Blepharoplasty Criteria

Iowa Medicaid Program:	Prior Authorization; Claims Pre-pay	**Effective Date:**	9/11/2009
Revision Number:	3	**Last Review Date:**	4/15/2016
Reviewed By:	Medicaid Clinical Advisory Committee	**Next Review Date:**	4/2017
Approved By:	Medicaid Medical Director	**Approved Date:**	6/13/2016

Criteria:
All requests <u>must</u> come with taped and untaped vision field tests. Blepharoplasty is considered medically necessary when one or more of the following criteria are met:

1. Upper Lid
    a. Diagnosis of blepharochalasis, blepharoptosis, dermatochalasis, or pseudoptosis due to tumor or preaponeurotic fat prolapse with a visual field loss of at least 30 degrees from point of fixation or 50 percent on Goldman visual field perimetry or other automated testing.
    b. Upper lid defect caused by trauma, tumor or ablative surgery.
        - Pre-operative frontal pictures must be supplied for all upper lid blepharoplasty.
2. Lower Lid
    a. Ectropion – Eyelid turned outward
    b. Entropion – Eyelid turned inward
    c. Trichiasis – Inward misdirection of eyelashes caused by entropion
    d. Corneal exposure
3. Both
    a. Computer generated visual field testing demonstrates visual impairment that cannot be addressed by one procedure alone
        - Lateral and full face photographs with attempt at brow elevation must be supplied for all blepharoplasty of both upper and lower lids.

CPT Codes:
Blepharoplasty - 15820-15823
Levator Resection/Advancement - 67903-67904

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:**
4/18/14	Medical Director	Combined Criterion #1 a-d under #1 a-b. Combined Criterion #3 b under #3 a.	1
4/17/15	CAC	Added last paragraph in References Used.	2
4/15/16	CAC	Criterion #1 added "due to tumor or preaponeurotic fat prolapse" and "Goldman visual field perimetry or other automated testing". Added criterion #2d.	3

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Consumer Directed Attendant Care Criteria

Iowa Medicaid Program:	Waiver Prior Authorization	**Effective Date:**	7/25/2011
Revision Number:	5	**Last Review Date:**	4/15/2016
Reviewed By:	Medicaid Clinical Advisory Committee	**Next Review Date:**	4/2017
Approved By:	Medicaid Medical Director	**Approved Date:**	8/4/2015

Criteria:

Initial Services:

1. Member is eligible for the Home and Community Based Services (HCBS), Health and Disability, Elderly, AIDS/HIV, Physical Disability, Intellectual Disability or Brain Injury Waiver.
2. Member would receive a service performed by a person to help a member with non-skilled or skilled service activities which the member would typically do independently if the member were otherwise able.
3. Skilled service activities shall be under the supervision of a licensed nurse or licensed therapist working under the direction of a physician.
4. Services are essential to the health and welfare of the member.
5. Service plan and Consumer Directed Attendant Care agreement is directed at meeting the individual member needs.
6. Service plan is consistent with the diagnosis and treatment of the member's condition.
7. Service plan is in accordance with standards of good medical practice.
8. Service plan documents how services will meet the medical need of the member and for the reasons other than the convenience of the member or the member's practitioner or caregiver.
9. The scope, frequency, and duration of services shall be indicated in the service plan and the approved and signed Consumer Directed Attendant Care agreement. Only direct services are billable.
10. Services are the least costly type of service which would reasonably meet the medical need of the member.
11. Consumer-directed attendant care services may not be simultaneously reimbursed with any other HCBS waiver services.

Only direct services are billable. Services not covered under Consumer Directed Attendant Care (CDAC) include but are not limited to:

a. Services provided simultaneously with any similar service regardless of funding source.
b. Services provided simultaneously with in-home health-related care services.

c. Service activities including parenting or child care for or on behalf of the member including, but not limited to: basic child care, taking a child to a playground, taking a child to school.
d. Transportation costs.
e. The costs of food.
f. Reminders and cueing.
g. Companionship.
h. Any activity related to supervising a member.
i. Services that are not documented in accordance with IAC 441-79.3 rules.
j. Any covered Consumer Directed Attendant Care service not identified in the member's Consumer Directed Attendant Care Agreement Form #470-3372.
k. Activities the member is able to perform.
l. Wait time for any activity.
   i. Examples: physician visits, laundry cycle, dishwasher cycle time.
m. Deep cleaning and chore services, as defined in IAC 441-78.37.
n. All pet related services, including but not limited to: feeding, walking, dropping removal, shopping for pet food/supplies, taking pet to veterinarian.
o. Moving and packing services.
p. Visiting, watching movies or television and playing games.
q. Taking the member to visit relatives, casino, bars, or for salon services, including but not limited to: manicure, pedicure, or massages.
r. Meal preparation, housekeeping, shopping or other activities that are completed for the benefit of people other than the member.
s. Non-essential shopping, including but not limited to: Christmas, birthday and window shopping.
t. Dining out a restaurants or take-out food brought to member.
u. Transportation time related to non-allowable activities.
v. Exercise that does not require skilled services (e.g., accompanying the member on a walk in the community).

12. Submitted documentation includes:
    a. Service plan
    b. Comprehensive assessment
    c. List of all natural, waiver, and non-waiver support services. Natural supports may include but are not limited to family, friends, or community resources.
    d. HCBS Consumer-Directed Attendant Care Agreement
    e. Supported community living plan of care, if applicable
    f. Home health agency plan of care, if applicable

<u>Continued Services:</u>

1. Initial service criteria are met.
2. Necessity for service and service intensity must be independently met for continued services regardless of past history of service approval.
3. Submitted documentation includes:
   a. Service plan
   b. Comprehensive assessment

c. List of all natural, waiver, and non-waiver support services. Natural supports may include but are not limited to family, friends, or community resources.
d. HCBS Consumer-Directed Attendant Care Agreement
e. Supported community living plan of care, if applicable
f. Home health agency plan of care, if applicable

References Used:
Iowa Administrative Code 441-78.34(7)
Iowa Administrative Code 441-78.37(15)
Iowa Administrative Code 441-78.38 (8)
Iowa Administrative Code 441-78.41(8)
Iowa Administrative Code 441-78.43(13)
Iowa Administrative Code 441-78.46(1)
Iowa 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:

Change Date:	**Changed By:**	**Description of Change:**	**New Version Number:**
10/19/12	CAC	Page 2 - “n” moved to be part of “m” and “o” through “y” relabeled to be “n” through “x”.	1
4/19/13	CAC	Services not covered “j” added IAC and “k” added Form.	2
4/18/14	Medical Director	Criterion #9 added “only direct services are billable”. Under services not covered removed “this is not an all-inclusive list” and added “include but are not limited to”. Combined some items not covered.	3

Change History (Cont.):

4/17/15	CAC	Combined two items under services not covered. Added last paragraph in References Used.	4
8/4/15	Policy Staff	Added “v” under services not covered.	5

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Gait Trainer Criteria

Iowa Medicaid Program:	Prior Authorization	**Effective Date:**	05/14/2008
Revision Number:	3	**Last Review Date:**	4/15/2016
Reviewed By:	Medicaid Clinical Advisory Committee	**Next Review Date:**	4/2017
Approved By:	Medicaid Medical Director	**Approved Date:**	6/13/2016

Criteria:
Pediatric or adult gait trainer will be considered on the following criteria:
1. Documentation of need for upper and lower body support to walk due to developmental delay in gross and fine motor skills relating to a neurological or neuromuscular disease. Ideally, the GMFCS level will be identified by a physical therapist and accompany the request. (Gross Motor Function Classification System).
2. Gait trainers require a trial before being considered for purchase.
3. Duplicate DME will not be covered

HCPCS Code:
Pediatric- E8000, E8001, and E8002
Adult- E1399

References Used:
Provider Manual, page 29

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Change History:

Change Date:	**Changed By:**	**Description of Change:**	**New Version Number:**
4/19/13	Policy Staff/CAC	Criterion #2 change requires a three month trial to requires a trial.	1
4/17/15	CAC	Added last paragraph in References Used.	2
4/15/16	CAC	Criteria - removed age range; added pediatric and adult. Added GMFCS to Criterion #1. Added Criterion #3 regarding duplication.	3

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Genetic Testing Criteria
(excludes BRCA testing and 21-gene RT-PCR assays, which are covered using NCCN guidelines, under separate criteria)

Iowa Medicaid Program:	Prior Authorization	**Effective Date:**	1/21/2011
Revision Number:	5	**Last Review Date:**	4/15/2016
Reviewed By:	Medicaid Clinical Advisory Committee	**Next Review Date:**	4/2017
Approved By:	Medicaid Medical Director	**Approved Date:**	5/9/2016

Criteria:
This criteria may not apply to testing for familial cancer syndromes. Separate criteria are used for BRCA 1 and 2 testing and the 21-gene RT-PCR assays. Other tests for familial cancer syndromes will be subject to criteria 1-6 below, but will also be assessed for consistency with best medical practice. Criteria published by the National Cancer Care Network (NCCN) and the Centers for Medicare and Medicaid Services (CMS) may apply to the evaluation of testing for familial cancer syndromes, when available.

