Augmentative Communication Systems

<table>
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<tr>
<th>Iowa Medicaid Program:</th>
<th>Prior Authorization</th>
<th>Effective Date:</th>
<th>1/1/2005</th>
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<tr>
<td>Revision Number:</td>
<td>4</td>
<td>Last Review Date:</td>
<td>1/11/2018</td>
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<tr>
<td>Reviewed By:</td>
<td>Speech-Language Specialist</td>
<td>Next Review Date:</td>
<td>7/2020</td>
</tr>
<tr>
<td>Approved By:</td>
<td>Medicaid Medical Director</td>
<td>Approved Date:</td>
<td>9/10/2019</td>
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Criteria:
Augmentative communication systems (speech generating devices) are covered for members unable to communicate their basic needs through oral speech or manual sign language.

Augmentative communication systems require prior authorization. In addition to the Request for Prior Authorization, form 470-2145, Augmentative Communication System Selection, is required.

Information requested on form 470-2145 includes a medical history, diagnosis, and prognosis completed by a physician.

A speech or language pathologist needs to describe current functional abilities in the following areas:
- Communication skills
- Motor status
- Sensory status
- Cognitive status
- Social status
- Emotional status
- Language status
- Required from the speech or language pathologist, developmental pediatrician or child psychiatrist is information on:
  - Educational ability and needs, if relevant
  - Vocational potential, if relevant
  - Anticipated duration of need
  - Prognosis regarding oral communication skills
  - Prognosis with a particular device
  - Recommendations

Medical Services consultant with expertise in speech pathology evaluates each request. The consultant may request a trial period with a particular device. Reimbursement for the rental of the equipment for up to three months for a trial period is available.

A minimum one-month trial period is required during which time the member should have access to the device daily in a variety of communication situations. Previous communication device use, cognitive level, and age of the member are considered in determining whether the trial period is adequate.
Payment is made for the most cost-effective item which meets basic communication needs commensurate with the person’s cognitive and language abilities.

Personal computers, electronic tablets, such as IPads, and software are not considered a communication device and are not covered.

**HCPCS Code:**

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<th>Description</th>
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**References Used:**

Medicaid Provider Manual

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:**

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<td>1/18/13</td>
<td>CAC</td>
<td>Removed 2nd paragraph under criteria</td>
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<tr>
<td>2/8/13</td>
<td>Policy Staff</td>
<td>Added reference to electronic tablets, such as IPADS under non-covered</td>
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<tr>
<td>12/29/14</td>
<td>Speech-Language Specialist</td>
<td>Criteria h - i and ii added “if relevant”.</td>
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<td>1/16/15</td>
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<td>Added last paragraph in References Used.</td>
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<tr>
<td>8/23/19</td>
<td>CAC</td>
<td>Criteria h - Added ‘developmental pediatrician or child psychiatrist’</td>
<td>5</td>
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</table>

Mark E Randleman, DO
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 availability of a suitable caregiver to administer the medications or perform
set-up is inadequate or non-existent.
3. 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.

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<tr>
<td>10/19/12</td>
<td>CAC</td>
<td>Criterion #2 - remove “two or more prescribed medications”</td>
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<tr>
<td>4/19/13</td>
<td>CAC</td>
<td>Criterion #2 - removed “and requires medication administration more than once per day”</td>
<td>2</td>
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<tr>
<td>4/26/13</td>
<td>Medical Director</td>
<td>Definitions of automated medication dispenser and telephone monitoring added</td>
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<tr>
<td>12/12/13</td>
<td>Medical Director</td>
<td>Formatting changes</td>
<td>4</td>
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<tr>
<td>1/16/15</td>
<td>CAC</td>
<td>Added last paragraph in References Used.</td>
<td>5</td>
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<tr>
<td>1/15/16</td>
<td>CAC</td>
<td>Added #4 under telephone monitoring</td>
<td>6</td>
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<tr>
<td>1/20/17</td>
<td>CAC</td>
<td>Removed criterion #2 regarding PRN and over-the-counter medications.</td>
<td>7</td>
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</tbody>
</table>

C. David Smith, MD
Bariatric Surgery Criteria

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

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 40 or a BMI greater than 35 with current evidence of at least one 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.
   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 lifelong 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:**

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<td>43770</td>
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<td>43772</td>
<td>Laparoscopy, surgical, gastric restrictive procedure, removal of adjustable gastric restrictive device component only</td>
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<td>43773</td>
<td>Laparoscopy, surgical, gastric restrictive procedure, removal and replacement of adjustable gastric restrictive device component only</td>
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<td>43774</td>
<td>Laparoscopy, surgical, gastric restrictive procedure, removal of adjustable gastric restrictive device and subcutaneous port components</td>
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<td>43775</td>
<td>Laparoscopic or open sleeve gastrectomy</td>
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<td>Vertical-banded gastroplasty</td>
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<td>43843</td>
<td>Other than vertical-banded gastroplasty</td>
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<td>43845</td>
<td>Biliopancreatic diversion with duodenal switch</td>
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<td>43845</td>
<td>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</td>
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<td>43847</td>
<td>Roux-en-y with small bowel reconstruction to limit absorption</td>
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<td>43848</td>
<td>Revision of gastric band</td>
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<td>43866</td>
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<td>43867</td>
<td>Gastric restrictive procedure, open; removal of subcutaneous port component only</td>
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<tr>
<td>43888</td>
<td>Gastric restrictive procedure, open; removal and replacement of subcutaneous port component only</td>
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References Used:
441 IAC 78.3(4)
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 Surgery Accreditation and Quality Improvement Program(MBSAQIP). Accessed 10/18/13.

