# Automated Medication Dispenser Criteria

| **Iowa Medicaid Program:** | Prior Authorization | **Effective Date:** | 11/1/2007 |
|---|---|---|---|
| **Revision Number:** | 6 | **Last Review Date:** | 1/15/2016 |
| **Reviewed By:** | Medicaid Clinical Advisory Committee | **Next Review Date:** | 1/2017 |
| **Approved By:** | Medicaid Medical Director | **Approved Date:** | 4/27/2016 |

An automated medication dispenser is a mechanical device for controlling the timed delivery of medications according to the prescribed schedule. The device may use auditory, visual or other sensory mechanisms to give reminders when medications are due. It also controls the dosing schedule based on a physician's instructions, verifies the medication is taken and can alert a caregiver if medication is not taken.

Telephone monitoring for a medication dispenser connects the device to a call center to help monitor the medication and usage. Real-time information about adherence and the status of the dispenser is available. Alerts and reports can be sent to caregivers, family members, or a physician.

**Criteria:**
Automated medication dispensers will be considered medically necessary when **ALL** of the following are met:

1. Member must have a diagnosis indicative of cognitive impairment or age-related factors that affect the member's ability to remember to take medications.
2. The member is taking prescribed medication, including prescribed over-the-counter and medications that are prescribed as PRN, if the documentation supports the member is regularly taking the PRN medication.
3. The availability of a caregiver to administer the medications or perform set-up is inadequate or non-existent.
4. Less costly alternatives, such as medisets or telephone reminders, have failed.

**Telephone monitoring**
Telephone monitoring for automated medication dispensers will be considered medically necessary when **ALL** of the following are met:

1. The medications prescribed and the member's condition necessitate that the medication be taken at a certain time to avoid complications.
2. The member lives alone or others living in the member's home are unable to provide assistance.
3. The member has no other services coming into the home or the frequency is insufficient to provide effective supervision of the medication regimen.
4. Member and/or caregiver demonstrates the ability to consistently and regularly answer the telephone.

**HCPCS Codes:**
T1505
S5185

**References Used:**
http://www.lifestylehealthsys.com/blog/technology-for-medication-management.html
Accessed 4/26/13

Development of utilization management criteria may also involve research into other state Medicaid programs, other payer policies, consultation with experts and review by the Medicaid Clinical Advisory Committee (CAC). These sources may not be referenced individually unless they are specifically published and are otherwise applicable to the criteria at issue.

**Change History:**

| Change Date: | Changed By: | Description of Change: | New Version Number: |
|---|---|---|---|
| 10/19/12 | CAC | Criterion #2 - remove "two or more prescribed medications" | 1 |
| 4/19/13 | CAC | Criterion #2 - removed "and requires medication administration more than once per day" | 2 |
| 4/26/13 | Medical Director | Definitions of automated medication dispenser and telephone monitoring added | 3 |
| 12/12/13 | Medical Director | Formatting changes | 4 |
| 1/16/15 | CAC | Added last paragraph in References Used. | 5 |
| 1/15/16 | CAC | Added #4 under telephone monitoring | 6 |

**C. David Smith, MD**

# Bariatric Surgery Criteria

| **Iowa Medicaid Program:** | Pre-procedure | **Effective Date:** | 9/11/2009 |
|---|---|---|---|
| **Revision Number:** | 7 | **Last Review Date:** | 1/15/2016 |
| **Reviewed By:** | Medicaid Clinical Advisory Committee | **Next Review Date:** | 1/2017 |
| **Approved By:** | Medicaid Medical Director | **Approved Date:** | 4/27/2016 |

**Criteria: <u>All of the below criteria must be met for referral of a member to a bariatric surgical center for clinically severe obesity</u>.**

The bariatric surgery center should demonstrate a competence and commitment to preparing members for surgery, diligence in postoperative care, and include extended yearly visits to evaluate the possible nutritional deficiencies and metabolic changes of the member.

1. Body mass index (BMI) greater than 35 with current evidence of **<u>at least one</u>** serious underlying co-morbidity.
    a. Any respiratory impairment caused or exacerbated by member's obesity resulting in impaired gas exchange. Evidence of hypoxemia or hypercarbia or significant restrictive lung disease needs to be demonstrated. Deconditioning or obstructive lung disease does not suffice.
    b. Significant hypertension requiring medical treatment.
    c. Type 2 diabetes mellitus requiring medication.
    d. Cardiovascular disease as evidenced by recent cardiac testing.
    e. Any medical condition(s) that be caused by or be worsening the member's health status due to obesity and that weight-loss will reverse or improve this condition.
        i. Documentation is to include relevant objective studies demonstrating the condition is related to the member's obesity and can be expected to improve with weight loss.

2. Documented successful participation in a six-month lifestyle modification program.
    a. Formal written documentation regarding completion of at least a six-month medically supervised diet and exercise programs completed within the past six months, which will include:
        i. A detailed diet and weight history documenting formal attempts at weight-loss for at least six-months prior to request for surgery.
        ii. Complete history and physical examination, including age, height, weight, and BMI which are followed on at least a monthly basis and are available for review.
        iii. Length of time on diets, compliance to dietary restrictions, ongoing documentation of weight through the supervised diet period, and reasons for weight gain, if applicable.
        iv. Medical evaluation of endocrine status, if applicable.
        v. Sample dietary and physical activity logs or dietary and exercise recall histories for at least two points during the supervised diet period.
    b. Weight loss during the supervised diet is **not** required, but documentation must show evidence of compliance to show that the member can maintain lifestyle changes post-operatively.

3. Medical clearance for surgery, specifically addressing age-related risks to the patient, must be obtained from an independent provider for members over age 65. Laboratory studies including CBC, urinalysis, liver function tests, lipid studies, blood chemistries, thyroid function, arterial blood gases, EKG, and pulmonary function tests are recommended as they are relevant to the member's medical condition.
4. Psychological Evaluation to rule out major mental health disorders which would contraindicate surgery and determine patient compliance with post-operative follow-up care and dietary guidelines.
5. Documentation of patient compliance in maintaining scheduled pre-surgical office visits, at a minimum of once a month, for three months prior to surgery.
6. Documentation of discussion of specific life-long dietary restriction requirements after surgery and the patient's willingness and/or ability to comply.
7. Repeat procedures must have documentation of the reasons for failure of the prior procedure and a reasonable expectation that such barriers to the success of another procedure have been mitigated.

**CPT/HCPCS Codes:**

43770 Lap Banding
43644 Lap Roux-en-y
43845 Biliopancreatic diversion with duodenal switch
43846 Open Roux-en-y
43847 Roux-en-y with small bowel reconstruction to limit absorption
43848 Revision of gastric band
43842 Vertical-banded gastroplasty
43843 Other than vertical-banded gastroplasty
43775 Laparoscopic or open sleeve gastrectomy
43771 Laparoscopy, surgical, gastric restrictive procedure, revision of adjustable gastric restrictive device component only
43772 Laparoscopy, surgical, gastric restrictive procedure, removal of adjustable gastric restrictive device component only
43773 Laparoscopy, surgical, gastric restrictive procedure, removal and replacement of adjustable gastric restrictive device component only
43774 Laparoscopy, surgical, gastric restrictive procedure, removal of adjustable gastric restrictive device and subcutaneous port components
43845 Gastric restrictive procedure with partial gastrectomy, pylorus-preserving duodenoileostomy and ileoileostomy (50 to 100 cm common channel) to limit absorption (biliopancreatic diversion with duodenal switch
43886 Gastric restrictive procedure, open; revision of subcutaneous port component only
43887 Gastric restrictive procedure, open; removal of subcutaneous port component only
43888 Gastric restrictive procedure, open; removal and replacement of subcutaneous port component only

**References Used:**

441 IAC 78.3(4)
National Institutes of Health (NIH) The Practical Guide Identification, evaluation and Treatment of Overweight and Obesity in Adults. NIH Publication # 00-4084, October 2000 http://www.nhlbi.nih.gov/guidelines/obesity/prctgd_b.pdf. Accessed 12-11-2013.
Kohatsu, ND et at, The University of Iowa College of Public Health. Obesity Management in Adults, 1-20-2006. A policy paper prepared for the Iowa Department of Human services, Iowa Medicaid Enterprise.