Genetic testing is considered medically necessary to establish a molecular diagnosis of an inheritable disease when **ALL** of the following are met:
1. The member displays clinical features of a suspected genetic condition; and
2. The testing is necessary to establish a diagnosis for symptoms/conditions of unknown etiology and/or to rule-out or rule-in a diagnosis; and
3. The result of the test will directly impact the clinical decision-making or clinical outcome for the member; and
4. The testing method is considered scientifically valid for the identification of a specific genetic condition; and
5. Documentation is provided from a genetic counselor or physician with genetic expertise, such as a medical geneticist, pediatric neurologist or developmental pediatrician, that supports the recommendation for testing based on a review of risk factors, clinical scenario, and family history **AND** that appropriate genetic counseling has been delivered.
6. For testing codes noted below, all relevant coverage criteria need to be met.

Definitions

- A *malformation* refers to abnormal structural development.
- A *major malformation* is a structural defect that has a significant effect on function or social acceptability. Examples include ventricular septal defect or a cleft lip.
- A *minor malformation* is a structural abnormality that has a minimal effect on function or societal acceptance. Examples: preauricular ear pit or partial syndactyly (fusion) of the second or third toes.

- A *syndrome* is a recognizable pattern of multiple malformations. Syndrome diagnoses are often relatively straightforward and common enough to be clinically recognized without specialized testing. Examples include Down's Syndrome, neural tube defects and achondroplasia. However, in the very young, or in the case of syndromes with variable presentation, confident identification may be difficult without additional testing.

Coverage Criteria: 81228 Cytogenomic Constitutional (Genome-Wide) **Microarray Analysis;** Interrogation of Genomic Regions for Copy Number Variants (e.g., Bacterial Artificial Chromosome [BAC] or Oligo-Based Comparative Genomic Hybridization [CGH] Microarray Analysis)

- BAC or oligo-based CMA is considered medically necessary for <u>ONE OR MORE OF</u> the following medical indications:
  - Multiple congenital anomalies, other than those associated with an obvious, specific, and well-defined genetic syndrome. After history, physical examination, pedigree analysis, genetic counseling, and completion of conventional diagnostic studies, a definitive diagnosis remains uncertain.
  - Developmental delay (DD) or Intellectual Disability (ID) when all of the following are met:
    - There is no known etiology for the DD/ID (e.g., trauma or infection)
    - The DD/ID is not suspected to be related to an obvious, specific, and well-defined genetic syndrome. After history, physical examination, pedigree analysis, genetic counseling, and completion of conventional diagnostic studies, a definitive diagnosis remains uncertain.
    - The member shows evidence of at least one major <u>**OR**</u> two or more minor congenital anomalies as defined above.
  - Autism spectrum disorders when accompanied by at least one major <u>**OR**</u> two or more minor congenital anomalies

Coverage Criteria: 81229 Cytogenomic Constitutional (Genome-Wide) Microarray Analysis; Interrogation of Genomic Regions for Copy Number and Single Nucleotide Polymorphism (SNP) Variants for Chromosomal Abnormalities

- SNP microarray analysis is considered medically necessary for the indications listed for CPT 81228 above and is only covered when this testing has been non-diagnostic. If member has already had CPT 81228 performed, he/she is only eligible for CPT 81229 if <u>AT LEAST ONE</u> of the following additional criteria is met:
  - Cosanguinity <u>AND</u> recessive disease are suspected.
  - Uniparental Disomy (UPD – both copies of a chromosome inherited from a single parent) is suspected.
  - Another mechanism is suspected that would not be detected by the oligo microarray (81228)

Coverage Criteria: 81243 *FMR1 (Fragile X mental retardation 1)* (e.g., fragile X mental retardation) gene analysis; evaluation to detect abnormal (e.g., expanded) alleles

- Fragile X carrier testing billed under code 81243 is not considered medically necessary for general population screening (e.g., screening in the absence of symptoms or family history).

- Fragile X diagnostic testing is considered medically necessary for males with unexplained intellectual disability, developmental delay, or autism or in females with these conditions when strong clinical suspicion is documented due to phenotype or family history

All genetic molecular testing must be conducted in a laboratory certified, at a minimum, under the Clinical Laboratory Improvement Amendments of 1988 (CLIA).

All genetic molecular testing must be accompanied by pre **AND** post test genetic counseling with a physician or a certified genetic counselor, which discusses the possible risks and benefits of early detection and prevention modalities.

Genetic testing is not covered to determine a specific diagnosis or syndromes when such diagnoses would not definitively alter the medical treatments of the member.

Genetic testing is not covered to determine the likelihood of associated medical conditions occurring in the future, when diagnosis of these conditions would not rely upon having the genetic diagnosis.

Genetic testing is not a covered service for the purposes of determining current or future family planning. Genetic testing is not covered for the purpose of investigating if a condition might affect the member's children or other family members if the diagnosis does not directly affect the medical treatment of the member.

CPT Codes:

2013 CPT Codes	Description	Coverage	Note
81201	APC (adenomatous polyposis coli) gene analysis; full gene sequence	PA	
81202	APC (adenomatous polyposis coli) gene analysis; known familial variants	PA	
81203	APC (adenomatous polyposis coli) gene analysis; duplication/deletion variants	PA	
81228	Cytogenetic constitutional (genome-wide) microarray analysis; interrogation of genomic regions for copy number variants	PA	This code has been effective since 1/1/13.
81229	Interrogation of genomic regions for copy number and single nucleotide polymorphism (SNP) variants for chromosomal abnormalities	PA	Not a new code in 2013. This code has been effective since 1/1/13.
81235	EGFR (epidermal growth factor receptor) gene analysis	PA	
81243	FMR1 (Fragile X Mental Retardation 1) gene analysis	PA	This code has been effective since 1/1/13.

2013 CPT Codes	Description	Coverage	Notes
81244	FMR1 (Fragile X Mental Retardation 1) gene analysis; characterization of alleles (eg, expanded size and methylation status	PA	Not a new code in 2013. This code has been effective since 1/1/13.
81253	GJB2 (gap junction protein, beta 2, 26kDA; connexin 26) gene analysis; known familial variants	PA	
81254	GJB6 (gap junction protein, beta 6, 30kDa, connexin 30) gene analysis, common variants	PA	
81321	PTEN (phosphatase and tensin homolog) gene analysis; full sequence analysis	PA	Cowden and Bannayan-Riley-Ruvalcaba Syndromes
81322	PTEN (phosphatase and tensin homolog) gene analysis; known familial variant	PA	
81323	PTEN (phosphatase and tensin homolog) gene analysis; duplication/deletion variant	PA	
81324	PMP22 (peripheral myelin protein 22) gene analysis; duplication/deletion analysis	PA	Charcot-Marie-Tooth
81325	PMP22 (peripheral myelin protein 22) gene analysis; full sequence analysis	PA	
81326	PMP22 (peripheral myelin protein 22) gene analysis; known familial variant	PA	
88261	Chromosome analysis; count 5 cells, 1 karyotype, with banding	Yes	
88262	Chromosome analysis; count 5 cells, 1 karyotype, with banding; count 15-20 cells, 2 karyotypes, with banding	Yes	
88263	Chromosome analysis; count 5 cells, 1 karyotype, with banding; count 45 cells for mosaicism, 2 karyotypes, with banding	Yes	
88264	Chromosome analysis; count 5 cells, 1 karyotype, with banding; analyze 20-25 cells	May require PA	

References Used:

Ad hoc genetics specialist panel, March 2014.
American Medical Association. CPT Professional Manual, 2013.
ACMG guidelines - Evaluation of the Newborn with Single or Multiple Congenital Abnormalities
Ahn et al.: Array CGH as a first line diagnostic test in place of karyotyping for postnatal referrals - results from four years' clinical application for over 8,700 patients. Molecular Cytogenetics 2013 6:16.
Battaglia A, et al., Confirmation of chromosomal microarray as a first-tier clinical diagnostic test for individuals with developmental delay, intellectual disability, autism spectrum disorders and dysmorphic features, European Journal of Paediatric Neurology (2013), http://dx.doi.org/10.1016/j.ejpn.2013.04.010
Coulter ME, M. D. (2011, September). Chromosomal microarray testing influences medical management. *Genetics in Medicine, 13*(9), 770 - 776.
Henderson LB, et al. Genet Med 13 March 2014. Doi:10.1038/gim.2014.18
Schaefer BG, et. Al., Genet Med 21 March 2013. Doi:10.1038/gim.2013.32
Shen Y, et al., Clinical Genetic Testing for Patients With Autism Spectrum Disorders. *Pediatrics* 2010;125;e727. DOI: 10.1542/peds.2009-1684

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Change History:

Change Date:	**Changed By:**	**Description of Change:**	**New Version Number:**
1/18/13	CAC	Criteria - add information on non-coverage in 6th paragraph.	1
12/12/13	Medical Director	Formatting changes and addition of sample CPT codes.	2
4/18/14	Medical Director	Total revision based on ad hoc committee input	3
4/17/15	CAC	Criteria - added "may not apply to testing for familial cancer syndromes". Added last paragraph in References Used.	4

Change History (cont.):

Change Date:	Changed By:	Description of Change:	New Version Number:
6/9/15	Policy staff and Medical Director	Criteria - added paragraph on familial cancer syndromes. Added criterion #2.	5

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Negative Pressure Wound Therapy (NPWT) Criteria

Iowa Medicaid Program:	Prior Authorization	**Effective Date:**	9/11/2009
Revision Number:	4	**Last Review Date:**	4/15/2016
Reviewed By:	Medicaid Clinical Advisory Committee	**Next Review Date:**	4/2017
Approved By:	Medicaid Medical Director	**Approved Date:**	6/13/2016

Criteria:
Medicaid will cover Negative Pressure Wound Therapy (NPWT) Vacuum-Assisted Closure (VAC) for non-healing wounds as medically necessary when **ALL** of the following conditions exist:

1. The member has one or more chronic wounds. "Chronic wounds" are wounds that have gone through the repair process without producing satisfactory anatomic and functional integrity.
    a. Wounds could include pressure ulcers, venous ulcers, and diabetic ulcers.
    b. Could also include surgical and traumatic wounds, and any other wound where the wound healing process is compromised.
2. Treatment must be prescribed by a licensed practitioner within the scope of practice under state law.
3. The Medical professional will be responsible for the evaluation and management of this therapy. This responsibility will include:
    a. Initial evaluation
    b. Ongoing assessment
    c. Continuous monitoring to support the continuation of this therapy
4. The wound has been debrided of all nonvitalized tissus.
5. An adequate blood supply to the wound is documented.
6. There is ongoing monitoring showing improvement in wound size documented every two to four weeks.

Coverage Position (outpatient setting): Member must meet ONE of the following:

1. There is a chronic or non-healing wound/ulcer after an adequate trial of traditional therapy.
    a. The therapy is to include the application of moist topical dressings, debridement, and the maintenance of adequate nutritional status. In addition, the wound has been measured (and has measurable length, width, and depth) and evaluated on a regular basis to document no change. All wound measurements must be provided.
2. There is a traumatic or surgical wound that is in need of accelerated formation of granulation tissue (due to exposed bone, tendons, vessels, etc.) **AND** the member has co-morbidities (such as diabetes mellitus, vascular disease, obesity, high dose prednisone use, etc.), that will not allow the normal healing process.

Coverage Position (inpatient setting): <u>Member must meet ONE of the following</u>:

1. An ulcer or wound is encountered in the inpatient setting, and standard wound therapy has been tried and failed. NPWT can be initiated when there is lack of healing despite standard wound therapy, and it is considered to be the best treatment option in the judgment of the Medical Professional

2. There is a traumatic or surgical wound that is in need of accelerated formation of granulation tissue (due to exposed bone, tendons, vessels, etc.) **<u>AND</u>** the patient has co-morbidities (such as diabetes mellitus, vascular disease, obesity, high dose prednisone use, etc.), that will not allow the normal healing process.

Codes:
Dressings - A6550
Canister - A7000
Negative pressure wound pump - E2402

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:**
10/27/12	CAC	Criteria - remove #1 and replace as definition of chronic wounds. Re-number #2 and #3 to be #1 and #2. Criterion #2 - remove “of the healing arts”. Coverage Position for outpatient and inpatient setting - Add Patient must meet ONE of the following: Coverage Position for outpatient setting #1 removed wound/ ulcer “with lack of healing”.	1

Change History (cont.):

Change Date:	Changed By:	Description of Change:	New Version Number:
4/18/14	Medical Director	Changed name from Wound Vacuum to Negative Pressure Wound Therapy (NPWT). Added under Coverage Position (Outpatient) #1 "all wound measurements must be provided". Formatting changes.	2
4/17/15	CAC	Added paragraph in References Used.	3
4/15/16	CAC	Added Criteria #4, #5, #6. Coverage position (outpatient and inpatient) removed "30 day timeframe".	4

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Non-Elastic Compression Devices Criteria

Iowa Medicaid Program:	Prior Authorization	**Effective Date:**	7/1/2010
Revision Number:	4	**Last Review Date:**	4/15/2016
Reviewed By:	Medicaid Clinical Advisory Committee	**Next Review Date:**	4/2017
Approved By:	Medicaid Medical Director	**Approved Date:**	6/13/2016

Criteria:

Inflatable compression garments, non-elastic binders, or individually fitted prescription graded compression stockings are considered medically necessary for members who have **ANY** of the following medical conditions which have failed traditional standard therapies:

1. Treatment of any of the following complications of chronic venous insufficiency:
    a. Varicose veins (except spider veins)
    b. Stasis dermatitis (venous eczema)
    c. Venous ulcers (stasis ulcers)
    d. Venous edema
    e. Lipodermatosclerosis
2. Prevention of thrombosis in immobilized persons e.g., immobilization due to surgery, trauma, general debilitation, etc.
3. Post thrombotic syndrome; post phlebitic syndrome
4. Persons with chronic lymphedema
5. Edema following surgery, fracture, burns, or other trauma
6. Post sclerotherapy
7. Postural hypotension
8. Severe edema in pregnancy
9. Edema accompanying paraplegia, quadriplegia, etc.

These compression garments for the legs are considered experimental and investigational for **ALL OTHER** indications.

The use of abdominal compression garments for the management of truncal edema is considered experimental and investigational.

Custom compression garments are deemed medically necessary when the member is unable to use non-customized compression garments or has failed the use of non-customized compression garments.

Non-elastic leg binders are similar to graded compression stockings in that they provide static compression of the leg, but unlike graded compression stockings, they do not use elastic, but use adjustable Velcro or buckle straps.

Non-elastic leg binders e.g., LegAssist, CircAid, Reid Sleeve are medically necessary for members with the above conditions who either fail the use of non-customized compression garments, custom compression garments and/or lymphedema pumps or are unable to use either of these due to body habitus or skin condition.

In addition to the medical necessity requirements for compression garments, non-elastic leg binders may be additionally medically necessary for members who meet **EITHER OF** the following criteria:

1. The member has a continuing requirement for bandaging 23 hours per day after completion of intensive lymphedema treatment, *or*
2. The member has a requirement for night-time compression with a documented inability of the member or an available caregiver to perform bandaging independently.

Although an item may be necessary, it must also be a reasonable expenditure for the Medicaid Program. Therefore, all less costly alternatives (such as bandaging or wrapping, non-customized compression garments, custom made compression garments, and non-elastic binders) must be tried and failed or contraindicated for the members' condition before recommending more costly items.