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<td>Revision of hypertension and co-morbidity requirement wording.</td>
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<td>3/28/13</td>
<td>Policy Staff</td>
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<td>Medical Director</td>
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<td>Changed By</td>
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<tr>
<td>1/17/14</td>
<td>CAC</td>
<td>Criterion #3 - changed “weight loss program” to “lifestyle modification program”. Criterion #5 - Medical clearance - added “for surgery, specifically”.</td>
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<td>1/16/15</td>
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<td>Removed criterion #2 regarding Center of Excellence (CoE) and Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP) requirement. Added criterion #9 regarding phentermine. Added last paragraph in References Used.</td>
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<td>4/30/15</td>
<td>Policy staff</td>
<td>Criterion #2a added “completion of”. Criterion #3 changed format of laboratory values from narrative to separate item list.</td>
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<td>1/15/16</td>
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<td>Revision of wording in criterion #1. Removal of criterion #2b regarding weight loss and criterion #9 regarding phentermine.</td>
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C. David Smith, MD
Bone Marrow and/or Peripheral Blood Stem Cell Transplant Criteria

Iowa Medicaid Program: Pre-procedure  Effective Date: 9/11/2009
Revision Number: 3  Last Review Date: 9/12/19
Reviewed By: Bone Marrow Transplant Specialist  Next Review Date: 1/2020
Approved By: Medicaid Medical Director  Approved Date: 9/12/19

Criteria:
Solid tumor requests which are not currently covered under 441-78.1(20)”a”(2) or (3) will be handled through the exception to policy process:
1. Must have clearance from Psych/Social consult
2. Documentation of underlying co-morbidity(ies)
3. Pertinent lab values
4. All radiology results pertinent to the disease process for which treatment is being requested
5. Dental clearance
6. Member has a diagnosis which is amenable to treatment with a stem cell transplant.

CPT Codes:
38240 - Allogeneic
38241 - Autologous

References Used:
IAC 441-78.1(20)”a”(2) or (3)

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<td>Under Criteria added IAC reference and also added under References Used.</td>
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<td>3/13/18</td>
<td>Medical Director</td>
<td>Added Criterion #6.</td>
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</table>

William (Bill) Jagiello, D.O.

Page 1 of 1
Botulinum Toxins Criteria
BOTOX® (onabotulinumtoxinA)
DYSPORT™ (abobotulinumtoxinA)
MYOBLOC® (rimabotulinumtoxinB)
XEOMIN® (incobotulinumtoxinA)

Iowa Medicaid Program: Prior Authorization; Effective Date: 7/1/2008
Claims Pre-pay
Revision Number: 9
Last Review Date: 2/22/2019
Reviewed By: Medicaid Clinical Advisory Committee
Next Review Date: 2/2020
Approved By: Medicaid Medical Director Approved Date: 3/21/2018

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. Studies have shown that onabotulinum A (BOTOX®) and incobotulinumA (XEOMIN®) are equipotent. 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”, though the clinical evidence suggests that BOTOX® and XEOMIN® have similar biologic activity.

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 over activity or well documented overactive bladder 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 RimabotulinumtoxinB (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:

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<td>11/2/10</td>
<td>Nick Ford, PA-C</td>
<td>New FDA criteria</td>
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<tr>
<td>2/18/13</td>
<td>Nick Ford, PA-C and Medical Director</td>
<td>Clarification and addition of information on incobotulinumtoxinA</td>
<td>2</td>
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<tr>
<td>1/17/14</td>
<td>CAC</td>
<td>Criterion #1&quot;o&quot; - remove &gt; 15 days per month with headache lasting four hours a day or longer</td>
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<td>1/30/14</td>
<td>Medical Director</td>
<td>HCPS Code - added note</td>
<td>4</td>
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<td>1/16/15</td>
<td>CAC</td>
<td>Added paragraph in References Used.</td>
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<tr>
<td>1/15/16</td>
<td>CAC</td>
<td>Removed criterion #1q as was duplicate of #1n. Under non-covered removed “wrinkles” and included in “cosmetic conditions”.</td>
<td>6</td>
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<tr>
<td>1/20/17</td>
<td>CAC</td>
<td>Criterion #1n removed over activity “associated with a neurologic condition such as spinal cord injury, multiple sclerosis” and added “or well-documented overactive bladder”</td>
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<td>5/1/17</td>
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<td>Formatting Changes.</td>
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<td>3/13/18</td>
<td>Medical Director</td>
<td>Added narrative under Description regarding Botox® and Xeomin® being equipotent and having similar biologic activity.</td>
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C. David Smith, MD
Criteria to be used for Chest CTA or a CT 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:**

Ches 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 or contraindicated
   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.

