

21-gene RT-PCR Assay (Oncotype DX[®]) Criteria

Iowa Medicaid Program:	Prior Authorization	Effective Date:	7/11/2013
Revision Number:	4	Last Review Date:	7/17/2015
Reviewed By:	Medicaid Clinical Advisory Committee	Next Review Date:	7/2016
Approved By:	Medicaid Medical Director	Approved Date:	11/18/2015

Criteria:

21-gene real-time polymerase chain reaction (RT-PCR) Assay (Oncotype DX[®]) is considered medically necessary to assess the need for adjuvant chemotherapy in women with recently diagnosed breast cancer within six months of diagnosis when ALL of the following criteria are met:

1. Breast tumor is stage 1 or stage 2, unilateral, and non-fixed. If multiple ipsilateral primary tumors are present, a specimen from only the tumor with the most aggressive histological characteristics should be submitted for testing. It is not necessary to conduct testing on each tumor; treatment is based on the most aggressive lesion.
2. Tumor size 0.6 to 1.0 cm with moderate/poor differentiation or unfavorable features (i.e., angiolymphatic invasion, high histologic grade, or high nuclear grade), OR tumor size > 1.0 cm.
3. The individual is axillary-node negative or has axillary-node micrometastasis no greater than 2.0 millimeters.
4. There is no evidence of distant metastatic breast cancer.
5. Breast tumor is estrogen-receptor positive.
6. Breast tumor is HER2-receptor negative or breast tumor is HER2-receptor positive and less than 1 cm in diameter. (Rationale: adjuvant chemotherapy with trastuzumab (Herceptin) is considered to be medically necessary regardless of an 21-gene RT-PCR assay (Oncotype DX[®]) score for HER2-receptor positive lesions 1 cm or more in diameter).
7. The individual is a candidate for possible adjuvant chemotherapy (i.e., chemotherapy is not precluded due to other factors), and testing is being done specifically to guide the decision as to whether or not adjuvant chemotherapy will be used. Member and physician (prior to testing) have discussed the potential results of the test and agree to use the results to guide therapy (i.e., member will forgo adjuvant chemotherapy if 21-gene RT-PCR assay (Oncotype DX[®]) score is low).

All other indications for 21-gene RT-PCR assay (Oncotype DX[®]), including determination of recurrence risk in breast cancer patients with positive lymph nodes, use in male breast cancer, or use for recurrent or metastatic breast cancer in a patient who already has a previous 21-gene RT-PCR assay (Oncotype DX[®]) result are considered **investigational** and not a covered benefit.

References Used:

21-gene RT-PCR assay (Oncotype DX[®]) product insert.

Coverage policies in effect for United Healthcare, Wellmark, Cigna, and Aetna, accessed online 9-12-12.

Paik S, Tang G, Shak S, et al. Gene expression and benefit of chemotherapy in women with node-negative, estrogen receptor-positive breast cancer. *J Clin Oncol.* 2006;24:3726-3734.

Goldstein L, Gray R, Badve S, et al. Prognostic utility of the 21-gene assay in hormone receptor-positive operable breast cancer compared with classical clinicopathologic features. *J Clin Oncol.* 2008;26:4063-4071.

National Cancer Care Network, NCCN Clinical Practice Guidelines in Oncology: Breast Cancer, version 2/2015. www.NCCN.org last accessed 7/14/15.

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:
3/4/13	Medical Director	Review by oncology consultant. Approved by CAC.	1
10/18/13	CAC	Criteria renamed with generic name of 21-gene RT-PCR (real-time polymerase chain reaction) Assay (Oncotype DX [®]).	2
7/14/15	Medical Director	Added NCCN reference.	3
7/17/15	CAC	Added last paragraph in References Used.	4



Jason Kessler, MD

Ado-trastuzumab emutansine (Kadcyla)

Iowa Medicaid Program:	Prior Authorization	Effective Date:	8/15/2013
Revision Number:	3	Last Review Date:	7/17/2015
Reviewed By:	Medicaid Clinical Advisory Committee	Next Review Date:	7/2016
Approved By:	Medical Director	Approved Date:	11/18/2015

KADCYLA is a HER2-targeted antibody and microtubule inhibitor conjugate indicated, as a single agent, for the treatment of patients with HER2-positive, metastatic breast cancer who previously received trastuzumab and a taxane, separately or in combination.

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

1. Must have a diagnosis of metastatic breast cancer with verified HER2 positive.
2. Must have previously received trastuzumab and either paclitaxel or docetaxel, either concurrently or separately.
3. Must have previously received therapy for metastatic disease or developed new metastatic disease within six months of completing adjuvant therapy.

References Used:

Kadcyla package insert, 2/2013 revision

NCCN Guidelines on Breast Cancer v 2.2015, last accessed 7/14/15

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Change History:

Change Date:	Changed By:	Description of Change:	New Version Number:
7/18/14	CAC	Removed narrative that was a duplication of what is listed under criteria.	1
7/14/15	Medical Director	Updated NCCN reference	2
7/17/15	CAC	Added last paragraph in References Used.	3



Jason Kessler, MD

Back-up Ventilators Criteria

Iowa Medicaid Program:	Prior Authorization	Effective Date: 11/18/2013
Revision Number:	1	Last Review Date: 7/17/2015
Reviewed By:	Medicaid Clinical Advisory Committee	Next Review Date: 7/2016
Approved By:	Medicaid Medical Director	Approved Date: 7/30/2015

For Prior Authorization (PA) of a Back-up Ventilator, the member must meet **ONE** of the following criteria:

Criteria:

1. Respiratory assistive devices are covered when prescribed because the member's ability to breathe is severely impaired. Back-up ventilators can be approved for members who cannot maintain spontaneous ventilation for four or more consecutive hours.
2. Members who live in an area where a replacement ventilator cannot be provided within two hours.
3. Members who require mechanical ventilation during mobility as prescribed in their plan of care.