**References Used (cont.):**

Kohatsu ND, Snetselaar LG, Beining R, The University of Iowa College of Public Health Department of Epidemiology, Management of Obesity, Overweight and Undernutrition in Children, 1-30-2006. A policy paper prepared for the Iowa Department of Human Services, Iowa Medicaid Enterprise.

World Health Organization, International Society of Hypertension Writing Group, 2003 World Health Organization (WHO)/International Society of Hypertension (ISH) statement on management of hypertension. J Hypertens. 2003:21:1983-1992.

http://www.mbsaqip.org,the joint program of the American College of Surgeons(ACS) and the American Society for Metabolic & Bariatric Surgery(ASMBS), known as Metabolic and Bariatric SurgeryAccreditation and Quality Improvement Program(MBSAQIP). Accessed 10/18/13.

https://www.unitedhealthcareonline.com/ccmcontent/ProviderII/UHC/en-US/Assets/ProviderStaticFilesPdf/Tools and Resources/Policies and Protocols/Medical Policies/Medical Policies/Bariatric Surgery.pdf. The criteria of another Iowa payer. Some wording was borrowed from this document regarding psychiatric evaluation. Accessed 12/11/13.

http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDid=57&ncdver=5&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=Iowa&KeyWord=bariatric+surgery&KeyWordLookUp=Title&KeyWordSearchType=And&bc=gAAAABAAAAAAAA%3d& CMS NCD on bariatric surgery. Accessed 12/11/13.

http://www.cms.gov/medicare-coverage-database/details/cd-details.aspx?LCDid=32904&Contrid=147CMS LCD on Bariatric Surgery for Morbid Obesity. Accessed 12/11/13.

Development of utilization management criteria may also involve research into other state Medicaid programs, other payer policies, consultation with experts and review by the Medicaid Clinical Advisory Committee (CAC). These sources may not be referenced individually unless they are specifically published and are otherwise applicable to the criteria at issue.

**Change History:**

| **Change Date:** | **Changed By:** | **Description of Change:** | **New Version Number:** |
|---|---|---|---|
| 3/26/13 | Medical Director | Revision of hypertension and co-morbidity requirement wording. | 1 |
| 3/28/13 | Policy Staff | Added Reference of 441 IAC 78.3(4). | 2 |
| 12/12/13 | Medical Director | Revision of criteria and added references. | 3 |

**Change History (Cont.):**

| Change Date: | Changed By: | Description of Change: | New Version Number: |
|---|---|---|---|
| 1/17/14 | CAC | Criterion #3 - changed "weight loss program" to "lifestyle modification program". Criterion #5 - Medical clearance - added "for surgery, specifically". | 4 |
| 1/16/15 | CAC | Removed criterion #2 regarding Center of Excellence(CoE) and Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP) requirement.<br>Added criterion #9 regarding phentermine.<br>Added last paragraph in References Used. | 5 |
| 4/30/15 | Policy staff | Criterion #2a added "completion of".<br>Criterion #3 changed format of laboratory values from narrative to separate item list. | 6 |
| 1/15/16 | CAC | Revision of wording in criterion #1. Removal of criterion #2b regarding weight loss and criterion #9 regarding phentermine. | 7 |

**C. David Smith, MD**

# Botulinum Toxins Criteria

BOTOX® (onabotulinumtoxinA)
DYSPORT™ (abobotulinumtoxinA)
MYOBLOC® (rimabotulinumtoxinB)
XEOMIN® (incobotulinumtoxinA)

| | | | |
|---|---|---|---|
| **Iowa Medicaid Program:** | Prior Authorization; Claims Pre-pay | **Effective Date:** | 7/1/2008 |
| **Revision Number:** | 6 | **Last Review Date:** | 1/15/2016 |
| **Reviewed By:** | Medicaid Clinical Advisory Committee | **Next Review Date:** | 1/2017 |
| **Approved By:** | Medicaid Medical Director | **Approved Date:** | 4/27/2016 |

**Description:**
Botulinum toxins are neurotoxins produced by the bacterium *Clostridium botulinum*. Botulinum toxins are used to treat various disorders of focal muscle spasm and excessive muscle contractions. When injected intramuscularly, the toxin blocks acetylcholine release at the neuromuscular junction. Advantage can be taken of this neuromuscular blockade to alleviate overactive neural activity in target organs (e.g., muscle or sweat glands) for therapeutic effect.

There are seven different botulinum neurotoxin serotypes referred to as A, B, C-1, D, E, F, and G.

Two different strains of *C. botulinum* produce the three commercial botulinum toxin biologics approved by the FDA: onabotulinumtoxinA (formerly botulinum toxin type A) (BOTOX®) and abobotulinumtoxinA (DYSPORT™) are produced by the Hall strain, and rimabotulinumtoxinB (formerly botulinum toxin type B) (MYOBLOC®) is produced by the Bean strain.

It is important to understand that BOTOX®, DYSPORT™, and MYOBLOC® are unique products that are not interchangeable. They are chemically, pharmacologically, and clinically distinct. Please note that each product's FDA-approved package insert states: "Units of biological activity cannot be converted into units of any other botulinum toxin or any other toxin assessed with any other specific assay method."

**Criteria:**
Iowa Medicaid covers OnabotulinumtoxinA (Botox®) injections when the following indications are met:

1. An appropriate medical diagnosis, such as:
   a. Focal Dystonias
   b. Blepharospasm, characterized by intermittent or sustained closure of the eyelids caused by involuntary contractions of the orbicularis oculi muscle.
   c. Individuals with cervical dystonia (spasmodic torticollis) of moderate or greater severity when the following criteria are met:
      i. Alternative causes of the member's symptoms have been considered and ruled out, including chronic neuroleptic treatment, contractures, or other neuromuscular disorders; and
      ii. There is sustained head torsion and/or tilt with limited range of motion in the neck; and

iii. There are clonic and/or tonic involuntary contractions of multiple neck muscles (e.g., sternocleidomastoid, splenius, trapezius, and/or posterior cervical muscles.

d. Adductor spasmodic dysphonia/laryngeal dystonia
e. Jaw closing oromandibular dystonia causing persistent pain, interference with nutritional intake or significant speech impairment
f. Meige's Syndrome/cranial dystonia
g. Spastic Conditions
   i. Cerebral palsy
   ii. Cerebrovascular accident
   iii. Localized adductor muscle spasticity in multiple sclerosis
   iv. Spinal cord injury
   v. Traumatic brain injury
h. Hemifacial spasms causing persistent pain or vision impairment
i. Strabismus disorders
j. Primary Esophageal Achalasia in patients who are considered poor surgical risks and patients who have a history of perforation
k. Chronic anal fissure in patients who have failed conservative treatment
l. Treatment of primary or secondary axillary or palmar hyperhidrosis when the condition is refractory to conventional medical treatment involving topical and pharmacotherapy. Must have documentation that the condition significantly interferes with ADLs and the condition is causing chronic skin irritations
m. Intracranial lesion or CVA induced voiding difficulty
n. Treatment of urinary incontinence due to detrusor overactivity associated with a neurologic condition such as spinal cord injury, multiple sclerosis in adults who have an inadequate response to or are intolerant of anticholinergic medication
o. Prophylaxis of chronic migraines when there is failure, contraindication, or intolerance to at least two different migraine prophylaxis medications (e.g., beta blockers, calcium channel blockers, tricyclic antidepressants or anticonvulsant medications)
p. Treatment of excessive glandular secretion refractory to pharmacotherapy (including anticholinergics) including EITHER of the following:
   i. Cholinergic-mediated secretions associated with a fistula (e.g., parotid gland, pharyngocutaneous)
   ii. Ptyalism/sialorrhea (excessive secretion of saliva, drooling) that is socially debilitating and refractory to pharmacotherapy (including anticholinergics).