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<td>10/19/12</td>
<td>CAC</td>
<td>Removed criterion #3</td>
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<td>4/19/13</td>
<td>CAC</td>
<td>Criterion #2 added or contraindicated. Added CPT codes.</td>
<td>2</td>
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<tr>
<td>1/16/15</td>
<td>CAC</td>
<td>Note after criterion #2 replaced pulmonary angiography as test of choice with CTA. Added last paragraph in References Used.</td>
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<tr>
<td>1/15/16</td>
<td>CAC</td>
<td>Omit Chest CT Angiography criteria and combined with this criteria. Added paragraph on standard of care. Added criterion #2 and #3.</td>
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<tr>
<td>2/22/19</td>
<td>CAC</td>
<td>Updated wording and added to criterion #3, item a- or contraindicated.</td>
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</table>

C. David Smith, MD
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: **ALL OF** 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. **AT LEAST ONE** 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 **recommended by the provider managing the member’s diabetes, 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:

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.

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<td>1/15/16</td>
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<td>Remove paragraph regarding investigational and non-coverage of artificial pancreas units (CGM and insulin pump therapies).</td>
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C. David Smith, MD
Enteral Products and Supplies Criteria

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<th>Prior Authorization</th>
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<td>Revision Number:</td>
<td>4</td>
<td>Last Review Date:</td>
<td>2/22/2019/19/2018</td>
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<td>Medicaid Clinical Advisory Committee</td>
<td>Next Review Date:</td>
<td>01/2020/1/2019</td>
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<tr>
<td>Approved By:</td>
<td>Medicaid Medical Director</td>
<td>Approved Date:</td>
<td>3/13/2018</td>
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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
- Oral aversion or other psychological condition that limits oral intake.

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:**

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**References Used:**

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

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<td>1/18/13</td>
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<td>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.</td>
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<td>2/8/13</td>
<td>Policy Staff</td>
<td>Changed reference to 51 percent of daily caloric intake to be provided by supplement.</td>
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<td>Date</td>
<td>Department</td>
<td>Change Description</td>
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<td>12/12/13</td>
<td>Medical Director</td>
<td>“The provider must supply the member’s daily caloric need OR the amount of calories the member consumes” - change OR to AND.</td>
<td>3</td>
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<td>1/16/15</td>
<td>CAC</td>
<td>Added last paragraph in References Used.</td>
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C. David Smith, MD
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 Children’s Mental Health (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. Services shall be provided under the recommendation and direction of the mental health professionals that are on the child’s interdisciplinary team. Items covered may include, but are not limited to:
   a. Smoke alarms
   b. Window or door alarms,
   c. Pager supports
   d. Motion sensors
   e.

2. The total cost of the item falls within the allowable costs of the individual waiver, currently at $6,366.61 per year.

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.

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<td>1/16/15</td>
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C. David Smith, MD
The human intestine contains approximately 10 to the 14th power of bacteria which typically coexist in a mutualistic or commensal relationship with their host. These bacteria represent four phyla of the Kingdom Protista. Alterations of the populations of bacteria in the intestine may result in sickness and disease. Repopulating the intestine with healthy bacteria has been used by physicians and veterinarians since the 4th century BC. Reemergence of this technology has been precipitated by the increase in antibiotic associated Clostridium difficile enterocolitis. While Clostridia difficile is a normal part of the microbiome of 3% of humans, it is present as a spore and metabolically inactive.

Current Standard treatment for an initial C. difficile infection is a 10 day course of vancomycin or fidaxomicin which provides a greater cure rate and less frequent recurrence than has been metronidazole, or vancomycin along with discontinuation of any and all antibiotics if possible. For refractory or recurrent infections cases, cholestyramine has been given to bind clostridia toxins, along with the use of probiotics in addition to a 10 day course of and Dificid (fidaxomicin), has shown efficacy in controlling the infection. Fulminant pseudomembranous colitis is life threatening due to toxic megacolon or perforation. Surgical colectomy is a last resort but can be life saving.

Fecal transplantation or fecal bacteriotherapy has been found to highly effective for Clostridium difficile infection (CDI). A common problem with CDI is the frequency of relapse with up to 40% of patients having at least one recurrence. Multiple relapses can occur due to reduced susceptibility to metronidazole. Treatments with prolonged courses of vancomycin are very expensive and are also prone to relapse. Fecal transplant offers many advantages including low cost, absence of side effects, no drug resistance issues and a high success rate.

Criteria:

1. A positive stool test for C. difficile toxin. And
2. Severe, recurrent or refractory diarrhea with 3 or more loose or watery stools per day for at least 2 days or 8 or more stools in a 48 hours period. And

Severe, recurrent or refractory diarrhea with 3 or more loose or watery stools per day for at least 2 days or 8 or more stools in a 48 hours period. And
3. Failure of both a ten day course of oral vancomycin with persistent or recurrent infection followed by a ten day course of fidaxomicin.

   No improvement after standard therapy of vancomycin dosed at 125 mg or greater given four times per day for at least ten days or metronidazole at a dose of 500 mg three times per day for at least ten days. Or

2. A positive stool test for C. difficile toxin.

3. No improvement after standard therapy of vancomycin dosed at 125 mg or greater given four times per day for at least ten days or metronidazole at a dose of 500 mg three times per day for at least ten days. Or

Contraindications

4. Patient co-morbidities
   a. Pregnancy
   b. Immunosuppression
   c. History of inflammatory bowel disease
   d. Any co-morbidity that increase the risk of mortality
   e. History of hospitalization for dehydration or an electrolyte imbalance or other diarrhea related complications unlikely to improve without further treatment.