References Used:

Iowa Administrative Code 441 Chapter 78.10(5)K

American Association for Respiratory Care (AARC) Clinical Practice Guideline

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Change History:

Change Date:	Changed By:	Description of Change:	New Version Number:
7/17/15	CAC	Added last paragraph in References Used.	1



Jason Kessler, MD

BRCA I/II Testing Criteria

Iowa Medicaid Program:	Prior Authorization	Effective Date:	5/14/2008
Revision Number:	4	Last Review Date:	7/17/2015
Reviewed By:	Medicaid Clinical Advisory Committee	Next Review Date:	7/2016
Approved By:	Medicaid Medical Director	Approved Date:	7/30/2015

All BRCA I/II requests must go through physician review.

Criteria:

1. Members from a family with a known BRCAI/BRCAII mutation.
2. Members with a personal history of breast cancer plus ONE of the following:
 - a. Cancer diagnosed at age 45 or younger, regardless of family history.
 - b. Diagnosed at any age with one or more close blood relatives with breast cancer age 50 or younger and/or one or more close blood relative with epithelial ovarian cancer at any age.
 - c. Two breast primaries when first breast cancer diagnosis occurred prior to age 50.
 - d. Diagnosed age 60 or younger with a triple negative breast cancer.
 - e. Diagnosed age 50 or younger with a limited family history***.
 - f. Diagnosed at any age, with two close blood relatives** with breast cancer at any age.
 - g. Diagnosed at any age with two or more close blood relatives with pancreatic cancer or aggressive prostate cancer (Gleason score seven or more) at any age.
 - h. Close male blood relative** with breast cancer.
 - i. Personal history of epithelial ovarian/fallopian/primary peritoneal cancer.
 - j. Member is of ethnicity associated with deleterious mutations.
3. Members with a personal history of epithelial ovarian cancer.
4. Personal history of male breast cancer.
5. Personal history of pancreatic cancer or aggressive prostate cancer (Gleason score seven or more) at any age with two or more close blood relatives with breast and/or ovarian and/or pancreatic or aggressive prostate cancer (Gleason score seven or more) at any age.
6. Family history only:
 - a. First* or second-degree+ blood relative meeting any of the above criteria.
 - b. Third-degree* blood relative with breast cancer and/or ovarian cancer with two or more close blood relatives with breast cancer (at least one with breast cancer at 50 years old or younger) and/or ovarian cancer.

BART testing (for rearrangement) will be covered as a reflex test when BRCA I & II testing is negative.

*First Degree Relative - Any relative who is one-meiosis away from a particular individual in a family (i.e., parent, sibling, offspring).

+Second Degree Relative - Any relative who is two meioses away from a particular individual in a pedigree; a relative with whom one quarter of an individual's genes is shared (i.e., grandparent, grandchild, uncle, aunt, nephew, niece, half-sibling).

**Close blood relative – First, second and third-degree relatives (i.e., first cousin).

***Individuals with limited family history, such as fewer than two first or second degree female relatives or female relatives surviving beyond 45 years in either lineage, may have an underestimated probability of a familial mutation.

HCPC/CPT Codes:

83891	83894
38398	83912
83904	S3820 – Comprehensive

References Used:

NCCN Guidelines Hereditary Breast and Ovarian Cancer (HBOC01), version 1.2013

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

Change History:

Change Date:	Changed By:	Description of Change:	New Version Number:
3/27/13	Nick Ford, Clinical Assistant to the Medical Director	Reflection of new guidelines issued by NCCN	1
4/19/13	CAC	Removed Criterion #7	2
7/19/13	CAC	Criteria - added BART testing (for rearrangement) will be covered as a reflex test when BRCA I & II testing is negative.	3
7/17/15	CAC	Added last paragraph in References Used.	4



Jason Kessler, MD

CT/MRI for Incidental Lesions

Iowa Medicaid Program:	Prior Authorization	Effective Date:	8/15/2013
Revision Number:	1	Last Review Date:	7/17/2015
Reviewed By:	Medicaid Clinical Advisory Committee	Next Review Date:	7/2016
Approved By:	Medical Director	Approved Date:	7/30/2015

Criteria:

CT or MRI imaging may be approved when **ALL** of the following are met:

1. An abnormality has been noted on CT or MRI imaging of an adjacent area.
2. Further imaging of the area adjacent to the concerning finding is necessary to obtain more information about the finding or determine its extent.

CPT Codes:

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:
7/17/15	CAC	Added paragraph in References Used.	1



Jason Kessler, MD

Habilitation Level of Care Criteria

Iowa Medicaid Program:	Habilitation	Effective Date:	1/1/2007
Revision Number:	2	Last Review Date:	7/17/2015
Reviewed By:	Medicaid Clinical Advisory Committee	Next Review Date:	7/2016
Approved By:	Medicaid Medical Director	Approved Date:	8/3/2015

Medicaid members must meet **AT LEAST ONE** of the criteria in Section I **AND** must meet **AT LEAST TWO** of the criteria in Section II on a continuing **or** intermittent basis for *at least two years* in order to qualify for Habilitation services.