HCPCS Code:
A4465
S8429

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:
7/27/12	CAC	"off the shelf" to non-customized	1
4/18/14	Medical Director	formatting changes. Added HCPCS Code of S8429.	2
4/17/15	CAC	Added last paragraph in References Used.	3
4/15/16	CAC	Under criteria, added "medical conditions which have failed traditional standard therapies.	4

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Personal Care Services for Children Criteria

Iowa Medicaid Program:	Prior Authorization	**Effective Date:**	9/11/2009
Revision Number:	1	**Last Review Date:**	4/15/2016
Reviewed By:	Medicaid Clinical Advisory Committee	**Next Review Date:**	4/2017
Approved By:	Medicaid Medical Director	**Approved Date:**	5/9/2016

Criteria

Plans of care and requests for service are reviewed and points are assigned based on the Function Needs Acuity Scoring Tool (FNAST) and the Social Needs Acuity Scoring Tool (SNAST). Points from each tool are added together and the total number of points is used to determine number of home health aide hours to meet need. See scoring guide below.

Need	**Assistance Needed**	**Frequency**	**Points**
Bathing	Independent		0.00
	Assistance needed		2.00
	Dependent		3.00
Dressing	Independent		0.00
	Assistance needed		2.00
	Dependent		3.00
Toileting	Independent		0.00
	Assistance needed		2.00
	Dependent		3.00
Continence - bowel	Incontinent		2.00
	Continent		0.00
Continence - bladder	Incontinent		2.00
	Continent		0.00
Eating	Independent		0.00
	Assistance needed		2.00
	Dependent		3.00
Orthotics:	Upper Extremities	q 2hr	2.50
		q 4hr	2.00
		On/Off daily	1.00
	Lower Extremities	q 2hr	2.50
		q 4hr	2.00
		On/Off daily	1.00
Transfer assist	Minimum assist		1.00
	Maximum assist		2.00
Ambulation:	Independent		0.00
	Assistance needed		2.00
	Dependent		3.00
Medical Equipment (Describe misc. medical equipment)	Wheelchair		2.00
	Hospital Bed		2.00
	Hoyer Lift		2.00
	Misc.		2.00
ROM		> q 2hr	4.00
		q 2hr	3.00
		q 4hr	2.00
		< q 4hr	1.00
Aggressive			3.00

Restraints	Soft Restraints		2.00
	Other (specify)		2.00
Harm to self or others			3.00
Vision	Impaired		2.00
	Functional		0.00
Hearing	Impaired		2.00
	Functional		0.00
Communication	Impaired		2.00
	Functional		0.00

SNAST

Measure	**Range**	**Points**
Number of persons in household over the age of 18. ** Exclude patient **	4 or more	0.00
	3	0.50
	2	1.00
	1	1.50
Number of persons in household under the age of 18 * Exclude patient *-**If other child(ren) under the age of 18 require assistance with activities of daily living (ADLs), do not allot points for this section. See below. **	Greater than 4	4.00
	3-4	3.00
	2	2.00
	1	1.00
Number of persons in household under the age of 21 requiring assistance with activities of daily living (ADLs) outside the normal developmental parameters (i.e., a 5 year-old would typically need some assistance, therefore this is considered “normal development”) ** Exclude patient **	Greater than 4	6.00
	4	5.00
	3	4.00
	2	3.00
	1	2.00
Does caregiver(s) work outside the home?	Yes	1.00
	No	0.00
Hours per day worked	4	1.00
	6	2.00
	8	3.00
	10	4.00
	12	5.00
Does the caregiver(s) attend school outside the home?	Yes	1.00
	No	0.00
Hours per day caregiver(s) at school	Less than 4	1.00
	4	1.50
	6	2.00
Days per week caregiver(s) at school/work	Less than 5	1.00
	5 or more	2.00
Travel time required to work or school	Less than 1 hour	1.00
	Greater than 1 hour	2.00
Documented back-up plan on file with agency.	Yes	0.00
	No	1.00
Are back-up caregiver(s) trained on all cares?	Yes	0.00
	No	1.00
Are back-up caregiver(s) capable of providing all cares	Yes	0.00
	No	2.00

Expected time frame for training of back-up caregiver(s)	Greater than 12 hours	5.00
	10 – 12 hours	4.00
	8 – 9 hours	3.00
	6 – 7 hours	2.00
	4 – 5 hours	1.00
	Less than 4 hours	0.50
Does patient attend school?	Yes	1.00
	No	2.00
Hours per day at school:	Less than 4	1.00
	4	1.00
	6	0.50
	8	0.50
Days per week at school:	Less than 5	1.00
	5	0.50

0-4 points = 0 hours
5-9 points – intermittent services
10-29 points = up to 4 hours
30-54 points = up to 5 hours
55-69 points = up to 7 hours
70 points or more are subject to individual consideration

References Used:
Virginia Medicaid Waiver Tool

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:**
4/17/15	CAC	Changed points for subject to individual consideration from “100 points or more” to “70 points or more”. Added last paragraph in References Used.	1

C. David Smith M.D.

C. David Smith, MD

Private Duty Nursing for Children Criteria

Iowa Medicaid Program:	Prior Authorization	**Effective Date:**	9/11/2009
Revision Number:	1	**Last Review Date:**	4/15/2016
Reviewed By:	Medicaid Clinical Advisory Committee	**Next Review Date:**	4/2017
Approved By:	Medicaid Medical Director	**Approved Date:**	5/9/2016

Criteria:
Plans of care are reviewed and points assigned based on the Medical Needs Acuity Scoring Tool (MNAST). Total points are used to determine number of hours to meet medical need. See scoring guide below.

Medical Need	**Frequency**	**Points**
Behavior that interferes with cares	Mild	1.00
	Moderate	2.00
	Severe	3.00
Requires Isolation		1.00
Skilled assessment of <u>one</u> system: (Choose one) ☐ Respiratory ☐ Neurological ☐ Cardiovascular ☐ Gastrointestinal ☐ Genitourinary ☐ Integumentary	Every 2 hours or more often	2.00
	Every 4 hours	1.50
	Every 8 hours	1.00
	Daily	0.50
Skilled assessment of <u>two or more</u> systems: (Check all that apply) ☐ Respiratory ☐ Neurological ☐ Cardiovascular ☐ Gastrointestinal ☐ Genitourinary ☐ Integumentary	Every 2 hours or more often	2.00
	Every 4 hours	1.50
	Every 8 hours	1.00
	Daily	0.50
Scheduled Medications: Excludes topical medications.	Simple: 1 or 2	3.00
	Moderate: 3 to 5	4.00
	Complex: 6 to 9	5.00
	Extensive: 10 or more	7.00
PRN Medications: <u>1 point given if PRN medication(s) are ordered</u>. ** Additional points may be given if documentation is submitted showing the frequency of specific PRN medication administration. **	PRN Medication Order	1.00
	Simple: 1 to 2	2.00
	Moderate: 3 to 5	3.00
	Complex: 6 to 9	4.00
	Extensive: 10 or more	5.00

Nebulizer Treatments: 1 point given if PRN nebulizer treatment is ordered. ** See above for additional points for PRN medications **	PRN Nebulizer treatments	1.00
	Scheduled at least daily, less often than every 8 hours	2.00
	Scheduled every 6 to 8 hours	3.00
	Scheduled every 4 to 5 hours	3.50
	Scheduled every 2 to 3 hours	4.00
IV Medications: Choose method of administration. ☐ Peripheral IV ☐ Central Line ☐ PICC line Hickman ☐ Other *** includes TPN, excludes heparin or saline flush ***	Weekly	1.00
	Daily	1.50
	Less often than every 8 hours	2.00
	Every 8 hours	2.50
	Every 6-7 hours	3.00
	Every 4-5 hours	3.50
	More often than every 4 hours	4.00
Tracheostomy Cares	Scheduled and/or PRN	6.00
Suctioning	Scheduled and/or PRN (Trach or NT)	5.00
	Scheduled and/or PRN (oral)	1.00
Pulse Oximetry	Continuous pulse oximetry with PRN oxygen parameters	1.00
	PRN or spot check pulse oximetry with PRN oxygen parameters	1.00
Ventilator	Ventilator, dependent, 24 hours per day	20.00
	Ventilator, intermittent 12 or more hours per day	18.00
	Ventilator, intermittent, 8 to 11 hours per day	16.00
	Ventilator, intermittent, 4 to 7 hours per day	14.00
	Ventilator, intermittent, less than 4 hours per day	12.00
BiPap or CPAP	BiPAP or CPAP more than 8 hours per day	5.00
	BiPAP or CPAP less than 8 hours per day	4.50
	BiPAP or CPAP used only at night	4.00
Chest Physiotherapy (CPT): (manual or with use of airway clearance vest)	PRN CPT	1.00
	Daily	1.00
	Every 8 hours or more	2.00
	Every 4 to 7 hours	3.00
	More often than every 4 hours	4.00