Fecal Suspension and Donor:
Inherent in the transplantation of bacteria from a donor is the transfer of other contagious diseases to the recipient. Donors should be healthy and undergo screening for hepatitis A, B, C, HIV1 and HIV 2, Syphilis, Ova and parasites, enteric pathogens, Salmonella, Shigella, E. coli HO157, and C. difficile toxin. Donors should be free of tattoos or body piercings within the preceding six months. They should be free of communicable disease or recent exposure to communicable disease, immunosuppressive drugs or antibiotics in the last six months. Transplantation may be delivered by a nasogastric tube, nasojejunal tube, serial retention enemas or colonoscopy. The claim for preparation of the fecal transplant should be submitted with the claim for the transplant using the codes provide below. The provider must obtain informed consent from the member as required by the US FDA division of Vaccines, Blood and Biologics bulletin 7/18/2013.

Contraindications:

1. Previous hemicolectomy
2. Inflammatory Bowel Disease
3. Diarrhea with etiology other than Clostridia difficile
4. No documentation of failure of multiple trials of standard therapies

Codes: 44705, G0455. 44799
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.

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<td>3/7/19</td>
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Heart Transplant Criteria

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<th>Effective Date:</th>
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<td>Revision Number:</td>
<td>10</td>
<td>Last Review Date:</td>
<td>8/8/19</td>
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<td>Reviewed By:</td>
<td>Heart Transplant Specialist</td>
<td>Next Review Date:</td>
<td>1/2020</td>
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<tr>
<td>Approved By:</td>
<td>Medicaid Medical Director</td>
<td>Approved Date:</td>
<td>3/21/2018</td>
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Criteria:
1. Patients should have Psycho/Social assessment prior to listing for transplantation. The evaluation should include an assessment of the patient’s ability to give informed consent and comply with instructions including drug therapy, as well as assessment of the support systems in place at home or in the community *(Level of Evidence: C)*
2. Dental exam and clearance must be provided.
3. Must be abstinent of all illicit drugs and not abuse any drugs or alcohol. Physician documentation must specifically address this issue. Need for laboratory testing to confirm compliance may be at the discretion of the attending physician.
4. Documentation of underlying co-morbidities must be provided.
5. Pertinent lab values must be provided.
6. Ejection Fraction is less than 45 percent per ECHO or cardiac catheterization.
7. Recent cardiac catheterization results.
8. Should be less than 70 years of age.
   a. Carefully selected candidates may be considered if older than 70.
9. For obese patients with body mass index greater than 35 kg.2, it is reasonable to request weight loss to decrease the BMI to less than 35 prior to listing for cardiac transplantation.

Contraindications:
Transplantation is not to be approved in the presence of the following:
1. Active smoking is not necessarily considered an absolute contraindication. Smoking cessation for a minimum of three months is required and validated by urine nicotine tests two to three weeks prior to surgery.
2. In those patients needing cardiac transplantation and who have a history of malignancy, collaboration with oncology specialist should occur to stratify each patient as to their risk of tumor recurrence. Cardiac transplantation should be considered when tumor recurrence is low based on tumor type, response to therapy, and negative metastatic work-up. The specific amount of time to wait to transplant after neoplasm remission will depend on the aforementioned factors and no arbitrary time period for observation should be used.
3. Untreatable advanced dysfunction of another major organ system. (Exception for dual-organ transplants).
4. Incurable chronic active or unresolved infection including chronic active viral hepatitis B, hepatitis C, and uncontrolled human immunodeficiency virus (HIV).
   a. Adequately controlled HIV infection is defined by **ALL OF** the following:
      i. CD4 count greater than 200 cells/mm3
      ii. HIV-1 ribonucleic acid (RNA) undetectable
      iii. Stable combination anti-retroviral therapy for more than three months
iv. Absence of serious complications associated with or secondary to HIV disease, such as progressive multifocal leukoencephalopathy, opportunistic infections within the past twelve months, including aspergillosis, tuberculosis or other mycobacterial infection, coccidiomycosis, resistant fungal infections, chronic intestinal cryptosporidiosis greater than one month, or Kaposi’s sarcoma or other neoplasm.

5. Documented non-adherence or inability to follow through with medical therapy or any aspect of follow-up care.

6. Untreatable psychiatric or psychological condition associated with the inability to cooperate or comply with medical therapy.

7. Absence of a consistent or reliable social support system.

8. Substance addiction (e.g., alcohol, tobacco, or narcotics) that is either active or within the last six months and has not been evaluated for or entered into a structured rehabilitative program.

Other coverage issues (heart-lung transplants):

- Heart-lung transplants are covered where bilateral or unilateral lung transplantation with repair of a congenital cardiac defect is contraindicated.
- Heart and heart-lung transplants require pre-procedure review and approval.
- Covered heart and heart-lung transplants are only payable when performed in a facility that meets the requirements under 441-78.3(10).
- Donor expenses incurred directly in connection with a covered transplant are payable.
- Expenses incurred for complications that arise with respect to the donor are covered only if they are directly and immediately attributed to surgery.
- Expenses of searching for a donor are not covered.