Criteria:

Section I

Risk factors. The member has **AT LEAST ONE** of the following risk factors:

1. The member has undergone or is currently undergoing psychiatric treatment more intensive than outpatient care e.g., emergency services, alternative home care, partial hospitalization, or inpatient hospitalization more than once in the member's life; or
2. The member has a history of psychiatric illness resulting in at least one episode of continuous, professional supportive care other than hospitalization.

Section II

Need for assistance. The member has a need for assistance demonstrated by meeting **AT LEAST TWO** of the following criteria on a continuing or intermittent basis for at least two years:

1. The member is unemployed, is employed in a sheltered setting, or has markedly limited skills and a poor work history.
2. The member requires financial assistance for out-of-hospital maintenance and is unable to procure this assistance without help.
3. The member shows severe inability to establish or maintain a personal social support system.
4. The member requires help in basic living skills such as self-care, money management, housekeeping, cooking, and medication management.
5. The member exhibits inappropriate social behavior that results in a demand for intervention.

References Used:

Iowa Administrative Code 441-78.27(2)

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:
7/14/15	Medical Director	First paragraph removed reference to admission and subsequent service review.	1
7/17/15	CAC	Added last paragraph in References Used.	2



Jason Kessler, MD

Idursulfase (Elaprase)

Iowa Medicaid Program	Prior Authorization	Effective Date:	1/1/2008
Revision Number:	4	Last Review Date:	7/17/2015
Reviewed By:	Medicaid Clinical Advisory Committee	Next Review Date:	7/2016
Approved By:	Medical Director	Approved Date:	7/30/2015

Criteria:

1. Only covered for confirmed diagnosis of mucopolysaccharidosis II (MPS II, Hunter Syndrome) in those age 5-65 years. (Safety and efficacy have not been established in pediatric patients less than 5 years of age. Clinical studies have not included patients over 65 and it is not known whether geriatric patients respond differently from younger patients).
2. In order to be approved for continuing treatment with Idursulfase (Elaprase) improvement on the medication must be documented with a 6-minute walk test.
 - a. The 6-minute walk test is recommended to be performed according to the American Thoracic Society guidelines available at:
<http://www.thoracic.org/statements/resources/pfet/sixminute.pdf>
 - b. This test was developed to evaluate mobility in patients with moderate to severe heart or lung disease, but is equally applicable in the patient with Hunter Syndrome (and other conditions). It is the only standard test which has been recommended for evaluation of walking in patients with MPS II.

Codes:

Drug - J1743 (1 mg)

References Used:

Shire Pharmaceuticals: Elaprase package insert (REV. 7, 11/2011)

<http://www.hunterpatients.com/healthcare-providers/pediatricians> Accessed 4/26/13

American Thoracic Society, ATS Statement: Guidelines for the Six-Minute Walk Test, March 2002. <http://www.thoracic.org/statements/resources/pfet/sixminute.pdf> Accessed 4/26/13

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

Change History:

Change Date:	Changed By:	Description of Change:	New Version Number:
7/27/12	CAC	generic name of medication and technical diagnosis name	1

Change History:

Change Date:	Changed By:	Description of Change:	New Version Number:
4/26/13	Medical Director	added details of drug indication and criteria around walking capacity at CAC request	2
7/19/13	CAC	Criterion #2 was removed and #3 became #2	3
7/17/15	CAC	Added last paragraph in References Used.	4



Jason Kessler, MD

Linear Accelerator Based Stereotactic Radiosurgery Criteria

Iowa Medicaid Program:	Prior Authorization	Effective Date:	5/14/2008
Revision Number:	3	Last Review Date:	7/17/2015
Reviewed By:	Medicaid Clinical Advisory Committee	Next Review Date:	7/2016
Approved By:	Medicaid Medical Director	Approved Date:	11/18/2015

Criteria:

At least ONE of the following criteria must be met:

1. For treatment of non-operable primary central nervous system tumors invading the spine.
2. For treatment of initial or recurrent primary brain malignancies for members otherwise in relatively good health.
3. Stereotactic radiosurgery is considered medically necessary for treatment of:
 - a. intracranial tumors in hard-to-reach locations; and
 - b. tumors with very unusual shapes; and
 - c. tumors located in such close proximity to a vital structure e.g., optic nerve or hypothalamus that even a very accurate high-dose single fraction of multi-source cobalt-60-based stereotactic radiosurgery could not be tolerated.
4. Arteriovenous malformations of the brain or spine that are not amenable to surgical resection.
5. Trigeminal neuralgia not responsive to medical management.
6. Essential tremor: coverage is limited to the patient who cannot be controlled with medication, has major systemic disease or coagulopathy, and who is unwilling or unsuited for open surgery. Coverage is further limited to unilateral thalamotomy. Gamma Knife pallidotomy remains non-covered and will be denied.

All other indications would not be covered as they are considered experimental, investigational or unproven.

Stereotactic Radiosurgery is not considered medically necessary under the following circumstances:

1. Treatment for anything other than a severe symptom or serious threat to life or critical functions.
2. Treatment unlikely to result in functional improvement of clinically meaningful disease stabilization, not otherwise achievable.
3. In patients, with more than three (3) primary or metastases lesions SRS is inappropriate and consideration should be given to whole brain irradiation.
4. Patients with wide spread cerebral or extra cranial metastases with limited life expectancy unlikely to gain clinical benefit within their remaining life.
5. Patients with poor performance status (Karnofsky Performance Status less than 40 or an ECOG Performance greater than 3).