**Iowa Medicaid covers RimabotuninumtoxinB (Myobloc®) when the following indications are met:**

1. Individuals with cervical dystonia (spasmodic torticollis) of moderate or greater severity when the following criteria are met:
   a. Alternative causes of the member's symptoms have been considered and ruled out, including chronic neuroleptic treatment, contractures; or other neuromuscular disorders ; and
   b. There is sustained head torsion and/or tilt with limited range of motion in the neck; and
   c. There are clonic and/or tonic involuntary contractions of multiple neck muscles (e.g., sternocleidomastoid, splenius, trapezius and/or posterior cervical muscles.
2. Ptyalism/sialorrhea (excessive secretion of saliva, drooling) that is socially debilitating and refractory to pharmacotherapy (including anticholinergics).

3. Intractable, disabling focal primary hyperhydrosis, when all of the following are met:
   i. Member is unresponsive or unable to tolerate pharmacotherapy prescribed for excessive sweating (e.g., anticholinergics, beta-blockers, or benzodiazepines) if sweating is episodic; *and*
   ii. Significant disruption of professional and/or social life has occurred because of excessive sweating; *and*
   iii. Topical aluminum chloride or other extra-strength antiperspirants are ineffective or result in a severe rash.

**Iowa Medicaid covers AbobotulinumtoxinA (Dysport™ Brand of Botulinum Toxin Type A) when the following indications are met:**

1. Blepharospasm, characterized by intermittent or sustained closure of the eyelids caused by involuntary contractions of the orbicularis oculi muscle.
2. Cervical dystonia, (spasmodic torticollis) of moderate or greater severity when all of the following criteria are met:
   a. Alternative causes of the member's symptoms have been considered and ruled out, including chronic neuroleptic treatment, contractures, or other neuromuscular disorders; and
   b. There is sustained head torsion and/or tilt with limited range of motion in the neck; and
   c. There are clonic and/or tonic involuntary contractions of multiple neck muscles (e.g., sternocleidomastoid, splenius, trapezius and/or posterior cervical muscles).
      i. Limb spasticity, including:
         1. Equinus varus deformity in children with cerebral palsy
         2. Hereditary spastic paraplegia;
         3. Limb spasticity due to multiple sclerosis;
         4. Limb spasticity due to other demyelinating diseases of the central nervous system (including adductor spasticity and pain control in children undergoing adductor-lengthening surgery as well as children with upper extremity spasticity);
         5. Spastic hemiplegia, such as due to stroke or brain injury.

**Iowa Medicaid covers IncobotulinumtoxinA (Xeomin®) for the following:**

1. Treatment of adults with cervical dystonia (spasmodic torticollis) of moderate or greater severity when the following criteria are met:
   a. Alternative causes of the member's symptoms have been considered and ruled out, including chronic neuroleptic treatment, contractures, or other neuromuscular disorders; and
   b. There is sustained head torsion and/or tilt with limited range of motion in the neck; and
   c. There are clonic and/or tonic involuntary contractions of multiple neck muscles (e.g. sternocleidomastoid, splenius, trapezius, and/or posterior cervical muscles)
   d. Adductor spasmodic dysphonia/laryngeal dystonia
   e. Jaw closing oromandibular dystonia causing persistent pain, interference with nutritional intake or significant speech impairment
   f. Meige's Syndrome/cranial dystonia
2. Treatment of blepharospasm in adults previously treated with OnabotulinumtoxinA (Botox®).

**Non-covered indications for the use of Botulinum Toxins due to being investigational, experimental or unproven:**

1. Chronic pain: low back pain, myofascial pain, and chronic neck pain
2. TMJ or chronic orofacial pain
3. Headache: tension, chronic daily headache
4. Tics
5. Voiding dysfunction associated with any of the following:
   a. BPH
   b. Urge incontinence refractory to anticholinergic therapy
6. Paralytic scoliosis
7. Diabetic gastroparesis

**Botulinum toxin therapy is considered not medically necessary for the treatment of cosmetic conditions.**

**HCPCS Code:**
For BOTOX®: J0585 (Injection, onabotulinumtoxinA, 1 unit)
For DYSPORT™: J0586 (Injection, abobotulinumtoxinA, 5 units)
For MYOBLOC®: J0587 (Injection, rimabotulinumtoxinB, 100 units)
For XEOMIN®: J0588 (Injection, incobotulinumtoxinA, 1 unit)

NOTE: List may not be complete. All PA requests subject to individual review.

**References Used:**

Development of utilization management criteria may also involve research into other state Medicaid programs, other payer policies, consultation with experts and review by the Medicaid Clinical Advisory Committee (CAC). These sources may not be referenced individually unless they are specifically published and are otherwise applicable to the criteria at issue.

**Change History:**

| Change Date: | Changed By: | Description of Change: | New Version Number: |
|---|---|---|---|
| 11/2/10 | Nick Ford, PA-C | New FDA criteria | 1 |
| 2/18/13 | Nick Ford, PA-C and Medical Director | Clarification and addition of information on incobotulinumtoxinA | 2 |
| 1/17/14 | CAC | Criterion #1”o” - remove > 15 days per month with headache lasting four hours a day or longer | 3 |
| 1/30/14 | Medical Director | HCPS Code - added note | 4 |
| 1/16/15 | CAC | Added paragraph in References Used. | 5 |

**Change History (cont.):**

| Change Date: | Changed By: | Description of Change: | New Version Number: |
|---|---|---|---|
| 1/15/16 | CAC | Removed criterion #1q as was duplicate of #1n. Under non-covered removed “wrinkles” and included in “cosmetic conditions”. | 6 |

**C. David Smith, MD**

# Cardiac Rehabilitation Criteria

| **Iowa Medicaid Program:** | Retrospective Review | **Effective Date:** | 7/1/2005 |
|---|---|---|---|
| **Revision Number:** | 5 | **Last Review Date:** | 1/15/2016 |
| **Reviewed By:** | Medicaid Clinical Advisory Committee | **Next Review Date:** | 1/2017 |
| **Approved By:** | Medicaid Medical Director | **Approved Date:** | 4/27/2016 |

**Criteria:**

General characteristics

Cardiac rehabilitation programs are intended to provide a supportive educational environment in which to facilitate behavior change with respect to:

- The accepted cardiac risk factors.
- To initiate prescribed exercise as a mode of facilitating the return of the member to everyday activities by improving cardiovascular functional capacity and work performance.
- To promote a long-term commitment to lifestyle changes that could positively affect the course of the cardiovascular disease process.