Other coverage issues (ventricular assist devices (VADs)):

- VADs as a temporary life-support system until a human heart becomes available for transplantation (i.e., “bridge” therapy) are covered, however, requires pre-procedure review and approval.

Services not covered:

- Artificial hearts and ventricular assist devices (VADs), as a permanent replacement for a human heart (i.e., “destination” therapy) are not covered. Coverage consideration for these devices can occur through exception to policy on a case-by-case basis.
- Expenses associated with organ preparation (e.g., “backbench prep”) are not separately payable and are considered paid as part of the transplant procedure.

CPT Codes:

33945 Heart
33935 Heart/Lung
0051T Artificial Heart
33975, 33976, 33979, 33990 Ventricular Assist Device
References Used:
441 IAC 78.1(20)“a”(5).
Listing Criteria for Heart Transplantation (Guidelines) (J Heart Lung Transplant 2006:25(9): (1024-1042).

References Used (cont.):
The 2016 International Society for Heart Lung Transplantation listing criteria for Heart Transplantation: A 10-year Update (J Heart and Lung Transplant 2016: (1-23).

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.

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<td>Re-ordering and new information added to Criteria #1-#8. Added Contraindications. Removed CPT Code for VAD. Added information under References.</td>
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<td>Policy Staff</td>
<td>Additions to criteria to reflect details contained in 441 IAC 78.1(20)“a”(5).</td>
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<td>11/27/13</td>
<td>Heart Transplant Specialist</td>
<td>Criterion #6 - Change from “Ejection fraction is less than 45 percent per ECHO or cardiac catheterization” to “End-stage heart disease not remediable by more conservative measures”. Added #9-15 under Contraindications.</td>
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<td>7/24/14</td>
<td>Medical Director</td>
<td>Criterion #8 added narrative after older than 70. Contraindication #4 - removed Hepatitis C and added definitions i-iv of adequately controlled HIV infection. Added other coverage issues (general) and (other related services). Services not covered removed reference to VADs. CPT Codes added for artificial heart and VADs.</td>
<td>4</td>
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<tr>
<td>1/16/15</td>
<td>Medical Director</td>
<td>Added last paragraph in References Used.</td>
<td>5</td>
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<tr>
<td>1/7/16</td>
<td>Heart Transplant Specialist</td>
<td>Added narrative to contraindication #2. Added narrative to contraindication #8. Deleted contraindications #9 through #15. Combined other coverage issues. Added narrative to services not covered. Added last two references.</td>
<td>6</td>
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<tr>
<td>4/6/16</td>
<td>Policy Staff</td>
<td>Added VADs under other coverage issues. Added “case-by-case basis” to services not covered.</td>
<td>7</td>
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<tr>
<td>12/20/16</td>
<td>Heart Transplant Specialist</td>
<td>Contraindication #2 removed “malignancy in the last two years with the exception of cutaneous squamous and basal cell tumors. In general, a five-year disease free interval is prudent”. Added “patients who have a history of malignancy”. Contraindication #4 iii added “combination”. Contraindication #4 iv added “progressive, multifocal leukoencephalopathy” “within the past twelve months” “other mycobacterial infection” and “chronic intestinal cryptosporidiosis greater than one month”.</td>
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<tr>
<td>4/11/17</td>
<td>Policy Staff</td>
<td>Other coverage issues added “bridge therapy”. Services not covered added “destination therapy” and second bullet regarding associated expenses.</td>
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<td>1/6/18</td>
<td>Heart Transplant Specialist</td>
<td>Added Criterion #9.</td>
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Mark E Randleman, D.O.
High Frequency Chest Wall Oscillation (HFCWO) Criteria

<table>
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<tr>
<th>Iowa Medicaid Program:</th>
<th>Prior Authorization</th>
<th>Effective Date:</th>
<th>2/12/2015</th>
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<tr>
<td>Revision Number:</td>
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<td>Last Review Date:</td>
<td>2/19/19</td>
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<td>Reviewed By:</td>
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<td>Next Review Date:</td>
<td>1/2020</td>
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<tr>
<td>Approved By:</td>
<td>Medicaid Medical Director</td>
<td>Approved Date:</td>
<td>3/13/2018</td>
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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) within 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-10 Codes:
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<th>Description</th>
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<tr>
<td>E84.9</td>
<td>Cystic fibrosis, unspecified</td>
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<tr>
<td>E84.0</td>
<td>Cystic fibrosis with pulmonary manifestations</td>
</tr>
<tr>
<td>J47.0</td>
<td>Bronchiectasis with acute lower respiratory infection</td>
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<tr>
<td>J47.1</td>
<td>Bronchiectasis with (acute) exacerbation</td>
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<tr>
<td>J47.9</td>
<td>Bronchiectasis, uncomplicated</td>
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<tr>
<td>Q33.4</td>
<td>Congenital bronchiectasis</td>
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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
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.

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C. David Smith, MD
Non-Preferred Diabetic Supplies Criteria

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<td>Revision Number:</td>
<td>3</td>
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<td>2/22/19</td>
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<td>Reviewed By:</td>
<td>Medicaid Clinical Advisory Committee</td>
<td>Next Review Date:</td>
<td>1/2020</td>
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<tr>
<td>Approved By:</td>
<td>Medicaid Medical Director</td>
<td>Approved Date:</td>
<td>6/21/19</td>
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</tbody>
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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-Home blood glucose monitor
E2100-Home blood glucose monitor with integrated voice
A4253-Blood glucose test strips
A4259- Lancets
S8490-Insulin syringes

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.