Nutrition: Choose all that apply ☐ Routine oral feeding ☐ Difficult, prolonged oral feeding ☐ Reflux and/or aspiration precautions ☐ G-tube ☐ J-tube ☐ Other	Physician ordered oral feeding attempts (i.e., treatment of oral aversion)	1.00
	Tube feeding (routine bolus or continuous	2.00
	Tube feeding (combination bolus and continuous)	2.50
	Complicated tube feeding (residual checks, aspiration precautions, slow feed, etc.)	3.00
Seizures: If Continuous Medical Monitoring and Assessment (CMMA) order present for neurological system, do not allow additional points for minimal interventions ***unless*** the specific intervention is documented. If CMMA order is not present, but documentation indicates daily seizure activity, allow points for minimal intervention if the plan of care has a seizure treatment plan included.	Seizure diagnosis, not activity documented	0.00
	Mild: daily, no intervention	0.00
	Moderate: minimal intervention daily	2.00
	Moderate: minimal intervention 2 to 4 times daily.	4.00
	Moderate: minimal intervention 5 or more times daily	4.50
	Severe: requires IM/IV/Rectal medications daily	5.00
	Severe: requires IM/IV/Rectal medications 2 to 4 times daily	5.50
	Severe: requires IM/IV/Rectal medications 5 or more times daily	6.00
Intermittent Catheter	Every 4 hours	5.00
	Every 8 hours	4.00
	Every 12 hours	3.00
	Daily or PRN	2.00
Strict I & O	Every 4 hours	4.00
	Every 8 hours	3.00
	Daily	2.00
Fractured or casted limb		1.00
Splinting schedule	On / Off daily	1.00
Basic range of motion (ROM)	At least every 8 hours	1.00
Body Cast		1.00

Miscellaneous skilled therapies (1.00 point each misc. therapy ordered) If diagnosis of skin disease, i.e. psoriasis, and PRN topical medications ordered, may allow 1 point for misc. therapies. If restraints are routinely used and documented, may allow 1 point for misc. therapies.	Daily or PRN	1.00
	Less often than every 8 hours	1.00
	Every 4 to 7 hours	2.00
	More often than every 4 hours	3.00
PEG or G-tube dressing change	At least daily	1.00
Choose all that apply ☐ Stage 1 – 2 pressure ulcer, ☐ IV change (new site)	At least daily	2.00
Choose all that apply ☐ Stage 3 – 4 pressure ulcer ☐ Multiple wound sites	At least daily	3.00

Units of service (hours) are authorized based on the following point accumulations:
0-4 points = 0 hours
5-9 points = up to 3 hours
10-14 points = up to 4 hours
15-19 points = up to 8 hours
20-29 points = up to 12 hours
30-39 points = up to 14 hours
40 or more points = up to 16 hours

References Used:

Virginia Medicaid Waiver Tool

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:
4/17/15	CAC	Added last paragraph in References Used.	1

C. David Smith M.D

C. David Smith, MD

Rhinoplasty Criteria

Iowa Medicaid Program:	Prior Authorization; Claims Pre-pay	**Effective Date:**	7/1/2008
Revision Number:	5	**Last Review Date:**	4/15/2016
Reviewed By:	Medicaid Clinical Advisory Committee	**Next Review Date:**	4/2017
Approved By:	Medicaid Medical Director	**Approved Date:**	5/9/2016

Criteria:
ALL of the following must be met:
1. The member must have a relevant history of any symptomatic trauma, surgical sequelae, congenital defect, or disease process causing a symptomatic functional impairment.
2. The procedure is performed for correction or repair of **ANY** of the following:
    a. Nasal deformity secondary to a cleft lip/palate or other congenital craniofacial deformity causing a functional impairment
    b. Chronic, nonseptal, nasal obstruction due to vestibular stenosis (i.e., collapsed internal valves).
    c. Secondary to symptomatic trauma, disease, congenital defect with nasal airway obstruction unresponsive to a recent trial of conservative medical management lasting at least six weeks that has either not resolved after previous septoplasty/turbinectomy or would not be expected to resolve with septoplasty/turbinectomy alone.
3. Preoperative photographs of any symptomatic external deformity showing anterior, base, left and right lateral view must be supplied and must be consistent with the need for rhinoplasty.

Procedures requested for cosmetic purposes will not be covered.

CPT Codes:
30460 – 30462 Cleft Lip/Palate
30400 – 30420 Primary
30430 – 30450 Secondary

References Used:
Medicare LCD 32763, http://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDid=32762&Contrid=330&ver=45&ContrVer=1&Date=&DocID=L32763&bc=iAAAAAgAAAAAAA%3d& Accessed 1/2/15.

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	Criteria - remove #1 and re-number #2 and #3 to #1 and #2. Add to #1 after disease process “causing a symptomatic functional impairment”	1
7/19/13	CAC	Criterion #1 corrected spelling of sequelae.	2
4/18/14	Medical Director	Formatting changes. Added “procedures for cosmetic purposes will not be covered”.	3
4/17/15	CAC	Added Criterion #2 and references.	4
6/8/15	Policy Staff	Removed “primarily” from procedures for cosmetic purposes will not be covered.	5

C. David Smith M.D.

C. David Smith, MD

Safety Beds Criteria

Iowa Medicaid Program:	Prior Authorization	**Effective Date:**	6/25/2013
Revision Number:	6	**Last Review Date:**	4/15/2016
Reviewed By:	Medicaid Clinical Advisory Committee	**Next Review Date:**	4/2017
Approved By:	Medicaid Medical Director	**Approved Date:**	6/13/2016

A safety bed is a bed designed to keep the user safe from falling out or injuring themselves as a result of being in bed or during sleep. Safety beds, for purposes of this criteria, do not include hospital beds, or institutional beds, but do include enclosed beds and adaptive beds, when used for safety purposes.

Safety beds may be clinically indicated for children or adults with medical diagnoses that result in seizure activity, uncontrolled movements or behaviors such that they have demonstrated danger of injury. They are not indicated and are not covered when used for confinement or caregiver convenience.

Safety beds covered under these criteria may include fully or partially enclosed beds, cubicle beds, canopy beds, tent beds or other beds designed for the purpose intended. It does not include hospital beds, or cribs.

Beds provided to Medicaid members will be the least physically-restrictive, most cost-efficient type available that meet the member's medical needs. Documentation must be provided to demonstrate the medical necessity of the type requested and any and all features and accessories requested.

Criteria:
An enclosed bed or cubicle bed or canopy bed is considered medically necessary when all of the following criteria are met:

1. There is a diagnosis related cognitive or communication impairment such as traumatic brain injury, cerebral palsy seizure disorder, or developmental delay with cognitive impairment or severe behavioral disorder that results in a safety risk.
2. There is a risk of injury due to the member's mobility
3. **At least one** of the following are documented:
    a. An active seizure disorder
    b. Uncontrolled movements related to a diagnosis which place individual at risk for injury
    c. Self-injurious behavior that would be expected to improve through use of the requested bed.
4. Documentation that **at least TWO** safety measures have been considered and either ruled out as contraindicated or tried and failed including, *but not limited to*:
    a. Side rails
    b. A mattress on the floor
    c. Protective helmet
    d. Posey vest
    e. Weighted blankets
5. Supporting documentation must include secondary diagnoses and pertinent history of at least one of the following:
    a. Risk of entrapment in a regular hospital bed.
    b. History of injuries or falls
    c. High risk for fractures

   d. At risk for hemorrhage due to thrombocytopenia or any other bleeding diathesis either acquired or iatrogenic
   e. Frequent upper respiratory infections and or other complications related to aspiration
   f. Respiratory complications related to positioning. Requires elevation of the head and upper body greater than 30 degrees
   g. Requires frequent positional changes
6. A signed physician's order and documentation that the member has been assessed for appropriateness of the bed and has no contraindications.

The purchase of a safety enclosure frame/canopy/bubble top (procedure code E1399) may be covered when it is for safety use. It is not a covered benefit when it is used for purposes of confinement or for the convenience of family or caregivers.

