Provider Press

December 2013 / Vol. 17, No. 4

For the health of all.

Health Literacy

Health Literacy is a bigger issue than you may realize. Most patients struggle to understand the information they are given regarding medication regimens, treatment protocols and how to coordinate their care between multiple doctors and specialists. It is imperative that all members of the care team understand how low health literacy can impact treatment effectiveness and health outcomes. To help with this, the Center for Health Care Strategies recently released a new series of health literacy fact sheets.

These fact sheets were created to help clinicians, patient advocates and other stakeholders improve care for patients with low health literacy. You can access the individual fact sheets below, or download the full packet using the link below.

FACT SHEETS

1. What is Health Literacy?
2. How is Low Health Literacy Identified?
3. Health Literacy and the Role of Culture
4. Improving Print Communication to Promote Health Literacy
5. Improving Oral Communication to Promote Health Literacy
6. Health Literacy: Policy Implications and Opportunities

To learn more about building a culture of health literacy at your practice, contact Alisha_Ellwood@bluecrossmn.com

To download the entire packet of fact sheets click here
http://www.chcs.org/usr_doc/CHCS_Health_Literacy_Fact_Sheets_2013.pdf

Provider Press

Provider Press is a quarterly newsletter available online at **providers.bluecrossmn.com**. Issues are published in March, June, September and December.

Inside preview

FYI

Publications available online

The following is a list of Quick Points and Bulletins published from September 2013 to November 2013 that are available online at **providers.bluecrossmn.com**. As a reminder, Bulletins are mailed to all participating providers affected by the information. Quick Points are available only on our website unless noted otherwise in the bottom left corner of the publication.

Quick Points	Title
QP18-13	Provider information for ICD-10 provider partner testing with Blue Cross
QP18R1-13	Revised: Provider information for ICD-10 provider partner testing with Blue Cross
QP19-13	Modifier NR is required for DME on rental to purchase changes
QP20-13	New Consumer Value network for individuals, families and small businesses
QP21-13	ICD-10 survey
QP2R1-13	Revised: ICD-10 survey
QP22-13	Behavioral health recovery request for underpayments of MA and Ph.D. level claims
QP23-13	Medical record retrieval coordinator for Affortable Care Act programs
QP24-13	Quality Improvement Project for SecureBlue (HMO-SNP) and Blue Essentials (HMO-POS) subscribers
QP25-13	Durable Medical Equipment (DME) changes for some MHCP subscribers
QP26-13	Provider cost data update
Bulletins	**Title**
P4R3-13	Revised: Changes to the National Drug Code submission on Minnesota health Care programs (MHCP) claims
P24-13	Positive airway pressure devices for the treatment of obstructive sleep apnea
P25-13	Reminder of Medicare training and education requirements
P25R1-13	Revised: Reminder of Medicare training and education requirements
P26-13	October 2013 ICD-9-CM and HCPCS code updates
P27-13	Medicare processing guidelines for durable medical equipment in a Skilled Nursing Facility or in a Nursing Facility
P28-13	Change in PCA billing requirements
P29-13	New collaborative process for PMAP/MNCare birth notification
P30-13	Changes to Blue Plus MHCP prior authorization list
P31-13	Medicare coverage of chiropractic services to treat acute or chronic subluxation
P32-13	Mental Health Targeted Case Management services
P33-13	Post-operative pain block recovery request and edit removal notification
P34-13	PPACA Preventive Benefit Package Changes for 2014

Provider Demographic Change Form

The Provider Demographic Change form needs to be completed when your address, phone number, hospital affiliation or office hours change. Go to **providers.bluecrossmn.com** and enter "provider demographic change form" in the search window to obtain the form. Completed forms can be:

Emailed to Provider_Data@bluecrossmn.com

Faxed to **(651) 662-6684**

Mailed to:

Blue Cross and Blue Shield of Minnesota
PDO, R316
P.O. Box 64560
St. Paul, MN 55164-0560

FYI

Provider Manual Updates

The following is a list of Blue Cross and Blue Shield of Minnesota provider manuals that have been updated from September 2013 to November 2013. As a reminder, provider manuals are available online at **providers.bluecrossmn.com**. To view the manuals, select "Forms & publications," then "manuals." Updates to the manuals are documented in the "Summary of changes" section of the online manuals.