CPT Codes:

Radiosurgery 77371 through 77373

References Used:

CMS LCD L30318, last accessed at CMS.gov on 7/14/15

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:
7/19/13	CAC	Criterion #3-c changed cobalt-60-bases to cobalt-60-based.	1
7/14/15	Medical Director	Added "at least one" of preface. Made other indications notation a separate paragraph. Added trigeminal neuralgia and thalamotomy for tremor and contraindications (as per CMS LCD L30318).	2
7/17/15	CAC	Added last paragraph in References Used.	3



Jason Kessler, MD

Memantine (Namenda) for Autistic Spectrum Disorder (ASD) Criteria

Iowa Medicaid Program:	Exception to Policy	Effective Date:	1/18/2013
Revision Number:	7	Last Review Date:	7/17/2015
Reviewed By:	Medicaid Clinical Advisory Committee	Next Review Date:	7/2016
Approved By:	Medicaid Medical Director	Approved Date:	9/4/2015

Criteria:

Memantine is an N-Methyl-D-Aspartic Acid (NMDA) receptor antagonist, approved by the United States Food and Drug Administration (FDA) for treatment of moderate to severe Alzheimer's Dementia in adults. It is an investigational treatment for children with autistic spectrum disorders. Several small, open-label studies and case series have supported its use for symptoms of hyperactivity, lethargy, irritability, language function and social behavior in at least a subset of this population, with strongest effects in verbal language function. There are currently no published randomized, placebo-controlled, blinded clinical trials published. No major medical societies have guidelines recommending its use.

Memantine is not covered under regular Medicaid for indications related to autism. It can only be considered under early and periodic screening, diagnosis and treatment program (EPSDT) as an exception to policy (ETP).

1. Children up to 21 years of age with autistic spectrum disorder (ASD) may be considered for memantine if **ALL** of the following are met:
 - a. Documentation is provided of **AT LEAST ONE** of the following behavioral abnormalities causing measurable problems in educational progress, home life or medical treatment:
 - Lethargy
 - Irritability
 - Deficits in expressive or receptive language function
 - Social withdrawal
 - Self-stimulatory stereotypic behaviors
 - b. Documentation is provided of **AT LEAST TWO** of the following have been used appropriately* for at least six months:
 - Risperidone
 - At least one Selective Serotonin Reuptake Inhibitor (SSRI)
 - At least one stimulant medication
 - Aripiprazole or quetiapine

*"used appropriately" means that the medication is used for an indication for which it is known to have an impact and that dose has been appropriately titrated, according to dosing recommendations of the manufacturer, or best available evidence. Providing a dosing reference is the responsibility of the provider when doses not approved by the manufacturer are used.
 - c. Therapeutic effects of the above medications, at optimal doses have been inadequate OR adverse reactions have occurred which required discontinuing the medication.
 - d. Ongoing intensive behavioral interventions have shown inadequate response.
 - e. A care plan is submitted for the member, including medication, behavioral and educational goals and plan.

- f. The medication is prescribed by a psychiatrist, psychiatric nurse practitioner or psychiatric physician assistant.
2. Initial ETPs meeting the above criteria can be approved for a six month trial. For continued approval after that time, **ALL** of the following must be met.
 - a. Clinically significant adverse effects of the medication have not been observed.
 - b. Compliance with the medication has been recorded.
 - c. The member has demonstrated significant clinical improvement of signs and symptoms as documented by **ALL** of the following:
 - Substantial improvement in target behaviors on subjective and/or objective reports from family, educational staff or clinical staff involved in the member's daily care
 - Sustained improvement in scores on a standardized, validated psychometric, behavioral OR educational evaluation tool
 - The clinical improvement has been validated by a licensed health care professional (other than the prescribing physician), and a member of the interdisciplinary team (other than the parent).
 3. Members who are over 21 years of age will not be approved through Medical Services.
 4. Memantine is considered investigational and will not be covered for the following:
 - a. Autistic spectrum disorder (ASD) not meeting the above criteria.
 - b. Down syndrome not associated with Alzheimer-type dementia
 - c. Attention-deficit hyperactivity disorder
 - d. Obsessive-compulsive disorder
 - e. Oppositional-defiant disorder
 - f. Depression
 - g. Intellectual disabilities not associated with ASD
 - h. Developmental disorders not associated with ASD
 - i. Parkinson's Disease
 - j. Chemical dependency/alcoholism
 - k. Pain syndromes
 - l. Glaucoma
 - m. Hypertension
 - n. AIDS dementia
 - o. Nystagmus
 - p. Migraines

References Used:

This criteria was developed with input from a panel of six (6) Iowa clinical psychiatrists. The pharmacy DUR mental health advisory group (MHAG), which had some overlap in membership was also invited to comment. (Spring/Summer of 2012).

[Clinicaltrials.gov/ct2/show/NCT01592773](https://clinicaltrials.gov/ct2/show/NCT01592773) Accessed 08-15-12

Doyle CA and McDougle CJ, Pharmacotherapy to control behavioral symptoms in children with autism. *Expert Opin. Pharmacother.* (2012) 13(11) 1615-1629.

A Systematic Review of Medical Treatments for Children With Autism Spectrum Disorders, McPheeters, et al. *Pediatrics*, Vol 127, No. 5, May 1, 2011.

References Used (cont.):

Comparative Effectiveness of Therapies for Children with Autism Spectrum Disorders: Clinician Guide. Agency for Healthcare Research and Quality, June 2011, 2 pp. Discusses the available evidence on the effectiveness, benefits, and harms of therapies used to address the core and associated symptoms seen among children aged 2-12 years with autism spectrum disorders. (AHRQ 11-EHC029-3).