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<td>Criterion #6 combined with Criterion #4. Added paragraph in References Used.</td>
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<td>3</td>
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<tr>
<td>2/22/19</td>
<td>CAC</td>
<td>Added titles to codes</td>
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C. David Smith, MD
Pancreas Transplant Criteria

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<th>Pre-procedure</th>
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<td>Pancreas Transplant Specialist</td>
<td>Next Review Date:</td>
<td>1/2020</td>
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<td>Approved By:</td>
<td>Medicaid Medical Director</td>
<td>Approved Date:</td>
<td>9/12/19</td>
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</table>

**Criteria:**
Pancreas transplants are covered for members with insulinrequiring diabetes mellitus and who meet the following criteria:

1. Must have clearance from Psycho/Social necessity consult. Evaluation should include an assessment of the patient’s ability to give informed consent and comply with instruction including drug therapy, as well as assessment of the support systems in place at home or in the community (*Level of Evidence: C*)
2. Dental exam and clearance must be provided.
3. Must be abstinent of all illicit drugs and not abuse any drugs or alcohol. Physician documentation must specifically address this issue. Need for laboratory testing to confirm compliance may be at the discretion of the attending physician. Social alcohol use and medicinal marijuana use are acceptable.
4. Documentation of underlying co-morbidities must be provided.
5. Pertinent lab values must be provided.
7. Report of Abdominal ultrasound study must be provided.
8. Documentation of complications related to diabetes must be provided including HbA1c level, C-peptide level, and daily insulin requirements.
9. Echocardiogram and cardiac stress test results must be provided.
10. Documentation of renal function to determine qualification for appropriate pancreas transplant category must be provided.
11. Request may come in as "pancreas alone" or "simultaneous kidney/pancreas" request.
   a. Medicaid will review for the pancreas only; do not need approval for the kidney portion for a simultaneous pancreas/kidney or pancreas after kidney.

**Contraindications:**
Transplantation cannot be approved in the presence of the following:

1. Active smoking is not necessarily considered an absolute contraindication; however, heavy smoking (>1 pack per day) is an absolute contraindication. Complete smoking cessation is strongly encouraged. For patients who smoke tobacco and have smoking-related morbidities (coronary artery disease, symptomatic or documented cerebrovascular or peripheral vascular disease, chronic obstructive lung disease, history of non-cutaneous malignancy), complete smoking cessation is required and should be validated by urine nicotine test prior to transplant.
2. Malignancy in the last two years, with the exception of cutaneous squamous and basal cell tumors. Disseminated or incompletely treated cancer is an absolute contraindication. In cases of localized and treated cancer, the cancer-free interval required will vary depending on the stage and type of cancer. Consultation with a board-certified oncologist is required in most cases to determine if the patient’s mortality in the absence of transplantation is predicted to be higher than their risk of recurrence.

3. Incurable chronic active or unresolved infection including chronic active viral hepatitis B, uncontrolled hepatitis C, or uncontrolled human immunodeficiency virus (HIV).
   a. Adequately controlled HIV infection is defined by **ALL OF** the following:
      i. CD4 count greater than 200 cells/mm³
      ii. HIV-1 ribonucleic acid (RNA) undetectable
      iii. Stable combination anti-retroviral therapy for more than three months
      iv. Absence of serious complications associated with or secondary to HIV disease, such as progressive multifocal leukoencephalopathy, opportunistic infections within the past twelve months, including aspergillosis, tuberculosis or other mycobacterial infection, coccidiomycosis, resistant fungal infections, chronic intestinal cryptosporidiosis greater than one month, Kaposi’s sarcoma or other neoplasm.
      v. However, in cases of chronic hepatitis C viral infection without cirrhosis, transplantation may precede treatment for HCV to take advantage of organs from HCV+ donors and provided that the patient has been accepted as a good candidate for anti-HCV treatment.

4. Documented non-adherence or inability to follow through with medical therapy or any aspect of follow-up care.

5. Untreatable psychiatric or psychological condition associated with the inability to cooperate or comply with medical therapy.

6. Absence of a consistent or reliable social support system.

7. Substance addiction (e.g., alcohol, tobacco, or narcotics) that is either active or within the last six months and has not been evaluated for or entered into a structured rehabilitation or cessation program.

8. Fasting C-peptide > 10 ng/ml or total daily insulin requirements > 1 unit/kg. In selected circumstances, patients with a type 2 diabetes phenotype will be considered for pancreas transplantation provided they are insulin-requiring for a minimum of three to five years and meet the above C-peptide and insulin requirement criteria. For those patients who do not meet these criteria, a discussion of risks and benefits must specifically address this in the clinical documentation.

9. BMI > 35 kg/m² is a relative contraindication. A discussion of risks and benefits must specifically address this in the clinical documentation.