Manual name	Chapter number and title	Change
Provider Policy and Procedure Manual	Chapter 8, Claims Filing	New topic added: Prepaid Medical Assistance (Blue Advantage PMAP & MSC) and MinnesotaCare Content change: Claims filing
Provider Policy and Procedure Manual	Chapter 11, Coding Policies and Guidelines, Behavioral Health section	New topics added: • Pre-certification and concurrent review for children's and adolescent residential mental health services • Pre-certification and concurrent review for eating disorder residential services • Pre-certification and concurrent review for residential substance use disorder services
Provider Policy and Procedure Manual	Chapter 11, Coding Policies and Guidelines, Durable Medical Equipment section	New topic added: Medicare guidelines for processing of oxygen and oxygen equipment
Provider Policy and Procedure Manual	Chapter 11, Coding Policies and Guidelines, Maternity section	New topics added: • Free Standing Birth Centers • Licensed Traditional Midwifes
Provider Policy and Procedure Manual	Chapter 11, Coding Policies and Guidelines, Public Programs section	Content change: Child and Teen Checkups
Provider Policy and Procedure Manual	Chapter 11, Coding Policies and Guidelines, Surgical Services section	Content change: Liposuction edit change
Blue Plus Manual	Chapter 3, Government Programs	Content changes: • Changed the number of visits allowed for Family Health Protocol • Added Timely Filing Exception

FYI

Helpful phone numbers	
BLUELINE (voice response unit)	**(651) 662-5200** or **1-800-262-0820**
BlueCard® member benefits or eligibility	**1-800-676-BLUE (2583)**
FEP® (voice response unit)	**(651) 662-5044** or **1-800-859-2128**
Availity	**1-800-282-4548**
Provider services	**(651) 662-5200** or **1-800-262-0820**
Please verify these numbers are correctly programmed into your office phones.	

Really Simple Syndication

Not all provider publications are mailed out to providers. The majority of our informational Quick Points and the quarterly Provider Press are posted to our website for providers to view. Providers frequently ask us how they can be advised when new publications are added to the website at **providers.bluecrossmn.com**.

Providers can sign up to get RSS (really simple syndication) feeds of our latest news releases and updates to provider-related forms and publications. A sample of the feeds that can be requested includes:

- Bulletins
- Forms: admin updates and contracting
- Forms: chemical dependency
- Forms: credentialing
- Forms: pre-certification and pre-authorization
- Manuals
- Provider Press
- Quick Points

Go to **providers.bluecrossmn.com** and enter "RSS" in the search window to learn more about RSS. Questions about RSS feeds specific to your internal systems should be directed to your IT support area.

Coding corner

Anesthesia Modifier Restriction

The anesthesia modifiers AA, AD, QK, QX, QY and QZ should only be reported with the CPT American Society of Anesthesiologists codes (ASA) codes 00100-01999. Other services (such as nerve blocks), may be performed by an anesthesiologist or CRNA, but should not be submitted with an anesthesia modifier. If an anesthesia modifier is appended to other than ASA codes that service will be denied.

Ear wax edit change

The edit between ear wax removal (69210) and an evaluation and management (E/M) service submitted on the same day has been reversed. Code 69210 will now deny incidental to an E/M. The policy indicating the opposite in the online Blue Cross Provider Policy and Procedure Manual will be corrected.

Coding edit decisions

Several edits have been reviewed. The code edits and decisions are listed below.

Codes and Edits	Decision/Actions
0256T denied invalid modifier with the -62 modifier	Edit removed 8/5/13
58350-59 denied incidental against 58662	Edit removed 8/5/13
E/M denied as incidental to 69210	Edit reversed 8/5/13; 69210 denies incidental to an E/M
No edit between G0268 and an E/M	Edit added 8/5/13; G0268 denies incidental to an E/M

Happy Coding Holidays!

