documentation in the patient's medical record must include:~~

~~1. A history of pertinent moderate to severe allergy related asthma.~~

~~2. Past and present asthma treatment and patient response and compliance.~~

~~3. A positive skin test or in vitro reactivity to a perennial aeroallergen.~~

~~4. IgE level prior to treatment.~~

~~5. Patient's weight.~~

~~6. Reason, dosage and frequency for the drug usage.~~

~~7. Patient smoking history.~~

~~Source: Miss. Code Ann. § 43-13-121~~

Rule 2.5: ~~Hyaluronate Joint Injection~~[Refer to Miss. Admin. Code Part 203, Rule 2.1]

~~A. The Division of Medicaid covers Hyaluronate injections when the following criteria are satisfied:~~

~~1. The patient is being treated for pain which is caused by osteoarthritis of the knee joint.~~

~~2. The patient does not have end-stage degenerative joint disease.~~

~~3. The patient does not respond adequately to conservative therapy such as physical therapy, weight loss, and/or simple analgesics.~~

~~4. The treatment is performed in accordance with acceptable standards of practice.~~

~~5. The medical necessity is documented on the claim by reporting the appropriate diagnosis code.~~

~~6. The appropriate modifier, when applicable, is used with the appropriate code which identifies a bilateral arthrocentesis of a major joint. If the first series of injections failed to prove beneficial, repeat injections are considered not medically necessary.~~

~~7. The medical device/solution must be FDA approved.~~

~~B. The provider must bill separately for each date of service and not combine and bill after the completion of the full series of injections.~~

~~C. The physician performing the procedure must document and maintain records in accordance with requirements set forth in Part 200, Chapter 1, Rule 1.3., and at a minimum, document the following relating to the medical necessity for the procedure:~~

1. Patient history,

2. Physical examinations,

3. Diagnosis(es),

4. Examination notes documenting the evaluation and management of the condition/diagnosis(es),

5. Relevant clinical signs and symptoms,

6. Abnormal laboratory, x-ray, and/or other diagnostic test results,

7. Failure of conservative treatment such as physical therapy, weight loss, and simple analgesics, and

8. Route of administration, the clinical information supporting the indication for use, and the frequency of its use.

Source: Miss. Code Ann. § 43-13-121

Rule 2.6: 17 Alpha Hydroxyprogesterone Caproate Injections (17-P) *[Refer to Miss. Admin. Code Part 203, Rule 2.1]*

The Division of Medicaid covers medically necessary intramuscular injections of 17 Alpha-Hydroxyprogesterone Caproate (17-P). [Refer to Miss. Admin. Code Part 203, Rule 2.1.A.]

Source: 42 CFR §§ 435.116, 440.210; Miss. Code Ann. § 43-13-121.

History: Revised eff. 09/01/2015.

Chapter 4: Surgery

Rule 4.13: Implantable Testosterone Pellets (Testopel) *[Refer to Miss. Admin. Code Part 203, Rule 2.1]*

A. Medicaid covers Implantable Testosterone Pellets (Testopel) for the following indications only:

1. Treatment of delayed male puberty, or

2. Treatment of male hypogonadism, primary or hypogonadotropic.

B. The following diagnoses are required for administration and billing of Implantable Testosterone Pellets (Testopel):

1. Pituitary hypogonadism, or

2. Testicular hypogonadism.

C. Implantable Testosterone Pellets (Testopel) are considered experimental and investigational for all other indications and Medicaid does not cover.

D. Implantable Testosterone Pellets (Testopel) are covered as a subcutaneous implantation and Medicaid covers for administration no more than every three (3) months.

Source: Miss. Code Ann. § 43-13-121

Rule 4.14: Insertion of Retisert (Fluocinolone Acetonide Intravitreal Implant) *[Refer to Miss. Admin. Code Part 203, Rule 2.1]*

A. Medicaid covers the insertion of Retisert for patients who are no longer tolerant of, or responsive to, more conservative treatment modalities.

1. Retisert is contraindicated in most viral diseases of the cornea and conjunctiva including, but not limited to:

a) Epithelial herpes simplex,

b) Keratitis (dentritic keratitis),

c) Vaccinia,

d) Varicella,

e) Mycobacterial infections of the eye, and

f) Fungal diseases of ocular structures.

2. Retisert may be placed unilaterally or bilaterally. The bilateral procedure may be done at the same time, or may be done at separate times.

3. Retisert may be replaced once every two and one half (2.5) years or thirty (30) months.

4. Insertion of Retisert is not covered in pediatric patients below the age of twelve (12).

B. Medical record documentation must be maintained by the performing physician and must include the clinical/medical necessity for the Retisert implant.

1. Documentation must include, but is not limited to, the signs, symptoms, and/or diagnosis(es) that support the need for the service.

2. All prior treatments must be identified and documented as to why they failed.

3. Documentation must also include the operative/procedure report and medical records including but not limited to, office notes, history and physical, etc., supporting the signs, symptoms and diagnosis.

Source: Miss. Code Ann. § 43-13-121