Treatment staff

Professional disciplines which must be represented on the treatment staff, either by employment by the facility (full-time or part-time), contract or referral, are as follows:

- At least one medically trained provider responsible for responding to emergencies must be readily available when patients are receiving cardiac rehabilitation services. The provider must be ACLS certified.
- A physician shall oversee the policies and procedures of the outpatient cardiac rehabilitation area. The physician medical director of the facility shall meet with the cardiac rehabilitation staff on a regular basis to review exercise prescriptions and any concerns of the team.
- A cardiac rehabilitation nurse shall carry out the exercise prescription after assessment of the patient. The nurse shall be ACLS certified and be able to initiate emergency action if necessary. The nurse shall assess and implement a plan of care for cardiac risk factor modification. The nurse shall have at least one year of experience in a coronary care unit.
- A physical therapist shall offer expertise as needed.
- A dietician shall assess the dietary needs of persons and appropriately instruct them on their prescribed diets.
- Social Services shall provide counseling as appropriate and facilitate a spouse support group. A licensed occupational therapist shall be available as necessary.

Physical environment and equipment

A cardiac rehabilitation unit must be an autonomous physical unit specifically equipped with the necessary telemetry monitoring equipment, exercise equipment, and appropriate equipment and supplies for cardiopulmonary resuscitation (CPR). The exercise equipment must have the capacity to measure the intensity, speed, and length of the exercises. The equipment must be periodically inspected and maintained in accordance with the hospital's preventive maintenance program.

Monitoring of services
The program shall be monitored by the hospital on a periodic basis using measuring criteria for evaluating cardiac rehabilitation services provided.

Admission criteria
Candidates for the program must be referred by a provider knowledgeable in the assessment and treatment of cardiovascular disease. The following conditions are eligible for the program:

- Post-myocardial infarction (within three months post-discharge)
- Post-cardiac surgery (within three months post-discharge)
- Post-thrombolytics
- Post-percutaneous transluminal angioplasty (within three months post-discharge)
- Patient with severe angina being treated medically because of member or provider's preference or due to cardiac disease not amenable to invasive interventional therapies.
-

Medical records
Medical records for each member receiving cardiac rehabilitation must consist of at least the following:

- Referral form
- Provider's orders
- Laboratory reports
- Electrocardiogram reports
- History and physical examination
- Angiogram report, if applicable
- Operative report, if applicable
- Preadmission interview
- Exercise prescription
- Rehabilitation plan, including participant's goals
- Documentation for exercise sessions and progress notes
- Nurse's progress notes
- Discharge instructions

Discharge plan
The member will be discharged from the program when the physician, staff, and patient agree that:

- The work level is functional for them and little benefit could be derived from further continuation of the program.
- Dysrhythmia disturbances are resolved.
- Appropriate cardiovascular response to exercise is accomplished.

Restrictions and limitations
Payment will be made for a maximum of three visits per week for a period of 12 weeks. Payment beyond 12 weeks is made when documentation indicates that the patient has not reached an exit level.

**HCPCs Codes:**
S9472

**References Used:**
441 IAC 78.31(4)”c”

Development of utilization management criteria may also involve research into other state Medicaid programs, other payer policies, consultation with experts and review by the Medicaid Clinical Advisory Committee (CAC). These sources may not be referenced individually unless they are specifically published and are otherwise applicable to the criteria at issue.

**Change History:**

| Change Date: | Changed By: | Description of Change: | New Version Number: |
|---|---|---|---|
| 1/18/13 | CAC | Criteria - add “one” of the following. Criterion #3 - add “for cardiac disease”. Physician Coverage - remove “in the facility”. Criterion #14 - correct spelling of intracardiac. | 1 |
| 2/28/13 | Policy Staff | Replaced criteria from the provider manual with revised criteria to reflect details contained in 441 IAC 78.31(4)”c”. | 2 |
| 1/17/14 | CAC | Treatment staff - changed “physically present in the hospital” to “readily available”. Cardiac rehab nurse - added ACLS certified. Physical therapist - changed “expertise in unusual exercise programs” to “expertise as needed”. Changed “Social Worker” to “Social Services”. Admission criteria - changed “Post-streptokinase” to “Post-thrombolytics”. | 3 |
| 1/16/15 | CAC | Added last paragraph in References Used. | 4 |

**Change History (cont):**

| Change Date: | Changed By: | Description of Change: | New Version Number: |
|---|---|---|---|
| 1/15/16 | CAC | Treatment staff - changed "physician" to "medically trained provider". Changed "certified to the level of basic life support" to "ACLS certified". Changed "director" to "physician medical director of the facility". Admission criteria - changed "attending physician" to "provider knowledgeable in the assessment and treatment of cardiovascular disease". Changed "inoperable" to "cardiac disease not amenable to invasive interventional therapies". Medical records - changed "physician" orders to "provider" orders. | 5 |

**C. David Smith, MD**

# Chest CTA and CT for Pulmonary Emboli Criteria

| **Iowa Medicaid Program:** | Prior Authorization | **Effective Date:** | 10/19/2012 |
|---|---|---|---|
| **Revision Number:** | 4 | **Last Review Date:** | 1/15/2016 |
| **Reviewed By:** | Medicaid Clinical Advisory Committee | **Next Review Date:** | 1/2017 |
| **Approved By:** | Medical Director | **Approved Date:** | 4/27/2016 |

Criteria to be used for Chest CTA or a CT is requested for Pulmonary Emboli which cannot be approved based on Interqual or Milliman criteria.

The current standard of care for members with suspected pulmonary embolism is a spiral CT scan, also called a CTA, CT PA (computed tomography pulmonary angiography), MDCT (multidector CT) or helical CT scan. The accuracy of the CTA is nearly 100 percent particularly when combined with D-dimer testing.

**Criteria:**
Chest CTA for Pulmonary Emboli is considered medically necessary to rule out pulmonary emboli when **ALL of** the following are met:

1. A Wells Score of > 4.0

   **Wells criteria and modified Wells criteria: clinical assessment for pulmonary embolism**

| | |
|---|---|
| Clinical symptoms of DVT (leg swelling, pain and palpation) | 3.0 |
| Other diagnosis less likely than pulmonary embolism | 3.0 |
| Heart rate > 100 | 1.5 |
| Immobilization (≥ 3 days) or surgery in the previous four weeks | 1.5 |
| Previous DVT/PE | 1.5 |
| Hemoptysis | 1.0 |
| Malignancy | 1.0 |

2. Other indications for CTA:
   a) suspected aortic dissection
   b) high energy trauma to the chest with suspected vessel injuries

3. A chest CT is approved when: (**ALL FOUR** conditions must be met)
   a) CTA is not available,
   b) A V/Q scan is unavailable,
   c) D-dimer is positive, and
   d) The suspicion of a pulmonary embolism remains high despite a normal chest x-ray.

   A plain CT scan of the chest offers little additional information not available on standard AP and lateral views of the chest.

Note: Patients with a normal D-dimer should not require any further imaging. CTA is the current diagnostic test of choice with high clinical probability of pulmonary emboli. MRA is inferior to CTA for diagnosing pulmonary emboli.

**CPT Codes:**
71250 71260 71270

**References Used:**
Data from van Bell, A, et al. JAMA 2006; 295:172

Development of utilization management criteria may also involve research into other state Medicaid programs, other payer policies, consultation with experts and review by the Medicaid Clinical Advisory Committee (CAC). These sources may not be referenced individually unless they are specifically published and are otherwise applicable to the criteria at issue.