'Tis the first part of December and all of the HCPCS codes are here.
Getting them loaded is nothing to fear.
We wish your updates are a success.
And we'll accept all new codes so there will be no mess.

We would like to remind you that the added, revised and discontinued codes for January 1, 2014 will be recognized and accepted by that date. A bulletin will be issued before the effective date to reiterate this information but sorry, we can't include the codes.

2014 Holiday schedule

Provider services will be closed on the following days in 2014:

Wednesday, January 1

Monday, May 26

Friday, July 4

Monday, September 1

Thursday, November 27

Friday, November 28

Thursday, December 25

Friday, December 26

With the exception of the dates stated above, representatives answering the provider services numbers are available to assist you 8 a.m. to 5 p.m. Monday through Thursday, and 9 a.m. to 5 p.m. on Friday.

Quality Improvement

PCC Quality of Care Complaint Report

Providers are required to complete the Blue Plus Quality of Care Complaint report for all written and verbal complaints from Blue Plus, Prepaid Minnesota Assistance Program and MinnesotaCare subscribers on a quarterly basis, per Minnesota Department of Health regulations. Complaints logged at the provider offices are to be investigated and resolved by the provider's office whenever possible.

These complaints are reported to Blue Plus in January, April, July and October for the preceding three months. The Primary Care Clinic (PCC) must submit a quarterly report even if the facility does not receive any complaints for the quarter. Your contract outlines the procedures required for your Quality of Care (QOC) PCC complaint reporting adherence agreement.

Complaints should no longer be directed to the attention of a single designated person. Sending your PCC QOC complaint report form to any source not listed below may delay the processing of your PCC QOC complaint report.

To access the PCC Blue Plus Quality of Care Complaint Report Form, go to **providers.bluecrossmn.com** and select "Forms & publications," then "forms - clinical operations."

Submit quarterly PCC QOC reports using one of these methods:

Email: pcc_complaint@bluecrossmn.com

Secure fax line: **651-662-4004**

Mail: Blue Plus
Attn: Quality Health Management Dept.
Route 4-72
P.O. Box 64179
St. Paul, MN 55164-0179

Blue Plus Reminders

Pharmacy Benefit for aspirin, calcium and vitamin D for seniors with Medicaid coverage

Blue Plus successfully completed the active phase of a project to increase the appropriate use of aspirin, calcium and vitamin D among seniors, and wants to continue the trend. A pharmacy benefit is provided for these supplements for seniors with SecureBlue℠ (MSHO) and Blue Advantage (MSC+) coverage. When physicians, nurses and pharmacists prescribe covered supplements, you increase the likelihood of patients using them by reducing the financial barrier.

Please write prescriptions for low-dose aspirin, calcium and vitamin D for seniors who can benefit from them. Contact provider services at **(651) 662-5200** or **1-800-262-0820** if you have questions about pharmacy benefits.

Human Papillomavirus (HPV) vaccination

Blue Plus successfully completed the active phase of a project to increase HPV vaccination among girls and young women with Prepaid Medical Assistance Program (PMAP) and MinnesotaCare coverage, and wants to continue the trend.
HPV vaccination has been shown to reduce the risk of cervical cancer.

The Center for Disease Control and American Academy for Pediatrics recommend vaccinating 11- and 12-year-old girls and catching up with vaccination for females ages 13 to 26.

Please:

- discuss the benefits of HPV vaccination with young women and parents or guardians of minor children,
- recommend vaccination and
- complete the 3-shot vaccination series for members who agree.

Use of statins for lipid management among members with coronary heart disease and/or diabetes

Blue Plus encourages continued clinical efforts to increase continuous use of statin drugs to reduce low density lipoprotein (LDL) cholesterol, particularly for members with coronary heart disease and/or diabetes. Blue Plus successfully completed the active phase of a project to increase use of statins among this population who have Prepaid Medical Assistance Program (PMAP) and MinnesotaCare coverage.