Namenda prescribing information accessed from Namenda.com on 9-19-12

American Psychiatric Association. Diagnostic and Statistical Manual, 5th Ed. (DSM-V).

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Change History:

Change Date:	Changed By:	Description of Change:	New Version Number:
7/27/12	CAC	generic name of medication	3
10/19/12	Medical Director	Complete revision	4
7/18/14	Medical Director	Formatting changes	5
7/14/15	Medical Director	Criteria #1, #4a, and #4h removed reference to Pervasive Developmental disorder (PDD). Criterion #4g added "not associated with ASD". Under References Used, removed individual names and listed as "panel" and added DSM-V reference.	6
7/17/15	CAC	Added last paragraph in References Used.	7



Jason Kessler, MD

Natalizumab (Tysabri) Criteria

Iowa Medicaid Program	Prior Authorization	Effective Date:	1/1/2008
Revision Number:	3	Last Review Date:	7/17/2015
Reviewed By:	Medicaid Clinical Advisory Committee	Next Review Date:	7/2016
Approved By:	Medicaid Medical Director	Approved Date:	11/18/2015

Criteria:

1. Indicated as monotherapy for treatment of patients with relapsing forms of Multiple Sclerosis (MS).
 - a. Documentation must show the member has failed or is unable to tolerate the use of **at least one of the preferred medications.**
2. Indicated for the treatment of moderate to severely active Crohn's Disease.
 - a. Must have inadequate treatment response or documented contraindication to steroids and tumor necrosis factor inhibitors.
 - b. Documentation must show the member has had inadequate response to **at least two of the preferred medications including aminosalicylates (mesalamine, sulfasalazine), azathioprine/6-mercaptopurine, and/or methotrexate.**
3. Must not be used in conjunction with immunomodulators or immunosuppressants (due to risk of progressive multifocal leukoencephalopathy).
4. Prescribing physician must be part of the "TOUCH prescribing program."
5. Requires a prior authorization.
6. Must be administered only to patients who are enrolled in and meet all the conditions of the TOUCH™ Prescribing Program.

Codes:

Drug – J2323 (20 mg = 1ml or 15ml = 300mg)

References Used:

Biogen Idec Inc. Tysabri (natalizumab) prescribing information, revised 5/2015. Accessed at www.tysabri.com on 7/14/15

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Change History:

Change Date:	Changed By:	Description of Change:	New Version Number:
10/19/12	CAC	Criterion 1a was removed and 1b was reworded to "member has failed or is unable to tolerate the use..."	1
7/14/15	Medical Director	Added prescribing information reference.	2
7/17/15	CAC	Added last paragraph in References Used.	3



Jason Kessler, MD

Pegloticase (Krystexxa®)

Iowa Medicaid Program:	Prior Authorization	Effective Date:	8/20/2011
Revision Number:	3	Last Review Date:	7/17/2015
Reviewed By:	Medicaid Clinical Advisory Committee	Next Review Date:	7/2016
Approved By:	Medicaid Medical Director	Approved Date:	11/18/2015

Criteria:

1. Pegloticase (Krystexxa® 8 mg 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 gout.
 - ii. On a prevention regimen including adequate fluid intake, weight reduction, dietary purine reduction, reduction in alcohol consumption.
 - iii. Treatment failure of colchicine in a preventive regimen at a dose of at least 1.2 mg per day for at least six months.
 - iv. Treatment failure of **TWO** xanthine oxidase inhibiting agents including allopurinol for at least six months each or in combination.
 - v. Treatment failure of probenecid for at least six months at a dose of 500-2,000 gm twice daily and sulfipyrazone for at least six months.
 - b. Trials may be overridden with documentation from physician of a medical contraindication to the trial medication.

Codes:

Diagnoses of gout 275.0-274.9, V77.5

References Used:

www.medicinenet.com

www.medscape.com

Crealta Pharmaceuticals LLC. Krystexxa® (pegloticase) prescribing information. Revised 12/2014. Accessed at www.krystexxa.com on 7/14/15

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:
7/18/14	CAC	Under Criteria - removed treatment failure of at least two non-steroidal anti-inflammatory drugs (NSAIDs).	1
7/14/15	Medical Director	Added prescribing information reference.	2
7/17/15	CAC	Added last paragraph in References Used.	3



Jason Kessler, MD

Percussors Criteria

Iowa Medicaid Program:	Prior Authorization	Effective Date:	1/21/2011
Revision Number:	2	Last Review Date:	7/17/2015
Reviewed By:	Medicaid Clinical Advisory Committee	Next Review Date:	7/2016
Approved By:	Medicaid Medical Director	Approved Date:	7/30/2015

Criteria:

A home model, electric or pneumatic percussor is covered (for purchase only) when:

1. Member is not using a vibratory airway clearance device such as a high frequency chest wall oscillation (HFCWO) device; and
2. Prescribed for mobilizing respiratory tract secretions in patients with chronic obstructive lung disease, chronic bronchitis, or emphysema, cystic fibrosis, neuromuscular conditions with impaired cough, bronchiectasis or ciliary dyskinesia; and
3. The member or operator of powered percussor has received appropriate training by a physician or therapist; and
4. No one competent and physically able to administer manual therapy is available due to the length and intensity of the treatment; and
5. Long-term chest therapy is medically necessary.