**Change History:**

| **Change Date:** | **Changed By:** | **Description of Change:** | **New Version Number:** |
|---|---|---|---|
| 10/19/12 | CAC | Removed criterion #3 | 1 |
| 4/19/13 | CAC | Criterion #2 added or contraindicated. Added CPT codes. | 2 |
| 1/16/15 | CAC | Note after criterion #2 replaced pulmonary angiography as test of choice with CTA. Added last paragraph in References Used. | 3 |
| 1/15/16 | CAC | Omit Chest CT Angiography criteria and combined with this criteria. Added paragraph on standard of care. Added criterion #2 and #3. | 4 |

**C. David Smith, MD**

# Continuous Glucose Monitoring (CGM) Criteria

| **Iowa Medicaid Program:** | Prior Authorization | **Effective Date:** | 2/12/2015 |
|---|---|---|---|
| **Revision Number:** | 1 | **Last Review Date:** | 1/15/2016 |
| **Reviewed By:** | Medicaid Clinical Advisory Committee | **Next Review Date:** | 1/2017 |
| **Approved By:** | Medicaid Medical Director | **Approved Date:** | 4/27/2016 |

Continuous Glucose Monitoring (CGM) is an FDA-approved device with three components (transmitter, receiver and sensors) used by placement of a sensor, subcutaneously, to continuously monitor and record glucose levels obtained from interstitial fluid. Real-time readings allow the member to monitor alerts indicating glucose issues and take immediate corrective action. This device does not replace finger stick readings.

This criteria refers to outpatient chronic interstitial real-time CGM. It does not include acute CGM in a hospital setting. Only long-term use is approved for coverage. CGM is not covered for convenience of member, provider or caretaker.

**Criteria: <u>ALL OF</u>** the following must be met**.**

1. Member has a diagnosis of Type 1 or Type 2 diabetes mellitus requiring the use of insulin 3 or more times a day or an insulin pump.
2. Ability to comply with at least 4x daily blood glucose monitoring is documented.
3. The member has demonstrated the ability to use such a device on a daily basis and analyze the data to make adjustments.
4. CGM is expected to be used continuously, for at least 6 days a week during most weeks.
5. Treatment guidelines are provided to patients to allow them to safely and effectively take advantage of the information provided to them by the monitor.
6. **<u>AT LEAST ONE</u>** of the following are documented:
    a. Hypoglycemic unawareness: patient is not aware of symptoms of hypoglycemia, but may be witnessed by others.
    b. Recurrent episodes of at least moderately severe hypoglycemia with a blood glucose <60 mg/dl
    c. Nocturnal hypoglycemia
    d. Despite good compliance and understanding, HbA1c levels remain above 7.0%
    e. Refractory postprandial hyperglycemia
    f. Recurring diabetic ketoacidosis
7. The requested device must be FDA-approved for the purpose and patient requested.

**Codes:**

A9276 – Sensor; invasive (e.g. subcutaneous), disposable, for use with interstitial continuous glucose monitoring system, 1 unit = 1 day supply
A9277 – Transmitter; external, for use with interstitial continuous glucose monitoring system
A9278 – Receiver (monitor); external, for use with interstitial continuous glucose monitoring system

**References Used:**

American Diabetes Association. 2014 ADA Clinical Practice Recommendations. http://professional.diabetes.org/ResourcesForProfessionals.aspx?cid=84160 Accessed 12/15/14.

Endocrine Society. J Clin Endocrinol Metab, October 2011, 96(1):2968-2979.

JDRF. http://advocacy.jdrf.org/our-work/medicarecovercgm/ Accessed 11/21/14.

Juvenile Diabetes Research foundation Continuous Glucose Monitoring Study Group. NEJM 2008;359:1464-76.

Development of utilization management criteria may also involve research into other state Medicaid programs, other payer policies, consultation with experts and review by the Medicaid Clinical Advisory Committee (CAC). These sources may not be referenced individually unless they are specifically published and are otherwise applicable to the criteria at issue.

**Change History:**

| **Change Date:** | **Changed By:** | **Description of Change:** | **New Version Number:** |
|---|---|---|---|
| 1/15/16 | CAC | Remove paragraph regarding investigational and non-coverage of artificial pancreas units (CGM and insulin pump therapies). | 1 |
| | | | |

**C. David Smith, MD**

# Diabetes Education Criteria

| **Iowa Medicaid Program** | Retrospective Review | **Effective Date:** | 7/1/2005 |
|---|---|---|---|
| **Revision Number:** | 6 | **Last Review Date:** | 1/15/2016 |
| **Reviewed By:** | Medicaid Clinical Advisory Committee | **Next Review Date:** | 1/2017 |
| **Approved By:** | Medicaid Medical Director | **Approved Date:** | 4/27/2016 |

**Criteria:**

Certification Requirement

In addition to certification by DHS/IME, diabetic education programs must also be certified by the department of public health.(See department of public health rules 641 - Chapter 9)

General characteristics

- An outpatient diabetes self-management education program shall provide instruction which will enable members with diabetes and their families to understand the diabetes disease process and its daily management.
- People with diabetes must learn to balance their special diet and exercise requirements with drug therapy (insulin or oral agents).
- They must learn self-care techniques such as monitoring their own blood glucose. They will be taught to self-treat insulin reactions, protect feet that are numb and have seriously compromised circulation, and accommodate their regimen to changes in blood glucose because of stress or infections.

Program staff

- Each person who provides services shall be determined to be competent to provide the services by reason of education, training, and experience.
- Professional disciplines which must be represented on the staff, either through employment by the facility (full-time or part-time), contract or referral, are:
    1. A physician (M.D. or D.O.)
    2. A registered nurse
    3. A registered dietician
    4. A licensed pharmacist
- The number of staff should be appropriate to the patient load of the facility.

Admission criteria

Members eligible for the program shall meet the following guidelines:

1. The member must have Type I or Type II diabetes, and
2. The member must be referred by the attending provider, and
3. The member must demonstrate an ability to follow through with self-management.

Health assessment

- An individualized and documented assessment of needs shall be developed with the member's participation.
- Follow-up assessments, planning and identification of problems shall be provided.

Restrictions and limitations on payment

- Diabetic education programs will include follow-up assessments at 3 and 12 months and as required without additional charge.
- Additional education is reimbursable as justified with documentation of member's poor diabetic control.

A complete diabetic education program (billed with HCPC code S9455) is payable by Iowa Medicaid. Nutritional counseling (CPT codes 97802-97804 or HCPC codes G0270-G0271) and patient self-management education (CPT codes 98960-98962 or HCPC codes G0108-G0109) may also be available to provide education to patients who need additional education.

**HCPCS code:**
S9455

**References Used:**
441 IAC 78.31(4)"f"
IAC 641-9.2 (135)
Iowa Senate File 8 of the 78th general assembly (1999) (Section 1-514C 14(2)(a) and (b)

Development of utilization management criteria may also involve research into other state Medicaid programs, other payer policies, consultation with experts and review by the Medicaid Clinical Advisory Committee (CAC). These sources may not be referenced individually unless they are specifically published and are otherwise applicable to the criteria at issue.