Medical and Behavioral Health Policy Update

Medical and behavioral health policies are available for your use and review on the Blue Cross and Blue Shield of Minnesota website at **providers.bluecrossmn.com.** From this site, there are two ways to access medical policy information depending on the patient's Blue Plan membership.

For out-of-area Blue Plan patients:

Select "Medical Policy PreCert/PreAuth Router" and click Go. You will be taken to the page where you select either medical policy or pre-certification/prior authorization and enter the patient's three-letter alpha prefix as found on their member identification card, and click Go. Once you accept the requirements, you will be routed to the patient's home plan where you can access medical policy or pre-certification/pre-authorization information.

For local Blue Cross and Blue Shield of Minnesota plan patients:

Select "Medical policy" (under the Tools & Resources), read and accept the Blue Cross Medical Policy Statement, and then select "View All Active Policies." You have now navigated to the Blue Cross and Blue Shield of Minnesota Medical and Behavioral Health Policy Manual, where there are several selections to assist with your inquiry.

The "What's New" section identifies our latest new or revised policies approved by Blue Cross' Medical and Behavioral Health Policy Committee at least **50** days ago. These policies are now effective, and providers should begin following these policies immediately. These policies also appear in the "Active Policy" section of the Medical and Behavioral Health Policy Manual.

The "Upcoming Policies" section lists new or revised policies approved by the Blue Cross Medical and Behavioral Health Policy Committee and are effective **50** days from the date they were posted to the "Upcoming Policies" section of the Medical and Behavioral Health Policy Manual.

The "Active Policy" section contains the entire list of policies effective at the time of your inquiry. Please note, DHS Programs (Coverage Guidelines for DHS Programs - MHCP Manual) and Medicare Contractors (Part A – National Government Services [NGS], Part B – National Government Services [NGS], Home Health and Hospice – National Government Services [NGS], Durable Medical Equipment Medicare Administrative Contractor – National Government Services [NGS], and The Centers for Medicare and Medicaid Services – CMS) have separate sections.

The "Pre-Certification/Pre-Authorization" section identifies various services, procedures, prescription drugs, and medical devices that require pre-certification/pre-authorization. The following Pre-Certification/Pre-Authorization Lists are provided for review: Commercial (including BlueLink TPA), MN Government Programs, and Blue Essentials (HMO-POS). These lists are not exclusive to medical policy services only; they encompass other services that are subject to pre-certification/pre-authorization requirements.

If you have additional questions regarding medical or behavioral health policy issues, call provider services at **(651) 662-5200** or **1-800-262-0820** for assistance.

Medical and Behavioral Health Policy Update

Medical and Behavioral Health Policy Activity

Policy Effective: 10/01/13 Notification Posted: 08/16/13

Policies developed

H.P. Acthar® Gel (Repository Corticotropin)

- Pre-Certification/Pre-Authorization: Yes
- Intramuscular or subcutaneous injection of H.P. Acthar® Gel (repository corticotropin) may be considered MEDICALLY NECESSARY for patients who meet ALL of the following criteria:

A. The patient does not have a contraindication to therapy (e.g., scleroderma, osteoporosis, systemic fungal infection, ocular herpes simplex, recent surgery, history or presence of a peptic ulcer, congestive heart failure, uncontrolled hypertension, sensitivity to proteins of porcine origin, concomitant use of live or live attenuated vaccines, suspected congenital infection in children under 2 years of age, primary adrenocortical insufficiency or adrenocortical hyperfunction).
AND

B. The patient has been diagnosed with ONE of the following conditions:
1. Infantile spasms (West syndrome); AND
   a. The patient is under 2 years of age; AND
   b. The dose is within 150 IU/m2 intramuscular in divided doses daily for 2 weeks, followed by a gradual taper (e.g., 30 IU/m2 in the morning for 3 days, 15 IU/m2 in the morning for 3 days, 10 IU/m2 in the morning for 3 days, and 10 IU/m2 every other morning for 6 days).
   Length of approval: 6 months

OR

2. Multiple sclerosis; AND
   a. The patient is an adult experiencing an acute exacerbation; AND
   b. The patient has failed corticosteroid therapy within the last 30 days or has a contraindication to corticosteroid therapy; AND
   c. The dose is within 80-120 IU intramuscular or subcutaneous daily for 2-3 weeks.
   Length of approval: 1 month

- Intramuscular or subcutaneous injection of H.P. Acthar® Gel (repository corticotropin) is considered INVESTIGATIVE for diagnostic testing of adrenocortical function.
- Intramuscular or subcutaneous injection of H.P. Acthar® Gel (repository corticotropin) is considered INVESTIGATIVE for ALL other indications due to the lack of clinical evidence demonstrating effectiveness or an impact on improved health outcomes.