10. Age ≥ 60 years is a relative contraindication. A discussion of risks and benefits must specifically address this in the clinical documentation.
11. Insufficient cardiovascular reserve with un-reconstructable coronary artery
disease, refractory congestive heart failure, left ventricular ejection fraction <30
percent, or severe irreversible pulmonary hypertension (right ventricular systolic
pressure/pulmonary artery systolic pressure ≥50 mm Hg confirmed by right heart
catheterization); cardiac history of high probability of death with general
anesthesia.
12. Chronic severe hypotension (may be marked by use of oral vasopressors such
as midodrine) with evidence of significant and irreversible cardiac dysfunction.
13. Chronic lung disease requiring continuous oxygen therapy.
14. Moderate to advanced cirrhosis.
15. Life expectancy < two years because of other irreversible systemic illness or
multiple co-morbidities.

Other coverage issues:
- Covered types of pancreas transplants are limited to the following:
  1. Simultaneous pancreas-kidney;
  2. Pancreas after kidney transplant;
  3. Pancreas transplants alone for members exhibiting any of the following:
     a) A history of frequent, acute, and severe metabolic complications, such as
        hypoglycemia, hyperglycemia, or ketoacidosis, which require medical
        attention;
     b) Clinical problems with exogenous insulin therapy that are so severe as to
        be incapacitating or causing a significant impairment in quality of life; and
     c) Consistent failure of insulin-based management to prevent either acute or
        chronic complications (i.e., retinopathy, peripheral or autonomic
        neuropathy, accelerated atherosclerosis).
- Pancreas transplants require pre-procedure review and approval.
- Covered pancreas transplants are only payable when performed in a facility that
  meets the requirements under 441-78.3(10).
- Donor expenses incurred directly in connection with a covered transplant are
  payable.
- Expenses incurred for complications that arise with respect to the donor are
  covered only if they are directly and immediately attributed to surgery.
- Expenses of searching for a donor are not covered.

Services not covered:
- Transplantation of islet cells or partial pancreatic tissue.
- Expenses associated with organ preparation (e.g., “backbench prep”) are not
  separately payable and are considered paid as part of the transplant procedure.

CPT Codes:
48554
References Used:
441 IAC 78.1(20)”a”(7).
Listing Criteria for Heart Transplantation (Guidelines) (J Heart Lung Transplant 2006;25(9): 1024-1042)

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.

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<td>1/18/13</td>
<td>CAC</td>
<td>Re-ordering and new information added to Criteria #1-#10. Added Contraindications. Added information under References.</td>
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<td>3/22/13</td>
<td>Policy staff</td>
<td>Additions to criteria to reflect details contained in 441 IAC 78.1(20)’a’(7).</td>
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<td>11/21/13</td>
<td>Pancreas Transplant Specialist</td>
<td>Under criteria, change coverage for members with Type 1 diabetes to insulin-requiring diabetes. Criterion #8 change insulin resistance to complications. Add Criterion #9 on echocardiogram and cardiac stress test. Add Criterion #10 on renal function. Under Contraindications, remove #4 regarding incurable viral disease. Add #8 on fasting C-peptide. Add #9 on BMI</td>
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<td>Medical Director</td>
<td>Contraindication #4 - removed Hepatitis C and added definitions i-iv of adequately controlled HIV infection.</td>
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<td>Medical Director</td>
<td>Added last paragraph in References Used.</td>
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<tr>
<td>1/7/16</td>
<td>Pancreas Transplant Specialist</td>
<td>Added narrative to criterion #3 and #8.</td>
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<tr>
<td>12/18/16</td>
<td>Pancreas Transplant Specialist</td>
<td>Added narrative to Contraindication #1. Contraindication #4 iii added “combination” Contraindication #4 iv added “progressive multifocal leukoencephalopathy” “within the past twelve months” “other mycobacterial infection” “chronic intestinal cryptosporidiosis greater than one month”. Contraindication #9 added narrative. Added Contraindication #11. Other coverage issues #3b added “or causing a significant impairment in quality of life”. Other coverage #3c added “retinopathy, peripheral or autonomic neuropathy, accelerated atherosclerosis”. Sentence on expenses incurred for complications added “or requisite immunosuppression”.</td>
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<tr>
<td>4/11/17</td>
<td>Policy Staff</td>
<td>Services Not Covered added second bullet regarding associated expenses.</td>
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<td>Date</td>
<td>Clique</td>
<td>Changes in Contraindication #1 and #2. Added Contraindication #3v. Added Contraindications 11 through 15.</td>
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<td>1/2/18</td>
<td>Pancreas Transplant Specialist</td>
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<tr>
<td>8/6/19</td>
<td>Pancreas Transplant Specialist</td>
<td>Amended criteria #3 to read: Incurable chronic active or unresolved infection including chronic active viral hepatitis B, uncontrolled hepatitis C, or uncontrolled human immunodeficiency virus (HIV).</td>
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</table>

Mark E. Randleman, D.O.
Pegloticase (Krystexxa®) is a recombinant porcine-like uricase which converts uric acid to allantoin enzymatically. It is pegylated to increase the elimination half-life from eight hours to ten to twelve days and decrease the immunogenicity of the foreign uricase protein. It was FDA approved in 2010. It is considered an option for three percent of individuals who are intolerant to standard medical therapy. Typically, it is given as an infusion every two weeks. It has a high rate of side effects including hemolysis with methemoglobinemia in patients with a glucose-6-phosphate dehydrogenase deficiency. Patients of African or Mediterranean ancestry should be screened for G6PD deficiency before starting treatment. Anaphylactic reactions are possible and require a healthcare setting capable of managing anaphylaxis. As such, administration of this drug should be done in an outpatient hospital, clinic, or physician office setting, so as to assure capability of providers to expeditiously address any untoward side-effects, such as anaphylaxis.