Procedure code E1399 may be used in conjunction with procedure codes E0328 or E0329 to request a pediatric fully-enclosed bed with a canopy.

"Fully-enclosed" is defined as four side enclosures and a top cover. A hospital bed with side rails that extend greater than 24 inches above the mattress spring is considered a crib.

Enclosed bed systems that are not approved by the Food and Drug Administration (FDA) are not a covered benefit.

HCPCS Code:
E0328
E0329

References Used:
Slifer KJ and Amari A Behavior Management For Children and Adolescents with Acquired Brain Injury Developmental Disabilities Research Reviews 15: 144-151 (2009).
Haynes T and Pratt ES, Bed enclosures: Suitable safety net? Nursing management, December 2009, 36-39.
Indiana Health coverage Programs Provider Bulletin BT200026, August 10, 2000.
Texas Medicaid Provider Procedures Manual, 2012 Online Edition, accessed at http://www.tmhp.com/HTMLmanuals/TMPPM/2012/Vol2_Children's_Services_Handbook.17.064.html on12/19/2012.
Iowa Administrative Code 78.10(2)d cross-reference 78.28(1)):
(1) Enclosed beds. Payment for an enclosed bed will be approved when prescribed for a patient who meets all of the following conditions:
   1. The patient has a diagnosis-related cognitive or communication impairment that results in risk to safety.
   2. The patient's mobility puts the patient at risk for injury.
   3. The patient has suffered injuries when getting out of bed.

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:**
7/27/12	CAC	Eliminate requirement for trials with the exception of totally closed beds. Documentation required is specified without requiring that it be provided by the physician.	1
4/19/13	Medical Director	Complete revision	2
4/26/13	Medical Director	Added definition of safety beds	3
5/13/13	Policy staff	Removed criterion #3 with reference to member suffering injuries when getting out of bed due to rule changes 9/1/13.	4
4/17/15	CAC	Added last paragraph in References Used.	5
4/15/16	CAC	Criterion #4 added d and e. Criterion #5d added “or any other bleeding diathesis either acquired or iatrogenic”.	6

C. David Smith, MD

Septoplasty Criteria

Iowa Medicaid Program:	Prior Authorization; Claims Pre-pay	**Effective Date:**	7/1/2008
Revision Number:	6	**Last Review Date:**	4/15/2016
Reviewed By:	Medicaid Clinical Advisory Committee	**Next Review Date:**	4/2017
Approved By:	Medicaid Medical Director	**Approved Date:**	6/13/2016

Criteria:
The presence of **AT LEAST ONE** of the following must be well-documented:

1. Septal deviation causing nasal airway obstruction resulting in prolonged or chronic nasal breathing difficulty or mouth breathing that has proved unresponsive to a recent trial of conservative and medical management, including smoking cessation, if applicable (e.g., topical/nasal corticosteroids, antihistamines) lasting at least six weeks.
2. Recurrent sinusitis secondary to a deviated septum that does not resolve after appropriate medical and antibiotic therapy and EITHER of the following indications are present:
   a. recurrent acute rhinosinusitis: four or more acute episodes per year
   b. chronic rhinosinusitis: duration more than 12 weeks.
3. Recurrent epistaxis related to a septal deformity.
4. Asymptomatic septal deformity that prevents access to other transnasal areas when such access is required to perform medically necessary procedures (e.g., ethmoidectomy).
5. Performed in association with cleft lip or cleft palate repair.
6. Obstructed nasal breathing due to septal deformity or deviation that has proved unresponsive to medical management and is interfering with the effective use of medically necessary Continuous Positive Airway Pressure (CPAP) for the treatment of an obstructive sleep disorder.

Septoplasty may also be approved when done in association with cleft palate repair.

Documentation must include the following:

1. Documentation must show the clinical history of the degree and duration of symptoms related to nasal obstruction or relevant functional impairment and failed previous attempts at conventional treatment.
2. Documentation must show any relevant history of symptomatic trauma or surgical sequelae, congenital defect or disease process or note the absence of any of these.
3. X-ray, CT scan, or nasal endoscopy results, if completed, must show the degree of nasal obstruction.

CPT Codes:
30520 – Septoplasty
30140 – Submucous Resection

References Used:

Centers for Medicare & Medicaid Services, Medicare LCD 32763, http://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=32763&ContrId=330&ver=45&ContrVer=1&Date=&DocID=L32763&bc=iAAAAAgAAAAAAA%3d%3d& Accessed 1/2/15.

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 #3 - change CAT scan to CT scan	1
7/19/13	CAC	Criterion #2 corrected spelling of sequelae	2
4/18/14	Medical Director	formatting changes	3
1/2/15	Medical Director	Added clinical criteria in addition to documentation criteria. Added reference.	4
4/17/15	CAC	Added last paragraph in References Used.	5
4/15/16	CAC	Criterion #1 added “including smoking cessation, if applicable”.	6

C. David Smith M.D

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Shower/Commode Chair Criteria

Iowa Medicaid Program:	Prior Authorization	**Effective Date:**	1/21/2011
Revision Number:	4	**Last Review Date:**	4/15/2016
Reviewed By:	Medicaid Clinical Advisory Committee	**Next Review Date:**	4/2017
Approved By:	Medicaid Medical Director	**Approved Date:**	5/9/2016

Criteria:
ALL of the following must be met:

1. The member is not able to stand for the duration of a shower or get in and out of a bathtub.
2. The member does not already have a bath chair that meets his or her needs.
3. The member needs support while sitting.
4. The member needs support for toileting.
5. The shower/commode chair will fit into member's bathroom and shower. Tilt-in-space is allowed if member needs to be tilted back for safety or pressure relief.

HCPCS Code:
E0240

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:
1/18/13	CAC	Criteria #3 and #4 removed “upper body”. Remove Criteria #6 and add it to Criteria #5.	1
7/19/13	CAC	Removed and/or and changed title to Shower/Commode Chair	2
4/18/14	Medical Director	formatting changes	3
4/17/15	CAC	Added paragraph in References Used.	4

C. David Smith, MD

Skilled Level of Care Criteria

Iowa Medicaid Program:	LTC Medical Criteria	**Effective Date:**	1/20/2012
Revision Number:	1	**Last Review Date:**	4/15/2016
Reviewed By:	Clinical Advisory Committee	**Next Review Date:**	4/2017
Approved By:	Medicaid Medical Director	**Approved Date:**	5/9/2016

For purposes of Iowa Medicaid criteria, "Skilled Nursing Facility (SNF)" level of care (LOC) is synonymous with "Skilled" level of care. The criteria apply to all uses of this level of care across long-term care settings, including nursing facilities, home and community-based services (HCBS) waivers and programs for all-inclusive care of the elderly (PACE).

Criteria:
In order to approve skilled level of care, **ALL OF** the following conditions must be met:

1. The member's medical condition requires skilled nursing services or skilled rehabilitation services as provided in 42 CFR 409.31(a), 409.32, and 409.34.

§ 409.31 Level of care requirement.
(a) ***Definition.*** As used in this section, *skilled nursing and skilled rehabilitation services* means services that:

(1) Are ordered by a physician;
(2) Require the skills of technical or professional personnel such as registered nurses, licensed practical (vocational) nurses, physical therapists, occupational therapists, and speech pathologists or audiologists; and
(3) Are furnished directly by, or under the supervision of, such personnel.

(b) ***Specific conditions for meeting level of care requirements.***

(1) The beneficiary must require skilled nursing or skilled rehabilitation services, or both, on a daily basis.
(2) Those services must be furnished for a condition -

(i) For which the beneficiary received inpatient hospital or inpatient CAH services; or
(ii) Which arose while the beneficiary was receiving care in a SNF or swing-bed hospital for a condition for which he or she received inpatient hospital or inpatient CAH services; or
(iii) For which, for an M C enrollee described in § 409.20(c)(4), a physician has determined that a direct admission to a SNF without an inpatient hospital or inpatient CAH stay would be medically appropriate.

§ 409.32 Criteria for skilled services and the need for skilled services.
(a) To be considered a skilled service, the service must be so inherently complex that it can be safely and effectively performed only by, or under the supervision of, professional or technical personnel.