Policies Effective: 10/21/13 Notification Posted: 08/29/13

Policies developed

None

Policies revised

Hematopoietic Stem-Cell Transplantation for Miscellaneous Solid Tumors in Adults

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- Pre-Certification/Pre-Authorization: Not applicable.
- Autologous OR allogeneic hematopoietic stem-cell transplantation (HSCT) is considered INVESTIGATIVE for the following malignancies in adults:
  - Lung cancer, any histology
  - Colon cancer
  - Rectal cancer
  - Pancreas cancer
  - Stomach cancer
  - Esophageal cancer
  - Gall bladder cancer
  - Cancer of the bile duct
  - Renal cell cancer
  - Cervical cancer
  - Uterine cancer
  - Cancer of the fallopian tubes
  - Epithelial ovarian cancer
  - Breast cancer
  - Prostate cancer
  - Nasopharyngeal cancer
  - Paranasal sinus cancer
  - Neuroendocrine tumors
  - Soft tissue sarcomas
  - Thyroid tumors
  - Tumors of the thymus
  - Tumors of unknown primary origin
  - Malignant melanoma

Interspinous Process Spacers

- Pre-Certification/Pre-Authorization: Not applicable
- Interspinous process spacers, including interspinous distraction spacers and interlaminar stabilization spacers, are considered INVESTIGATIVE for all indications, due to a lack of evidence demonstrating an impact on improved health outcomes.

Single Photon Emission Computed Tomography (SPECT) for Mental Health Disorders

- Pre-Certification/Pre-Authorization: Not applicable.
- Single photon emission computed tomography (SPECT) for evaluation and treatment planning for all mental health disorders is considered INVESTIGATIVE, due to a lack of evidence demonstrating an impact on improved health outcomes. These disorders include, but are not limited to:
  - Attention-deficit/hyperactivity disorder (ADHD)
  - Autism spectrum disorders
  - Cognitive or mental health disorders related to a medical condition.

Medical and Behavioral Health Policy Update

Sleep Disorder Testing in Adults

- Pre-Certification/Pre-Authorization: No.
- Polysomnography – Initial Study
  Supervised polysomnography performed in a sleep laboratory may be considered MEDICALLY NECESSARY as a diagnostic test in patients with:
  A. One of following
     1. Observed apneas during sleep;
     2. Moderate or severe congestive heart failure, stroke/transient ischemic attack, coronary artery disease or significant tachycardia or bradycardic arrhythmias in patients who have nocturnal symptoms suggestive of a sleep-related breathing disorder or otherwise are suspected of having sleep apnea;
     3. Obesity hypoventilation syndrome.

  OR

  B. At least two of the following:
     1. Excessive daytime sleepiness evidenced by an Epworth Sleepiness Scale greater than 10, inappropriate daytime napping (e.g., during driving, conversation or eating), or sleepiness that interferes with daily activities and is not explained by other conditions;
     2. Habitual snoring, or gasping/choking episodes associated with awakenings;
     3. Documented hypertension;
     4. A body mass index greater than 35 kg/m2;
     5. Craniofacial or upper airway soft tissue abnormalities.
- Polysomnography – Repeat Study
  Repeat supervised polysomnography performed in a sleep laboratory may be considered MEDICALLY NECESSARY under any of the following circumstances:
  A. To initiate and titrate continuous positive airway pressure (CPAP) when split-night PSG on the initial study is not feasible in adult patients with clinically significant OSA defined as those patients who have one of the following:
     1. An AHI of 15 or greater;