HCPC Codes:

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:
7/14/15	Medical Director	Criterion #1 replaced "The Vest" with HFCWO device.	1
7/17/15	CAC	Added paragraph in References Used.	2



Jason Kessler, MD

Prophylactic Mastectomy Criteria

Iowa Medicaid Program:	Prior Authorization	Effective Date:	1/21/2011
Revision Number:	6	Last Review Date:	7/17/2015
Reviewed By:	Medicaid Clinical Advisory Committee	Next Review Date:	7/2016
Approved By:	Medicaid Medical Director	Approved Date:	11/18/2015

Criteria:

A member must meet **ONE** of the following:

1. Positive BRCA I or BRCA II mutation confirmed by testing (including rearrangements detected via BRAT).

OR

2. At least one first-degree relative* or at least two second-degree relatives+ who have breast cancer **and ONE** of the following:
 - a. A personal history of unilateral breast cancer.
 - b. A biopsy revealing Lobular Carcinoma in Situ.
 - c. A personal history of two breast primaries (includes bilateral disease or cases where there are two or more clearly separate ipsilateral primary tumors) when the first breast cancer diagnosis occurred prior to age 50.

*First Degree Relative - Any relative who is one-meiosis away from a particular individual in a family (i.e., parent, sibling, offspring).

+Second Degree Relative - Any relative who is two meioses away from a particular individual in a pedigree; a relative with whom one quarter of an individual's genes is shared (i.e., grandparent, grandchild, uncle, aunt, nephew, niece, half-sibling).

HCPCs Codes:

19303

19304

References Used:

http://www.nccn.org/professionals/physician_gls/pdf/breast_risk.pdf - Breast Cancer Risk Reduction version 1.2012.

Zagouri, F, Chrysikos DT, Sergeantanis TN, Giannakopoulou G, Zografos CG, Papadimitriou CA, Zografos GC.
Am Surg. 2013 Feb;79(2):205-12.Review.

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 - changed "all" of the following to "two" of the following.	1
3/26/13	PA staff Medical Director	Added HCPCs Codes. Added References Used.	2
7/19/13	CAC	Changed criteria to a member must meet criterion #1 or criterion #2 and one of criterion #3.	3
7/18/14	Medical Director	Formatting changes	4
7/14/15	Medical Director	Criterion #1 added "including rearrangements detected via BRAT".	5
7/17/15	CAC	Added last paragraph in References Used.	6

**Jason Kessler, MD**

Pulmonary Rehabilitation Criteria

Iowa Medicaid Program:	Retrospective Review	Effective Date:	7/1/2005
Revision Number:	6	Last Review Date:	7/17/2015
Reviewed By:	Medicaid Clinical Advisory Committee	Next Review Date:	7/2016
Approved By:	Medicaid Medical Director	Approved Date:	7/30/2015

Criteria:

General characteristics

Pulmonary rehabilitation is an individually tailored, multidisciplinary program through which accurate diagnosis, therapy, emotional support, and education stabilizes or reverses both the physio- and psychopathology of pulmonary diseases and attempts to return the patient to the highest possible functional capacity allowed by the pulmonary handicap and overall life situation.

Initial assessment

A comprehensive assessment must occur initially, including:

- A diagnostic workup which entails proper identification of the patient's specific respiratory ailment
- Appropriate pulmonary function studies
- A chest radiograph
- An electrocardiogram
- When indicated
 - arterial blood gas measurements at rest and during exercise
 - sputum analysis
 - blood theophylline measurements
- Behavioral considerations include:
 - emotional screening assessments, treatment, and/or counseling when required or appropriate
 - estimating the member's learning skills and adjusting the program's interaction with the member based on his/her ability to learn
 - assessing the member's family and social supports
 - potential employment skills and opportunities for the member
 - community support resources available for the member, as needed

Admission criteria

Criteria include the member being diagnosed with and symptomatic of chronic obstructive pulmonary disease (COPD), and having the following:

- Cardiac stability
- Ability to tolerate periods of sitting time
- Being a nonsmoker for six months, or if a smoker, willingness to quit and a physician's order to participate anyway

Factors which would make a person ineligible include, but are not limited to:

- Acute or chronic illness that may interfere with rehabilitation
- Any illness or disease state that affects comprehension or retention of information
- A strong history of medical noncompliance
- Unstable cardiac or cardiovascular problems
- Orthopedic difficulties that would prohibit exercise

Plan of treatment

- Individualized long- and short-term goals will be developed for each member participating in the program
- The treatment goals will be based on the problems and needs identified in the assessment and specify the regular times at which the plan will be reassessed,
- The members and their families need to help determine and fully understand the goals, so that they realistically approach the treatment phase
- Members are reassessed to determine current clinical problems, needs, and responses to treatment
- Changes in treatment are documented
- Components of pulmonary rehabilitation to be included are:
 - Physical therapy and relaxation techniques
 - Exercise conditioning or physical conditioning for those with exercise limitations
 - Respiratory therapy
 - Education
 - An emphasis on the importance of smoking cessation
 - Nutritional information

Discharge plan

- Ongoing care will generally be the responsibility of the primary care physician
- Periodic reassessment will be conducted to evaluate progress and allow for educational reinforcement

Restrictions and limitations on payment

Medicaid will pay for a maximum of 25 treatment days. Payment beyond 25 days is made when documentation indicates that the patient has not reached an exit level.