**Change History:**

| Change Date: | Changed By: | Description of Change: | New Version Number: |
|---|---|---|---|
| 1/18/13 | CAC | Criterion #1a - add information on Nutritional Counseling. Remove 6th paragraph under criteria. | 1 |
| 2/18/13 | Medical Director | Added IAC definition of diabetes education from IAC (note this is from a section of IAC under public health. It is a program definition for purposes of certification, not a Medicaid coverage definition.) | 2 |
| 3/22/13 | Policy Staff | Replaced criteria from the provider manual with revised criteria to reflect details contained in 441 IAC 78.31(4)"f". | 3 |

**Change History (cont.):**

| Change Date: | Changed By: | Description of Change: | New Version Number: |
|---|---|---|---|
| 1/17/14 | CAC | General characteristics - Change “they must learn to self-treat” to “they will be taught to self-treat”. Restrictions and limitations on payment - added “complete” to diabetic self-management education program. Added paragraph about diabetic education program with CPT and HCPC codes. | 4 |
| 1/16/15 | CAC | Added last paragraph in References Used. | 5 |
| 1/15/16 | CAC | Restrictions and limitations - remove “payment for complete diabetic self-management education once in member’s lifetime”. Add follow-up assessments at 3 and 12 months “and as required without additional charge”. Add “additional education is reimbursable as justified with documentation of member’s poor diabetic self-control”. | 6 |

**C. David Smith, MD**

# Enteral Products and Supplies Criteria

| **Iowa Medicaid Program:** | Prior Authorization | **Effective Date:** | 7/1/2005 |
|---|---|---|---|
| **Revision Number:** | 4 | **Last Review Date:** | 1/15/2016 |
| **Reviewed By:** | Medicaid Clinical Advisory Committee | **Next Review Date:** | 1/2017 |
| **Approved By:** | Medicaid Medical Director | **Approved Date:** | 2/5/2016 |

**Criteria:**

1. Daily enteral nutrition therapy is considered reasonable and necessary when the member has one of the following:
    - A metabolic or digestive disorder that prevents the member from obtaining the necessary nutritional value from usual foods in any form and cannot be managed by avoidance of certain food products.
    - Severe pathology of the body that will not allow ingestion or absorption of sufficient nutrients from regular food to maintain weight and strength commensurate with the member's general condition.
    - A medication-induced nutritional deficiency.
2. Milk or food allergies are covered indications for children under five years of age only.
3. Metabolic formulas as an oral supplement are approvable for a member with a diagnosis affecting their ability to adequately metabolize nutrients needed to maintain a healthy nutritional status regardless of percentage of daily caloric intake.
4. Food thickener may be approved through prior authorization for a member with a diagnosis supporting the need for thickened liquids as evidenced by the results of a swallow study.
5. Pump rental may be approved if any of the following are present:
    a. the member has a medical diagnosis that necessitates the use of a pump versus gravity.
    b. the member has a jejunostomy or nasogastric feeding tube.
    c. the member is receiving an oil based enteral formula.
    d. the administration rate is <100 ml/hr.

Examples of conditions that do **not** justify approval of enteral nutrition therapy are:

- Weight-loss diets
- Wired-shut jaws
- Diabetic diets
- Milk or food allergies for members five years of age and older
- The use of enteral products for convenience reasons when regular food in pureed form would meet the medical need of the member

**Oral supplementation** of a regular diet is reimbursable:

- When a member is unable to ingest or absorb sufficient nutrients from regular food due to a metabolic, digestive, or psychological disorder or pathology.
- Supplementation is necessary to provide 51 percent or more of the daily caloric intake OR the use of oral nutritional products is determined medically necessary in accordance with evidence-based guidelines for treatment of the member's condition (prescriber should provide the guidelines). Such conditions may include:

- Acquired immunodeficiency syndrome (AIDS)
- Burns
- Cancer
- Failure to thrive syndrome
- Problems with the kidney, liver, lungs, pancreas, or stomach
- Prolonged infections
- Surgery
- Trauma

If an oral supplement is being requested, the provider must supply the member's daily caloric need AND the amount of calories that the member consumes daily from regular/ pureed foods.

**HCPC Codes:**

| | | | | |
|---|---|---|---|---|
| B9002 | B4036 | B4082 | B4150 | B4160-4162 |
| B4034 | B4086 | B4100 | B4152-4155 | S9435 |
| B4035 | B4081 | B4102-B4104 | B4157-B4159 | |

**References Used:**

Provider Manual, pages 33 through 35
IAC 441-78.10(3)c(2) to 78.10(3)c(3)3 and
IAC 441-78.28(1)c(1) to 78.28(1)c(3)

Development of utilization management criteria may also involve research into other state Medicaid programs, other payer policies, consultation with experts and review by the Medicaid Clinical Advisory Committee (CAC). These sources may not be referenced individually unless they are specifically published and are otherwise applicable to the criteria at issue.

**Change History:**

| **Change Date:** | **Changed By:** | **Description of Change:** | New Version Number: |
|---|---|---|---|
| 1/18/13 | CAC | Replace Criteria #1 with new information. Criteria #2 add "indications" and "only". Criteria #4 remove effective date. After Criteria #5 add new examples and information on oral supplementation. References - Add IAC information. | 1 |
| 2/8/13 | Policy Staff | Changed reference to 51 percent of daily caloric intake to be provided by supplement. | 2 |

**Change History (cont.):**

| | | | |
|---|---|---|---|
| 12/12/13 | Medical Director | “The provider must supply the member’s daily caloric need OR the amount of calories the member consumes” - change OR to AND. | 3 |
| 1/16/15 | CAC | Added last paragraph in References Used. | 4 |

**C. David Smith, MD**

# Environmental Modification and Adaptive Devices Criteria

| **Iowa Medicaid Program:** | Waiver Prior Authorization | **Effective Date:** | 9/6/2011 |
|---|---|---|---|
| **Revision Number:** | 2 | **Last Review Date:** | 1/15/2016 |
| **Reviewed By:** | Medicaid Clinical Advisory Committee | **Next Review Date:** | 1/2017 |
| **Approved By:** | Medicaid Medical Director | **Approved Date:** | 2/5/2016 |

**Criteria:**
Environmental modification and adaptive devices are necessary items installed or used within the member's home that are used by the member to address the member's need. Environmental modification and adaptive devices are inclusive within the definition of allowable items set forth in the Iowa Administrative Code as it pertains to the CMH Waiver. Environmental modifications and adaptive devices will be considered for payment when **ALL of** the following are met:

1. Member is eligible for the Children's Mental Health (CMH) Home and Community Based Services Waiver that designates Environmental Modification and Adaptive Devices as an allowable service option.
2. The total cost of the item falls within the allowable costs of the individual waiver.
3. Environmental modifications and adaptive devices will meet the documented health, mental health, or safety concerns of the member and are for reasons other than the convenience of the member or the member's practitioner or caregiver.
4. Services are the least costly type of service which would reasonably meet the documented health, mental health, or safety concerns of the member. Pricing includes a designation of manufacturer's suggested retail price, dealer cost, or wholesale price.
    - Manufacturer's suggested retail price = price minus 15 percent
    - Dealer Cost = price plus 10 percent
    - Wholesale price = price minus 10 percent
5. Above requirements are evidenced by documentation, which includes:
    - Complete medical necessity form
    - Three comparable invoices from a Medicaid provider
    - Designation on estimate if cost is manufacturer's suggested retail price, dealer cost, or wholesale price
    - Comprehensive functional assessment
    - Service plan
    - Recommendation from a Mental Health Professional or Medical Professional
    - Denial for state plan durable medical equipment, if applicable

6. Exclusions include those modifications or devices:
    - Necessary or desirable without regard to the member's health, mental health or safety needs
    - Ordinarily covered by Medicaid
    - Funded by educational or vocational rehabilitation programs
    - Provided by voluntary means
    - Repair and maintenance of items purchased through the waiver
    - Fencing

**References Used:**
Iowa Administrative Code 441-78.52(249A)
Iowa Administrative Code 441-78.52(1)
Iowa Administrative Code 441-78.52(2)
DHS Informational letter No. 928, No. 951, No. 1035 and No. 1039

Development of utilization management criteria may also involve research into other state Medicaid programs, other payer policies, consultation with experts and review by the Medicaid Clinical Advisory Committee (CAC). These sources may not be referenced individually unless they are specifically published and are otherwise applicable to the criteria at issue.