Criteria:

1. Pegloticase (Krystexxa®) 8 mg IV every two weeks provided in single use vials is covered for use in adult members for the treatment of chronic gout refractory to conventional therapy.
   a. Must meet **ALL** of the following:
      i. Diagnosis of symptomatic gout refractory to all conventional therapy.
      ii. On a prevention regimen including adequate fluid intake, weight reduction, dietary purine reduction, and reduction in alcohol consumption.
      iii. Treatment failure of at least two NSAIDs or medical contraindication to use of NSAIDS.
      iv. Treatment failure of colchicine in a preventive regimen at a dose of at least 1.2 mg per day for at least six months or medical contraindication to such a trial.
      v. Treatment failure of **TWO** xanthine oxidase inhibiting agents including allopurinol for at least six months each or in combination.
      vi. Treatment failure of probenicid for at least six months at a dose of 500-2,000 gm twice daily and sulfinpyrazone for at least six months.
      vii. Uric acid level less than 6 mg/dl after start of treatment.
      viii. Age must be over 18.
   b. Trials may be overridden with documentation from physician of a medical contraindication to the trial medication.
   c. Premedication prior to administering Pegloticase using corticosteroid medication and antihistamine medication is strongly recommended by the manufacturer.
d. Must be administered in a healthcare setting by a health care professional prepared to provide anaphylaxis treatment. Patient must be closely monitored after the infusion.

Codes:
Diagnoses of gout 275.0-274.9, V77.5

References Used:
www.medicinenet.com
www.medscape.com


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.

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<td>CAC</td>
<td>Under Criteria - removed treatment failure of at least two non-steroidal anti-inflammatory drugs (NSAIDs).</td>
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<td>5/1/17</td>
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<td>Added settings for administration of this medication to introductory paragraph.</td>
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<tr>
<td>1/19/18</td>
<td>CAC</td>
<td>Under Criterion #1 added “8 mg IV every two weeks provided in single use vials.” Added 1viii “Age must be over 18.”</td>
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C. David Smith, MD
Pembrolizumab (Keytruda®)

<table>
<thead>
<tr>
<th>Iowa Medicaid Program:</th>
<th>Prior Authorization</th>
<th>Effective Date:</th>
<th>4/30/2015</th>
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<tr>
<td>Revision Number:</td>
<td>2</td>
<td>Last Review Date:</td>
<td>2/22/19/19/2018</td>
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<td>Reviewed By:</td>
<td>Medicaid Clinical Advisory Committee</td>
<td>Next Review Date:</td>
<td>01/2020/19/2019</td>
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<tr>
<td>Approved By:</td>
<td>Medicaid Medical Director</td>
<td>Approved Date:</td>
<td>3/21/2018</td>
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Pembrolizumab is an injectable anti-PD-1 humanized monoclonal antibody antineoplastic. It was approved by the U.S. Food and Drug Administration (FDA) for the treatment of unresectable, metastatic melanoma if BRAF V600 mutation positive. The BRAF gene assists in regulating cellular growth. Mutations of this gene in cancerous tissue may increase the growth and spread of cancer cells. Pembrolizumab, Atezolizumab, Durvalumab, and Avelumab are all monoclonal antibodies directed at the PD1 and PD-L1 cell surface protein on T lymphocytes.

Pembrolizumab has also been approved for the treatment of advanced metastatic non-small cell lung cancer (NSCLC) that has failed traditional chemotherapy AND is positive for PD-L1 receptor based on the PD-L1 IHC 22C3 pharmDx test. Response rates to other tumors which are PD-L1 positive is being reported varying from pancreatic cancer, vulvar carcinoma, thyroid carcinoma, esophageal cancer and carcinoid tumors.

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 and have progression on or after platinum based chemotherapy.
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)

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.

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<td>1/15/16</td>
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<td>Removed dosing information. Removed reference to ipilimumab (Yervoy). Added information on non small cell lung cancer (NSMCLC).</td>
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<td>1/19/18</td>
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<td>Criterion #3 added “and have progression on or after platinum based chemotherapy.”</td>
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C. David Smith, MD
Power Seat Elevation for Power Wheelchairs Criteria

<table>
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<th>Iowa Medicaid Program:</th>
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<tr>
<td>Approved By:</td>
<td>Medicaid Medical Director</td>
<td>Approved Date: 6/21/19</td>
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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 by physician, a physician’s assistant or nurse practitioner 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) which cannot be completed without the use of the power lift. (ADL’s include 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.

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<td>Added paragraph in References Used.</td>
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<td>CAC</td>
<td>Criterion #1 added prescribed by “physician, PA, or ARNP.” Added needed to complete ADL’s “which cannot be completed without the use of the power lift.”</td>
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<td>2/22/19</td>
<td>CAC</td>
<td>Updated wording for criterion #1 to include: a physician’s assistant or nurse</td>
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<td></td>
<td></td>
<td>practitioner</td>
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C. David Smith, MD