     OR

     2. An AHI between 5 and 14 with any of the following associated symptoms:
        a. Excessive daytime sleepiness
        b. Documented hypertension
        c. Ischemic heart disease
        d. History of stroke

  B. To assess efficacy of treatment (e.g., CPAP, oral appliances, surgery);

  OR

  C. To re-evaluate the diagnosis of obstructive sleep apnea and need for continued CPAP. Examples include significant change in weight or change in symptoms suggesting that CPAP should be re-titrated or possibly discontinued.
- Unattended Portable Sleep Study: Initial Study
  A. A single unattended portable sleep study in the home or clinic setting with a Type II or III device (minimum of 4 recording channels including oxygen saturation, respiratory movement, ECG or heart rate and airflow) may be considered MEDICALLY NECESSARY under the following circumstances:
     1. Performed and interpreted under the supervision of a physician;

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AND

2. Patient meets ALL of the following:
   a. Habitual snoring and/or observed apneas;

AND

   b. Excessive daytime sleepiness (Epworth sleepiness scale score greater than 10);

   AND

   c. Patient has no evidence by history or physical examination of a health condition that might alter ventilation or require alternative treatment, including any of the following:
      - Central sleep apnea;
      - Congestive heart failure;
      - Moderate to severe chronic pulmonary disease;
      - Pulmonary hypertension;
      - Obesity hypoventilation syndrome;
      - Narcolepsy;
      - Periodic limb movements in sleep;
      - Restless leg syndrome.

B. Unattended sleep studies are considered INVESTIGATIVE for all other indications including but not limited to the following due to a lack of evidence demonstrating improved health outcomes.
   1. Unattended portable sleep studies with a Type IV device or any device that does not record RDI/AHI and also simultaneously record oxygen saturation, heart rate and respiratory analysis.
   2. The use of overnight pulse oximetry to screen patients for sleep apnea.

- Unattended Portable Sleep Study – Repeat Study

  Repeat unattended portable sleep studies with a minimum of four recording channels (including oxygen saturation, respiratory movement, airflow, and ECG/heart rate) may be considered MEDICALLY NECESSARY in adult patients under the following circumstances when performed and interpreted under the supervision of a physician.

  A. To assess efficacy of surgery or oral appliances/devices;

  OR

  B. To re-evaluate the diagnosis of OSA and need for continued CPAP. Examples include significant change in weight or change in symptoms suggesting that CPAP should be re-titrated or possibly discontinued.

- Multiple consecutive nights of attended or unattended portable sleep studies that do not meet criteria for repeat studies are considered INVESTIGATIVE due to a lack of evidence demonstrating improved health outcomes.
- Use of an abbreviated daytime sleep study (e.g. PAP-NAP) as a supplement to standard sleep studies is considered INVESTIGATIVE due to a lack of evidence demonstrating improved health outcomes.
- Multiple Sleep Latency Testing (MSLT)

  A. MSLT is considered MEDICALLY NECESSARY to exclude or confirm narcolepsy in patients with the following:
     1. Symptoms characteristic of narcolepsy including cataplexy, hypnagogic hallucinations and/or sleep paralysis;

     OR

     2. Epworth Sleepiness Scale score greater than 10 with an AHI or RDI of 5 or less on PSG.

  B. MSLT is considered INVESTIGATIVE for all other indications including but not limited to assessing the effectiveness of therapy or the routine evaluation of patients who are suspected of having excessive sleepiness due to OSA, insomnia, circadian rhythm disorders, periodic limb movement disorder, medical disorders or neurologic disorders.

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There is a lack of evidence demonstrating improved health outcomes.

C. MSLT is considered INVESTIGATIVE for all other indications including but not limited to assessing the effectiveness of therapy or the routine evaluation of patients who are suspected of having excessive sleepiness due to OSA, insomnia, circadian rhythm disorders, periodic limb movement disorder, medical disorders or neurologic disorders. There is a lack of evidence demonstrating improved health outcomes.