HCPCS codes:

S9473

References Used:

441 IAC 78.31(4)"g"

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Change History:

Change Date:	Changed By:	Description of Change:	New Version Number:
1/18/13	CAC	Criterion #7 added "if on theophylline".	1
2/28/13	Policy Staff	Replaced criteria from the provider manual with revised criteria to reflect details contained in 441 IAC 78.31(4)"g".	2
7/19/13	CAC	Criteria - remove the section on diagnosis and treatment staff.	3
10/4/13	Policy Staff	Added behavioral considerations under initial assessment.	4
7/18/14	CAC	Under Admission Criteria - removed absent social, family, and financial resources.	5
7/17/15	CAC	Added last paragraph in References Used.	6



Jason Kessler, MD

Reduction Mammoplasty/Mastopexy

Iowa Medicaid Program:	Prior Authorization; Claims Pre-pay	Effective Date:	7/1/2008
Revision Number:	6	Last Review Date:	7/17/2015
Reviewed By:	Medicaid Clinical Advisory Committee	Next Review Date:	7/2016
Approved By:	Medicaid Medical Director	Approved Date:	11/18/2015

Criteria:

1. The individual is at least 22 years of age and diagnosed with macromastia.
2. There **must** be **ALL** of the following conditions and/or symptoms for at least a **recent** continuous six-month trial with documented failure of appropriate conservative management:
 - a. Recurrent or persistent symptomatic submammary intertriginous rash
 - b. Chronic back, neck, shoulder or breast pain
 - c. Persistent shoulder grooving despite the use of support devices appropriate support bra, wide strap bra, or similar item.
3. **And at least ONE** of the following conditions and/or symptoms present:
 - a. Chronic headaches
 - b. Sleeping problems
 - c. Loss of sensation in the breast, arms, fingers
 - d. Difficulty exercising
4. Weight of tissue planned to be removed **from** each breast **must** be:
 - a. At least 500 grams for BMI of 29 or less
 - b. At least 700 grams for BMI of 30 or greater

CPT/HCPCS Codes:

19318 - Reduction mammoplasty
19316 - Mastopexy

References Used:

American Society of Plastic Surgeons, Evidence-based Clinical Practice Guideline: Reduction Mammoplasty. *Plast Reconstr Surg.* 2012 Oct;130(4):785-9. Accessed at www.plasticsurgery.org 7/14/15

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Change History:

Change Date:	Changed By:	Description of Change:	New Version Number:
1/18/13	CAC	Criterion #1 added "diagnosed with macromastia". Removed criterion #5.	1

Change History (cont):

Change Date:	Changed By:	Description of Change:	New Version Number:
7/19/13	CAC	Change criterion #2-a to be recurrent or persistent symptomatic, remove causing cellulitis, skin necrosis, and/or ulceration. Change criterion #4 to remove average from weight.	2
10/4/13	Policy Staff	Criterion #2c added "or similar item".	3
7/18/14	Medical Director	Formatting changes.	4
7/14/15	Medical Director	Added plastic surgery reference.	5
7/17/15	CAC	Added last paragraph in References Used.	6



Jason Kessler, MD

Strollers and Wheelchairs for Safety Criteria

Iowa Medicaid Program:	ETP/EPSTD	Effective Date:	9/05/2014
Revision Number:	1	Last Review Date:	7/17/2015
Reviewed By:	Medicaid Clinical Advisory Committee	Next Review Date:	7/2016
Approved By:	Medicaid Medical Director	Approved Date:	7/30/2015

Wheelchair and strollers are primarily mobility devices, but are occasionally needed to assure the safety of an individual who is otherwise ambulatory. This criteria will not apply when a deficit in age-appropriate ambulation exists. In that case, the request should be evaluated based on the mobility needs of the member, using the appropriate mobility-related criteria.

Criteria:

Documentation of **ALL** of the following must be submitted. If any of the below do not apply, specific information from the provider indicating the reason the criterion does not apply must be included:

1. The member has an impaired safety awareness.
2. The member has a history of placing self in a situation where safety is compromised or potentially severely compromised or such risk is predictable.
3. Caregivers are unable to mitigate safety risk.
4. Use of a stroller or wheelchair for the sole purpose of safety for recreational activities and family outings such as shopping is not sufficient. The member must require the device for safety in other environments necessary for health and well-being.
 - a. Necessary environments include:
 - i. Medical or therapy appointments
 - ii. Environments necessary for education or work
 - iii. Transportation to other necessary environments
 - iv. Environments required for the free practice of religion
 - v. Other environments when supported by medical documentation
 - b. Documentation should support the medical need of the member to be in the potentially dangerous situation requiring use of a stroller or wheelchair for safety.
5. The needs of the member cannot be met by a less costly means, such as:
 - a. Avoidance of situations in which the member is prone to safety risks
 - b. Behavioral management of unsafe behaviors
 - c. Manipulation of the environment to reduce risk
 - d. Less costly devices or more efficient use of devices already available. This may include use of seat belts, closing and locking doors, fences and home security systems, motion detectors or GPS-enabled location devices.
 - e. Medical management, when appropriately prescribed by a licensed provider
6. Behavioral methods of decreasing risk have not been successful or are not clinically indicated for specified reasons.

7. A plan of use for the stroller or wheelchair is submitted and includes all of the following:
 - a. The device (referring to stroller or wheelchair) must be needed in the community setting, but need not be exclusively for community use. (The device cannot be exclusively used in the home, school, or in an institutional setting.)
 - b. The member is never to be unattended in the device. It is not a part of a respite or break plan for caregivers, or for purposes of allowing caregiver focus to be more easily shifted from the care of the member.
 - c. A maximum hours of daily use, based on anticipated activities and an assessment of the tolerance of the member.
8. The device is to be used for safety only and not for discipline, restraint, or as a substitute for supervision.