(b) A condition that does not ordinarily require skilled services may require them because of special medical complications. Under those circumstances, a service that is usually nonskilled (such as those listed in § 409.33(d)) may be considered skilled because it must be performed or supervised by skilled nursing or rehabilitation personnel. For example, a plaster cast on a leg does not usually require skilled care. However, if the patient has a preexisting acute skin condition or needs traction, skilled personnel may be needed to adjust traction or watch for complications. In situations of this type, the complications, and the skilled services they require, must be documented by physicians' orders and nursing or therapy notes.

(c) The restoration potential of a patient is not the deciding factor in determining whether skilled services are needed. Even if full recovery or medical improvement is not possible, a patient may need skilled services to prevent further deterioration or preserve current capabilities. For example, a terminal cancer patient may need some of the skilled services described in § 409.33.

§ 409.34 Criteria for “daily basis”.

(a) To meet the daily basis requirement specified in § 409.31(b)(1), the following frequency is required:

- **(1)** Skilled nursing services or skilled rehabilitation services must be needed and provided 7 days a week; or
- **(2)** As an exception, if skilled rehabilitation services are not available 7 days a week those services must be needed and provided at least 5 days a week.

(b) A break of one or two days in the furnishing of rehabilitation services will not preclude coverage if discharge would not be practical for the one or two days during which, for instance, the physician has suspended the therapy sessions because the patient exhibited extreme fatigue.

“Supervision” means to coordinate, direct, and inspect on an ongoing basis the accomplishments of another, or to oversee, with the power to direct, the implementation of one’s own or another’s intentions. Performance of supervised services should be held to the same standard of care applied to the supervising practitioner.

Supervision includes, but is not limited to: (1) Personal hands-on instruction regarding all services provided; (2) Initial evaluation of the abilities of persons under the supervision of skilled personnel to complete goals of treatment; (3) The continuous availability of direct communication either in person or by electronic communications between the service provider and the supervising skilled personnel; (4) The personal review of the service provider’s practice and performance. (5) The delineation of a plan for emergencies; (6) Documentation of direct evaluation by the supervising practitioner, at a minimum, quarterly regarding the member’s progression to meeting specified goals and outcomes of the skilled service.

2. Services are provided in accordance with general provisions for all Medicaid providers and services as described within 441-79.9.
3. Services require another individual, either skilled technical or professional personnel or others acting under the supervision of such personnel, to deliver

the services. The services are not administered by the member to his or her own person, unless the presence of skilled technical or professional personnel or others acting under the supervision of such personnel is required on a daily basis as defined above.

4. Documentation submitted for review must indicate that the member has:
   a. A physician order for all skilled services.
   b. Services that require the skills of medical personnel including registered nurses, licensed practical nurses, physical therapists, occupational therapists, speech pathologists, or audiologists.
   c. An individualized care plan that addresses identified deficit areas.
   d. Confirmation that skilled services are provided to the member.
   e. Skilled services provided by, or under the supervision of medical personnel as described above.
   f. Skilled nursing services needed and provided seven days a week or skilled rehabilitation services needed and provided at least five days a week.

References:

42 CFR 409.31(a), 409.32, and 409.34
42 CFR 484.2 and 484.4 Definitions and Personnel qualifications
IAC 441 – 79.9
441-79.9(249A) General provisions for Medicaid coverage applicable to all Medicaid providers and services.
79.9(1) Medicare definitions and policies shall apply to services provided unless specifically defined differently.
79.9(2) The services covered by Medicaid shall:

a. Be consistent with the diagnosis and treatment of the patient's condition.
b. Be in accordance with standards of good medical practice.
c. Be required to meet the medical need of the patient and be for reasons other than the convenience of the patient or the patient's practitioner or caregiver.
d. Be the least costly type of service which would reasonably meet the medical need of the patient.
e. Be eligible for federal financial participation unless specifically covered by state law or rule.
f. Be within the scope of the licensure of the provider.
g. Be provided with the full knowledge and consent of the recipient or someone acting in the recipient's behalf unless otherwise required by law or court order or in emergency situations.
h. Be supplied by a provider who is eligible to participate in the Medicaid program. The provider must use the billing procedures and documentation requirements described in 441-Chapters 78 and 80.

79.9(3) Providers shall supply all the same services to Medicaid eligibles served by the provider as are offered to other clients of the provider.
79.9(4) Recipients must be informed before the service is provided that the recipient will be responsible for the bill if a noncovered service is provided.
79.9(5) Coverage in public institutions. Medical services provided to a person while the person is an inmate of a public jail, prison, juvenile detention center, or other public penal institution of more than four beds are not covered by Medicaid.
This rule is intended to implement Iowa Code section 249A.4.

American Medical Directors Association; Supervision and Collaboration: A Review of Definitions. https://www.amda.com/advocacy/ReviewDefinitions.pdf Accessed 2/24/15.

CMS State Operations Manual, Appendix B. (https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_b_hha.pdf) Accessed 2/24/15.

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:**
4/17/15	Medical Director	Insertion of relevant code, definition of “supervision,” added criterion #3 and insert references. Addition of introductory paragraph.	1

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Standing Frame System Criteria

Iowa Medicaid Program:	Prior Authorization	**Effective Date:**	1/1/2006
Revision Number:	3	**Last Review Date:**	4/15/2016
Reviewed By:	Medicaid Clinical Advisory Committee	**Next Review Date:**	4/2017
Approved By:	Medicaid Medical Director	**Approved Date:**	6/13/2016

Criteria:

1. Documentation must support that the standing frame being requested is needed due to the member needing to promote skin integrity, postural alignment, improved circulation, decrease muscle spasms, atrophy of leg muscles, bone integrity, and prevention of contractures to assist with transfer and transition ability. The member's GMFCS should be known.
2. There must be a standing frame regimen prescribed by the member's licensed practitioner within their scope of practice or documented as a need in the physical therapy assessment.
3. Standing frame systems require a trial before considered for purchase.
4. For sit-to-stand, mobile, and tri-standers the documentation must support the member's need for these features.
5. Duplication of medical equipment is not identified.

HCPCS Code:

E0637
E0638
E0641
E0642

References Used:

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Change History:

Change Date:	**Changed By:**	**Description of Change:**	**New Version Number:**
4/19/13	Policy Staff/CAC	Criterion #3 change requires a three month trial to requires a trial.	1

Change History (cont.):

Change Date:	**Changed By:**	**Description of Change:**	**New Version Number:**
4/17/15	CAC	Added paragraph in References Used.	2
4/15/16	CAC	Criterion #1 added “the member’s GMFCS should be known”. Criterion #2 changed “physician” to “licensed practitioner within their scope of practice”. Added Criterion #5 regarding duplication.	3

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Vagus Nerve Stimulator Criteria

Iowa Medicaid Program:	Prior Authorization	**Effective Date:**	1/21/2011
Revision Number:	2	**Last Review Date:**	4/15/2016
Reviewed By:	Medicaid Clinical Advisory Committee	**Next Review Date:**	4/2017
Approved By:	Medicaid Medical Director	**Approved Date:**	5/9/2016

Criteria:

1. Covered for treatment of medically intractable seizures when there is failure, contraindication, or intolerance to approved surgical and pharmaceutical management.

CPT Code:
61885

References Used:
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Change History:

Change Date:	Changed By:	Description of Change:	New Version Number:
10/19/12	CAC	Criterion #1 removed “to all suitable medical” and changed to “to all approved surgical …”	1
4/17/15	CAC	Criterion #1 removed “all” from intolerance to approved surgical and pharmaceutical management. Added paragraph in References Used.	2

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Varicose Vein Treatment Criteria

Iowa Medicaid Program:	Prior Authorization	**Effective Date:**	7/1/2008
Revision Number:	2	**Last Review Date:**	4/15/2016
Reviewed By:	Medicaid Clinical Advisory Committee	**Next Review Date:**	4/2017
Approved By:	Medicaid Medical Director	**Approved Date:**	5/9/2016

Criteria:
Treatments for varicose veins: Phlebectomy, ligation and excision, endovenous laser therapy (EVLT), Sclerotherapy and radiofrequency ablation (RFA).

1. There is documentation of **AT LEAST ONE** of the following:
   a. Leg ulcerations that are due to saphenous vein insufficiency and are refractory to conservative management.
   b. Recurrent bleeding from the saphenous vein or other varicosities
   c. History of a single, significant episode of bleeding, especially if transfusion is required.