- Maintenance of wakefulness testing (MWT) is considered INVESTIGATIVE for evaluation, diagnosis or assessment of response to therapy for OSA due to a lack of evidence demonstrating improved health outcomes.

Sleep Studies/Polysomnograms in Children and Adolescents

- Pre-Certification/Pre-Authorization: No.
- Supervised Polysomnography

A. Supervised polysomnography performed in a sleep laboratory may be considered MEDICALLY NECESSARY as a diagnostic test in children and adolescents for the following situations when habitual snoring is present:

1. Excessive daytime sleepiness that interferes with daily activities and is not explained by other conditions, or the patient exhibits behavior that may indicate increased efforts to stay awake such as difficulty in attentiveness, hyperactivity, aggressive or disruptive behavior;
2. Failure to thrive;
3. Cor pulmonale;
4. Polycythemia;
5. Down's or Pierre Robin syndrome or any craniofacial abnormalities resulting in mid or lower facial disorders;
6. Sickle cell disease;
7. Obesity defined as BMI greater than the 95th percentile for age and gender;
8. Neuromuscular disease;
9. Adenotonsillar hypertrophy, when the only indication for performing the tonsillectomy and adenoidectomy is the presence of obstructive sleep apnea.

B. Supervised polysomnography performed in a sleep laboratory may be considered MEDICALLY NECESSARY as a diagnostic test in children and adolescents for the following situations:

1. Suspected narcolepsy;
2. Suspected idiopathic hypersomnia characterized by disabling daytime sleepiness (i.e., 1-2 hour episodes of non-REM sleep) or prolonged (e.g., >10 hours) nighttime sleep, after exclusion of inadequate sleep hygiene;
3. Suspected restless leg syndrome or period limb movement disorder, when iron deficiency has been ruled out and the use of dopaminergic agents is being considered;
4. Seizures;
5. Laryngomalacia (small oropharynx);
6. In children with tracheostomies prior to removal of the tracheostomy tube;
7. Positive airway pressure (PAP) titration in children with OSA.

C. Use of supervised polysomnography performed in a sleep laboratory is considered INVESTIGATIVE for all other indications due to a lack of evidence demonstrating improved health outcomes.

- Use of unattended (unsupervised) sleep studies or polysomnography in children and adolescents is considered INVESTIGATIVE.
- Multiple Sleep Latency Testing (MSLT) and Maintenance of Wakefulness Testing (MWT)

Medical and Behavioral Health Policy Update

A. MSLT may be considered MEDICALLY NECESSARY to evaluate symptoms of narcolepsy after PSG has ruled out OSA.
B. MSLT is considered INVESTIGATIVE for all other indications due to a lack of evidence demonstrating an improvement in health outcomes in this group of patients.
C. MWT is considered INVESTIGATIVE due to a lack of evidence demonstrating improved health outcomes.

Panniculectomy/Excision of Redundant Skin or Tissue

- Pre-Certification/Pre-Authorization: Yes.
- Criteria for panniculectomy and documentation requirements have not changed. Criteria for excision of redundant skin or tissue of other anatomical areas have changed as follows:

A. Excision of redundant skin or tissue of other anatomical areas including but not limited to the upper extremities (e.g., brachioplasty), lower extremities, thighs or buttocks, may be considered MEDICALLY NECESSARY when at least one of the following are met:
   1. Documentation by the treating physician that the redundant skin or tissue is associated with chronic, recurrent infection that is refractory to medical management (e.g., antifungal, antibacterial, and moisture-absorbing agents; supportive garments; topically-applied skin barriers);
      OR
   2. The redundant skin or tissue results in a functional deficit due to a severe physical deformity or disfigurement AND the surgery is expected to restore or improve the functional deficit.

B. Excision of redundant skin or tissue of other anatomical areas including but not limited to the upper extremities (e.g., brachioplasty), thighs or buttocks not meeting criterion IIA is considered COSMETIC.
C. Tissue excision procedures of the labia and/or the vagina when performed primarily to enhance or otherwise alter physical appearance without correcting or improving a physiological function are considered COSMETIC.