Documentation must be provided from a physical or occupational therapist, or physician/PA/NP verifying that the requested device is appropriate and necessary for the member's well-being.

Codes:

- E1236 – Convoid Cruiser (2241/1885) (includes Convoid Scout, Convoid EZ Rider)
- E0960 – 5-point harness (165)
- E0978 – Pelvic Positioning belt
- E0960 – Chest harness
- E1228 – Back Frame modification
- E1037 Transport Chair, pediatric size (includes Convoid Metro)

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:
7/17/15	CAC	Added paragraph in References Used.	1



Jason Kessler, MD

Zytaze

Iowa Medicaid Program:	Prior Authorization	Effective Date:	4/26/2011
Revision Number:	1	Last Review Date:	7/17/2015
Reviewed By:	Medicaid Clinical Advisory Committee	Next Review Date:	7/2016
Approved By:	Medical Director	Approved Date:	7/30/2015

Criteria:

1. Zytaze (zinc citrate 25 mg and phytase 1500mg) is covered for use in patients approved for botulinum toxin injections for blepharospasm and hemifacial spasm.
2. Zytaze is a pre-treatment for four days prior to procedure.
 - a. It is taken twice a day for four days prior to and on the day of treatment.
3. Quantity limit is 10 capsules per approved procedure.

Codes:

References Used:

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Change History:

Change Date:	Changed By:	Description of Change:	New Version Number:
7/17/15	CAC	Added paragraph in References Used.	1



Jason Kessler, MD

Oritavancin (Orbactiv™) Criteria

Iowa Medicaid Program	Prior Authorization	Effective Date:	11/18/2015
Revision Number:		Last Review Date:	7/17/2015
Reviewed By:	Medicaid Clinical Advisory Committee	Next Review Date:	7/2016
Approved By:	Medicaid Medical Director	Approved Date:	11/18/2015

Oritavancin diphosphate (Orbactiv™) is indicated for acute bacterial skin and skin structure infections (ABSSSI). The recommended dosage for oritavancin diphosphate is a 1,200 mg single dose administered by intravenous infusion over three hours.

Criteria - ALL OF the following must be met:

1. An adult patient with acute bacterial skin and skin structure infections (ABSSSIs) caused or suspected to be caused by susceptible isolates of the following Gram-positive microorganisms: *Staphylococcus aureus* (including methicillin-susceptible [MSSA] and-resistant [MRSA] isolates), *Streptococcus pyogenes*, *Streptococcus agalactiae*, *Streptococcus dysgalactiae*, *Streptococcus anginosus* group (includes *S. anginosus*, *S. intermedius*, and *S. constellatus*) and *Enterococcus faecalis* (vancomycin-susceptible isolates only).; and
2. A patient-specific, clinically significant reason why the member cannot use vancomycin, linezolid (Zyvox®) or other cost-effective therapeutic equivalent medication(s).

A quantity limit of three vials per 30 days will apply.

Codes:

J3490
C9444

References Used:

Oklahoma Health Care Authority
Sep 29, 2014 - Update on Medication **Coverage** Authorization Unit/FDA Safety ... 30-Day Notice to Prior Authorize Sivextro™ (Tedizolid), Dalvance™ (Dalbavancin), and **Orbactiv™** Update the Anticoagulant Prior Authorization **Criteria**.
<http://www.okhca.org/providers.aspx?id=1228&terms=Orbactiv>. Accessed 6/29/15

Orbactiv® (oritavancin) product insert. Accessed at <http://www.orbactiv.com> on 6/29/15

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Change History:

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



Jason Kessler, MD

Fluocinolone acetate intravitreal implant (Iluvien® and Retisert)

Iowa Medicaid Program:	Prior Authorization	Effective Date:	11/18/2015
Revision Number:		Last Review Date:	7/17/2015
Reviewed By:	Medicaid Clinical Advisory Committee	Next Review Date:	7/2016
Approved By:	Medicaid Medical Director	Approved Date:	11/18/2015

Criteria:

Fluocinolone acetate intravitreal implant 0.59 mg for surgical implantation (Retisert) is indicated for chronic non-infectious uveitis. It is a 30-month topical steroid releasing mechanism. Fluocinolone acetate intravitreal implant (Iluvien®) 0.19 mg is FDA indicated for chronic diabetic macular edema (DME). It lasts 36 months. Side effects include cataracts (very high incidence) and increased intraocular pressure (IOP).

For uveitis (Retisert):

1. Contraindicated and not covered in the presence of infection
2. Member must have trial and failure or contraindication to:
 - a. Steroid drops such as prednisone or difluprednate OR;
 - b. Periocular injection of a glucocorticoid

For DME (Iluvien®):

1. Member must have had a previous course of corticosteroids without a clinically significant rise in IOP.
2. Member must have trial and failure or contraindication to anti-VEGF therapy (aflibercept, bevacizumab, pegaptanib, ranibizumab).

Codes:

J7311

References Used:

Up-ToDate (Uveitis:Treatment) Accessed today

Retisert and Iluvien® prescribing information

J Ocul Pharmacol Ther. 2013 Jun;29(5):501-7. doi: 10.1089/jop.2012.0180. Epub 2013 Jan 8.,

Drugs. 2013 Feb;73(2):187-93. doi: 10.1007/s40265-013-0010-x

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Change History:

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



Jason Kessler, MD