OR

2. There is documentation of **ALL** of the following:
   a. Incompetence/reflux with Doppler evaluation and/or Duplex ultrasound of the symptomatic varicosity, and documented vessel size >3mm.
   b. Failure of conservative management (e.g., leg elevation, compression therapy) for six consecutive months.
   c. At least **ONE** of the following associated clinical conditions:
      i. Pain in the affected extremity, resulting in impaired mobility or inability to perform ADLs
      ii. Recurrent phlebitis or thrombophlebitis
      iii. Refractory dependent edema
      iv. Persistent stasis dermatitis

Treatments for varicose veins are *not covered* when performed primarily for cosmetic purposes. Treatment is not covered for varicose veins <3mm in diameter as this is considered cosmetic in nature.

CPT Codes:

Saphenous - 37700-37735, 37780
Radiofrequency closure - 36475
Stab phlebectomy - 37765
Sclerotherapy - 36468-36471

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:
4/18/14	Medical Director	Formatting changes. Added CPT codes.	1
4/17/15	CAC	Added paragraph in References Used.	2

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Vitamin, Mineral, Amino Acid Supplement Criteria

Iowa Medicaid Program:	Prior Authorization	**Effective Date:**	7/1/2008
Revision Number:	2	**Last Review Date:**	4/15/2016
Reviewed By:	Medicaid Clinical Advisory Committee	**Next Review Date:**	4/2017
Approved By:	Medicaid Medical Director	**Approved Date:**	5/9/2016

Criteria:
ONE of the following must be met:
1. Medical documentation must show a documented gastrointestinal, metabolic, psychological or other condition for which the use of a vitamin, mineral, or amino acid is required and supported in evidence-based literature.
2. For vitamin, mineral, or amino acid deficiencies, lab results must show the deficiency for which the supplement is intended to treat.

HCPCS Codes:
A9152
A9153
S9434

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:
4/18/14	Medical Director	Formatting changes. Added to Criterion #1 “and supported in evidence-based literature”.	1
4/17/15	CAC	Added paragraph in References Used.	2

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Eteplirsen Criteria

Iowa Medicaid Program:	Eteplirsen	**Effective Date:**	4/21/2017
Revision Number:	Prior Authorization	**Last Review Date:**	4/21/2017
Reviewed By:	Medicaid Clinical Advisory Committee	**Next Review Date:**	4/2018
Approved By:	Medicaid Medical Director	**Approved Date:**	

Eteplirsen (Exondys 51) is an antisense oligonucleotide indicate for the treatment of Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 51 skipping. The approval of this controversial drug has been accelerated by CMS based on an increase in dystrophin in skeletal muscle observed in some patients. Dystrophin is a rod shaped cytoplasmic protein that connects the cytoskeleton of a muscle fiber to the surrounding extracellular matrix through the cell membrane. A clinical benefit has not been established and continued approval is contingent on verification of clinical improvement in confirmatory trials.

Exon skipping is a form of RNA splicing used to cause cells to “skip” over faulty or misaligned sections of genetic code resulting in a truncated but still functional protein, despite the genetic mutation.

<u>ALL</u> Criteria must be met:

1. Member has a confirmed mutation of the DMD gene amenable to exon 51 skipping
2. Eteplirsen has been initiated in childhood after age 3 and before 14 years of age.
3. Member is able to achieve an average distance of at least 180m while walking independently over six minutes.
4. Medication is prescribed by or in consultation with a physician who specializes in treatment of pediatric neurologic disorders.
5. Eteplirsen is dosed based on FDA approved dosing at 30mg/kg/week.
6. Progressive disease is documented despite standard corticosteroid therapy.
7. Approval of initiation of treatment is for six months.
8. Medication administration is performed in a treating physician’s clinic, home by healthcare professional, or hospital.

Continuation of Treatment after six months:

1. Continuation of treatment requires documentation of stability of member’s physical capacity to improve or maintain distance walked in six minutes. A decline of 20 percent from baseline distance in six months would indicate little or no meaningful therapeutic effect.
2. Renewal of treatment is required every six months based on clinical parameters documenting improvement, stability, or a decline in capacity which is significantly better than anticipated.

References Used:
Duchenne Muscular dystrophy and dystrophin: pathogenesis and opportunities for treatment, Nowak, KJ et.al, EMBO Reports, 2004 Sep, 5(9): 872-876

Longitudinal Effect of Eteplirsen versus Historical Control on Ambulation in Duchenne Muscular Dystrophy, Mendall, JR et all., Ann.Neurology 2016; 79:257-271.

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Change History:

Change Date:	**Changed By:**	**Description of Change:**	**New Version Number:**

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Nusinersen Criteria

Iowa Medicaid Program:	Nusinersen	Effective Date:	4/21/2017
Revision Number:	Prior Authorization	**Last Review Date:**	4/21/2017
Reviewed By:	Medicaid Clinical Advisory Committee	**Next Review Date:**	4/2018
Approved By:	Medicaid Medical Director	**Approved Date:**	

Nusinersen (Spinraza) is an antisense obligonucleotide indicated for the treatment of spinal muscular atrophy (SMA). Spinal muscle atrophy is a rare genetic disorder caused by a mutation in the SMN1 gene which codes for survival motor neuron (SMN) protein. Survival of patients beyond infancy is due to low amounts of the SMN protein produced from the SMN2 gene. Nusinersen causes splicing of the SMN2 gene essentially converting it to produce the SMN protein at the level produced by the SMN1 gene.

Spinal muscular atrophy is the second most common fatal autosomal recessive disorder after cystic fibrosis with an estimated incidence of 1 in 6,000 to 1 in 10,000 live births. FDA approval has been expedited based on early favorable results from the CHERISH study. This study reported preliminary results which indicated a "highly significant" improvement in motor function as measured by the Hammersmith Functional Motor Scale Expanded.

Criteria:

1. Member is at least 3 weeks old and has been shown to have a homozygous gene deletion or mutation of the SMN1 gene.
2. Recommended dosing as outlined by the FDA is 12 mg intrathecally with the first three doses given fortnightly and the 4th loading dose given 30 days following the 3rd dose. Thereafter, maintenance doses are given every four months.
3. Platelet counts, PT, PTT and quantitative spot urine protein testing is indicated prior to each dose.
4. Continued use beyond six months will require documentation of improvement from baseline based on Total Motor Milestone Score (HIINE).

References Used:

Treatment of infantile-onset spinal muscular atrophy with Nusinersen: A phase 2, open-label, dose escalation study. Finkel, RS, et al, Lancet, 2016, Dec 17:388(10063): 3017-3026.

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Change History:

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

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Transcranial Magnetic Stimulation Criteria

Iowa Medicaid Program:	Transcranial Magnetic Stimulation	**Effective Date:**	4/21/2017
Revision Number:	Prior Authorization	**Last Review Date:**	4/21/2017
Reviewed By:	Medicaid Clinical Advisory Committee	**Next Review Date:**	4/2018
Approved By:	Medicaid Medical Director	**Approved Date:**	

Transcranial magnetic stimulation (TMS) is a noninvasive procedure that uses magnetic fields to stimulate nerve cells in the brain to improve symptoms of depression. Treatment for depression involves the delivery of repetitive magnetic pulses from an electromagnetic coil placed over the forehead near the scalp. The painless electromagnetic pulses are believed to stimulate frontal lobes of the brain involved with mood control and depression. This procedure is offered for major depressive disorder following failure of psychotherapy and at least four antidepressive medications. TMS does not achieve the success rate of ECT; however, it is not associated with the memory loss of ECT. Typically, the procedures are performed in the physician's office or clinic. Treatments are performed for one hour, five times per week for four to six weeks.

Criteria:

1. Member has failed to respond to at least four medication trials from at least two antidepressant medication classes.
2. Member is currently on an antidepressant.
3. Member has declined ECT therapy or has concurrent illness preventing safe electroconvulsive therapy.

References Used:

The clinical TMS Society Consensus Review and Treatment Recommendations for TMS Therapy for Major Depressive Disorder; Perera, T, et al, Brain Stimulation Journal, 2016, in press.

Transcranial Magnetic Stimulation (TMS) for Major Depression: A Multisite, Naturalistic Observational Study of Acute Treatment Outcomes in Clinical Practice; Carpenter, LL, et al, Depression and Anxiety, 2012, 29:587-596.

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:

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