**Change History:**

| **Change Date:** | **Changed By:** | **Description of Change:** | **New Version Number:** |
|---|---|---|---|
| 12/11/13 | Medical Director | Formatting changes | 1 |
| 1/16/15 | CAC | Added last paragraph in References Used. | 2 |

**C. David Smith, MD**

# High Frequency Chest Wall Oscillation (HFCWO) Criteria

| **Iowa Medicaid Program:** | Prior Authorization | **Effective Date:** | 2/12/2015 |
|---|---|---|---|
| **Revision Number:** | | **Last Review Date:** | 1/15/2016 |
| **Reviewed By:** | Medicaid Clinical Advisory Committee | **Next Review Date:** | 1/2017 |
| **Approved By:** | Medicaid Medical Director | **Approved Date:** | 2/5/2016 |

High-frequency chest wall oscillation (HFCWO) is a form of chest physical therapy in which an inflatable vest is attached to a machine that vibrates it at high frequency. The vest vibrates the chest to loosen and thin mucus. The loosened secretions may require another intervention to be cleared from the airway.
This criteria applies to the medical equipment and supplies needed for HFCWO treatment.

**Criteria:** ***ALL of*** the following 1-5, must be met.

1. The member must have one of the following applicable diagnoses.
    a. Cystic fibrosis
    b. Bronchiectasis - Confirmed by high resolution or spiral chest CT
        i. Daily productive cough for at least six months continuously or
        ii. More than two exacerbations per year, requiring antibiotic therapy
    c. Chronic or recurrent atelectasis as demonstrated by X-ray or CT.
    d. Neuromuscular diseases affecting the ability to cough or clear respiratory secretions with prior history of pneumonia or other significant worsening of pulmonary function, such as:
        i. Post-polio
        ii. Acid maltase deficiency
        iii. Anterior horn cell diseases
        iv. Multiple sclerosis
        v. Quadriplegia
        vi. Hereditary muscular dystrophy
        vii. Myotonic disorders
        viii. Other myopathies
        ix. Paralysis of the diaphragm
        x. Amyotrophic lateral sclerosis
        xi. Spinal muscular atrophy
2. ***ONE of*** the following must be documented.
    a. Pulmonary function tests (PFTs) for the 12 months before the initiation of the vest demonstrate an overall significant decrease in lung function.
    b. Increased frequency of hospitalizations for pulmonary issues, compared to the prior year OR three pulmonary hospitalizations within one year.
    c. If a renewal or treatment has already started must demonstrate improvement in PFTs, or decrease in incidence of hospitalizations, exacerbations or antibiotic use
3. ***ALL of*** the following, a.-e. must be well-documented
    a. Effective chest physiotherapy is required
        i. There must be demonstrated presence of bronchopulmonary secretions with documented need for airway clearance

        1. Documentation of frequent respiratory infections should be indicated.
    b. Manual CPT is unavailable, ineffective, or not tolerated. There should be documented failure of standard treatments (chest physiotherapy and, if appropriate, use of an oscillatory positive expiratory pressure device, or cough assist), or valid reasons why standard treatment cannot be performed. Examples of valid reasons why standard treatment cannot be performed may include ***ANY of*** the following.
        i. There are two or more individuals with cystic fibrosis, chronic bronchiectasis, or chronic neuromuscular disorder (meeting criteria above) in the family; ***or***
        ii. The caregiver is unable (physically or mentally) to perform chest physical therapy at the required frequency; ***or***
        iii. There is no available parental or partner resource to perform chest physical therapy; ***or***
        iv. The member has a medical condition that precludes use of standard treatments.
        v. Age alone is not considered sufficient contraindication to any method of airway clearance.
    c. Treatment by flutter device failed or is contraindicated.
    d. Treatment by intrapulmonary percussive ventilation failed or is contraindicated.
    e. A trial period is required to determine patient and family compliance. Sufficient and appropriate usage of the device during the trial period must be documented.
4. The prescriber is a pulmonologist.
5. None of the following apply. These conditions do not support medical necessity to HFCWO.
    a. HFCWO is being used as an adjunct to chest physical therapy (CPT), or along with mechanical in/exsufflation device
    b. The member has COPD, or chronic bronchitis, unless accompanied by a diagnosis under #1
    c. HFCWO is being used prophylactically to prevent onset of respiratory symptoms
    d. Contraindications exist for external manipulation of the thorax, as outlined by the American Association of Respiratory Care (AARC) and contained in their clinical practice guidelines for Postural Drainage Therapy, which include, but may not be limited to: unstable head or neck injury; active hemorrhage with hemodynamic instability; subcutaneous emphysema; recent epidural, spinal fusion or spinal anesthesia; recent skin grafts or flaps on the thorax; burns, open wounds, and skin infections of the thorax; recently placed transvenous pacemaker or subcutaneous pacemaker; suspected pulmonary tuberculosis; lung contusion; bronchospasm; osteomyelitis of the ribs; osteoporosis; coagulopathy; and complaint of significant chest wall pain.
    e. HFCWO is not covered for convenience or to upgrade to newer technology when the current components remain functional.

Continued use of a HFCWO device is considered medically necessary when ongoing use, (that is, compliance with use) is documented at 6 month to 12 month intervals. (Note: For

HFCWO devices with usage meters, documentation should reflect use, in general, at least 67% of the prescribed time.)

**Codes:**
94669, Mechanical chest wall oscillation to facilitate lung function, per session.
A7025, high frequency chest wall oscillation system vest, replacement for use with patient owned equipment, each
A7026, high frequency chest wall oscillation system hose, replacement for use with patient owned equipment, each
E0481, intrapulmonary percussive ventilation system and related accessories
E0483, high frequency chest wall oscillation air-pulse generator system, (includes hoses and vest), each
E0484
S8185

**ICD-9 Codes:**

| | |
|---|---|
| 011.50 - 011.56 | tuberculous bronchiectasis unspecified examination - tuberculous bronchiectasis tubercle bacilli not found by bacteriological or histological examination but tuberculosis confirmed by other methods (inoculation of animals) |
| 138 | late effects of acute poliomyelitis |
| 277.00 | cystic fibrosis without meconium ileus |
| 277.02 | cystic fibrosis with pulmonary manifestations |
| 277.6 | other deficiencies of circulating enzymes |
| 335.0 - 335.9 | werdnig-hoffmann disease - anterior horn cell disease unspecified |
| 340 | multiple sclerosis |
| 344.00 - 344.09 | quadriplegia unspecified - other quadriplegia |
| 359.0 | congenital hereditary muscular dystrophy |
| 359.1 | hereditary progressive muscular dystrophy |
| 359.21 - 359.29 | myotonic muscular dystrophy - other specified myotonic disorder |
| 359.4 - 359.6 | toxic myopathy - symptomatic inflammatory myopathy in diseases classified elsewhere |
| 359.89 | other myopathies |
| 494.0 | bronchiectasis without acute exacerbation |
| 494.1 | bronchiectasis with acute exacerbation |
| 519.4 | disorders of diaphragm |
| 748.61 | congenital bronchiectasis |

**ICD-10 Codes**:

| | |
|---|---|
| E84.9 | Cystic fibrosis, unspecified |
| E84.0 | Cystic fibrosis with pulmonary manifestations |

| | |
|---|---|
| J47.0 | Bronchiectasis with acute lower respiratory infection |
| J47.1 | Bronchiectasis with (acute) exacerbation |
| J47.9 | Bronchiectasis, uncomplicated |
| Q33.4 | Congenital bronchiectasis |

**References Used:**


Local Coverage Determination (LCD) for High Frequency Chest Wall Oscillation Devices (L12739) Accessed 9/11/14 at: https://www.noridianmedicare.com/dme/coverage/docs/lcds/current/high_frequency_chest_wall.htm

Strickland SL, Rubin BK, Drescher GS, et al. AARC clinical practice guideline: effectiveness of nonpharmacologic airway clearance therapies in hospitalized patients. Respir Care. 2013; 58(12):2187-2193.

The Cystic Fibrosis Foundation, http://www.cff.org/treatments/Therapies/Respiratory/AirwayClearance/#High-frequency_Chest_Wall_Oscillation Accessed 11/19/14


IAC 78.10(5)

c. Vest airway clearance systems. Payment will be approved for a vest airway clearance system when prescribed by a pulmonologist for a member with a diagnosis of a lung disorder if all of the following conditions are met:

(1) Pulmonary function tests for the 12 months before the initiation of the vest demonstrate an overall significant decrease in lung function.
(2) The member resides in an independent living situation or has a medical condition that precludes the caregiver from administering traditional chest physiotherapy.
(3) Treatment by flutter device failed or is contraindicated.
(4) Treatment by intrapulmonary percussive ventilation failed or is contraindicated.
(5) All other less costly alternatives have been tried.

Development of utilization management criteria may also involve research into other state Medicaid programs, other payer policies, consultation with experts and review by the Medicaid Clinical Advisory Committee (CAC). These sources may not be referenced individually unless they are specifically published and are otherwise applicable to the criteria at issue.

**Change History:**

| Change Date: | Changed By: | Description of Change: | New Version Number: |
|---|---|---|---|
| | | | |
| | | | |

**C. David Smith, MD**

# Non-Preferred Diabetic Supplies Criteria

| **Iowa Medicaid Program:** | Prior Authorization | **Effective Date:** | 2/3/2014 |
|---|---|---|---|
| **Revision Number:** | 3 | **Last Review Date:** | 1/15/2016 |
| **Reviewed By:** | Medicaid Clinical Advisory Committee | **Next Review Date:** | 1/2017 |
| **Approved By:** | Medicaid Medical Director | **Approved Date:** | 4/27/2016 |

**Criteria:**
**ALL of** the following must be met:

1. The member must have a diagnosis of diabetes from a licensed provider.
2. There must be a prescription for the desired monitor and/or supplies.
3. There must be a documented need for special monitor and/or supplies; i.e., vision problems, learning difficulties, dexterity limitations, etc.
4. Rationale for requesting a non-preferred monitor and/or supplies must be provided by the prescriber **OR** the rationale for additional testing supplies must be provided by the prescriber.
5. Documentation of diabetic testing must be provided.

**HCPCS Code:**
E0607
E2100
A4253
A4259
S8490

**References Used:**
Development of utilization management criteria may also involve research into other state Medicaid programs, other payer policies, consultation with experts and review by the Medicaid Clinical Advisory Committee (CAC). These sources may not be referenced individually unless they are specifically published and are otherwise applicable to the criteria at issue.

**Change History:**

| **Change Date:** | **Changed By:** | **Description of Change:** | **New Version Number:** |
|---|---|---|---|
| 1/17/14 | Medical Director | Formatting changes | 1 |
| 1/16/15 | CAC | Criterion #6 combined with Criterion #4. Added paragraph in References Used. | 2 |

**Change History (cont):**

| Change Date: | Changed By: | Description of Change: | New Version Number: |
|---|---|---|---|
| 1/15/16 | CAC | Criterion #1 changed “physician, physician assistant or nurse practitioner” to “licensed provider” | 3 |

**C. David Smith, MD**

# Pembrolizumab (Keytruda®)

| Iowa Medicaid Program: | Prior Authorization | Effective Date: | 4/30/2015 |
|---|---|---|---|
| Revision Number: | 1 | Last Review Date: | 1/15/2016 |
| Reviewed By: | Medicaid Clinical Advisory Committee | Next Review Date: | 1/2017 |
| Approved By: | Medicaid Medical Director | Approved Date: | 4/27/2016 |

Pembrolizumab is an injectable anti-PD-1 humanized monoclonal antibody antineoplastic, U.S. Food and Drug Administration (FDA) has approved as Keytruda® (pembrolizumab) with unresectable, metastatic melanoma if BRAF V600 mutation positive, a BRAF inhibitor. It has also been approved for the treatment of advanced metastatic non small cell lung cancer (NSMCLC) that has failed traditional chemotherapy AND is positive for PD L1 receptor based on the PD L1 IHC 22C3 pharmDx test.

**Criteria: ALL OF THE FOLLOWING** must be met:

1. The member must have unresectable or metastatic melanoma or a NSCLC which has progressed or failed to respond to traditional chemotherapy.
2. For metastatic melanoma, the BRAF V600 inhibitor must be positive.
3. Members with metastatic NSCLC must have tumors which test positive for the PD-1 ligand.
4. The member is not pregnant. Nursing should be discontinued during treatment.
5. Female patients of reproductive potential must be advised of potential hazard to a fetus. Advise females of reproductive potential to use highly effective contraception during treatment and for 4 months after the last dose of Keytruda®.
6. If hypophysitis is present, the member must be on appropriate physiologic replacement endocrine therapy.

Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials. Should additional information from these trials fail to support ongoing FDA approval, the Medical director has authority to discontinue authorizing use of pembrolizumab (Keytruda®) immediately on receipt of this information pending further investigation.

**Codes:**
HCPCS Codes:
J9999
J3590
J3490
C9399
(for use only on Medicare hospital outpatient claims)

**References Used:**
Merck Sharp & Dohme Corp., Keytruda® product information www.keytruda.com (8/14)
NCCN Guidelines® on Melanoma Version 1.2015; www.nccn.org (Accessed 10/17/2014)

**References Used (cont):**
Development of utilization management criteria may also involve research into other state Medicaid programs, other payer policies, consultation with experts and review by the Medicaid Clinical Advisory Committee (CAC). These sources may not be referenced individually unless they are specifically published and are otherwise applicable to the criteria at issue.

**Change History:**

| Change Date: | Changed By: | Description of Change: | New Version Number: |
|---|---|---|---|
| 1/15/16 | CAC | Removed dosing information. Removed reference to ipilimumab (Yervoy). Added information on non small cell lung cancer (NSMCLC). | 1 |
| | | | |

**C. David Smith, MD**

# Power Seat Elevation for Power Wheelchairs Criteria

| | | |
|---|---|---|
| **Iowa Medicaid Program:** | Prior Authorization | **Effective Date:** 2/3/2014 |
| **Revision Number:** | 1 | **Last Review Date:** 1/15/2016 |
| **Reviewed By:** | Medicaid Clinical Advisory Committee | **Next Review Date:** 1/2017 |
| **Approved By:** | Medicaid Medical Director | **Approved Date:** 2/5/2016 |

For Prior Authorization (PA) of a Power Seat Elevation for a Power Wheelchair, the member must meet the following criteria:

**Criteria:**

1. Power Seat Elevation is covered when prescribed to allow the member to complete independent transfers and to allow the member to independently reach items that are needed to complete activities of daily living (ADL's). (ADL's includes dressing, grooming, toileting, and personal hygiene.)

**HCPCS Code:**
E2300

**References Used:**

Development of utilization management criteria may also involve research into other state Medicaid programs, other payer policies, consultation with experts and review by the Medicaid Clinical Advisory Committee (CAC). These sources may not be referenced individually unless they are specifically published and are otherwise applicable to the criteria at issue.

**Change History:**

| Change Date: | Changed By: | Description of Change: | New Version Number: |
|---|---|---|---|
| 1/16/15 | CAC | Added paragraph in References Used. | 1 |
| | | | |

**C. David Smith, MD**