Surgical Treatment of Gender Dysphoria

- Pre-Certification/Pre-Authorization: Yes.
- Criteria for breast and genital surgery have not changed. The diagnostic criteria for gender dysphoria have been updated as follows:
- Criteria for All Surgical Treatment

Surgical treatment of gender dysphoria may be considered MEDICALLY NECESSARY when all of the following criteria have been met. These criteria are based on the Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People, from the World Professional Association for Transgender Health.

A. A comprehensive diagnostic evaluation has been completed by a psychiatrist, a clinical psychologist, or other licensed mental health professional who
   1. Is experienced in the evaluation and treatment of gender dysphoria; and
   2. Has competence in the diagnosis of gender nonconforming identities and expressions, as well as in diagnosing possible comorbid disorders such as psychotic disorders, personality disorders, and substance related disorders,
   3. Meets the Minnesota Department of Human Services qualifications for a mental health professional, as set forth in Minn.Stat.245.4871, subds.26 and 27 (2011) and Minn.Stat.245.462, subds. 17 and 18 (2011).

Note: If the level of competence of the evaluating or treating mental health professional is uncertain, the health plan will seek a second opinion from a known expert in the diagnosis and treatment of gender dysphoria.

AND

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B. Based on the comprehensive evaluation, the individual meets the diagnostic criteria for gender dysphoria in adolescents and adults per the Diagnostic and Statistical Manual of Mental Disorders Fifth Edition (DSM- 5):
   1. A marked incongruence between one's experienced/expressed gender and assigned gender, of at least 6 months' duration as manifested by at least two of the following:
      a. A marked incongruence between one's experienced/expressed gender and primary and/or secondary sex characteristics.
      b. A strong desire to be rid of one's primary and/or secondary sex characteristics because of a marked incongruence with one's experienced/expressed gender.
      c. A strong desire for the primary and/or secondary sex characteristics of the other gender.
      d. A strong desire to be the other gender (or some alternative gender different from one's assigned gender).
      e. A strong desire to be treated as the other gender (or some alternative gender different from one's assigned gender).
      f. A strong conviction that one has the typical feelings and reactions of the other gender (or some alternative gender different from one's assigned gender).

   AND

   2. The condition is associated with clinically significant distress or impairment in social, occupational, or other important areas of functioning.

Chelation Therapy

- Pre-Certification/Pre-Authorization: No.
- Chelation therapy may be considered MEDICALLY NECESSARY in the treatment of ANY of the following conditions:
  A. Control of ventricular arrhythmias or heart block, when associated with digitalis toxicity; OR
  B. Acute or long-term lead poisoning; OR
  C. Extreme conditions of metal toxicity (e.g., aluminum, mercury, arsenic, zinc, iron, copper); OR
  D. Chronic iron overload (e.g., transfusional hemosiderosis or nontransfusion-dependent thalassemia); OR
  E. Copper storage disease (i.e., Wilson's disease or hepatolenticular degeneration); OR
  F. Emergency treatment of hypercalcemia.
- Chelation therapy is considered INVESTIGATIVE in the treatment of all other conditions including, but not limited to, the following:
  A. Coronary artery or peripheral vascular disease (e.g., atherosclerosis or secondary prevention of adverse cardiovascular events in patients with a history of myocardial infarction);
  B. Hypercholesterolemia;
  C. Multiple sclerosis;
  D. Arthritis;
  E. Diabetes;
  F. Scleroderma;
  G. Porphyria;
  H. Alzheimer's disease;
  I. All mental health disorders;
  J. All substance-related disorders;
  K. Mercury release from dental amalgams.

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Reduction Mammoplasty

- Pre-Certification/Pre-Authorization: Yes.
- Reduction mammoplasty may be considered MEDICALLY NECESSARY for patients 18 years of age and older who meet ALL of the following criteria:
  - A. Documentation of at least a six (6) month history of two (2) or more of the following clinical symptoms related to the excess breast tissue;
    1. Shoulder, neck, or back pain that is not responsive to at least six (6) weeks of conservative therapy (e.g., appropriate support bra, exercises, heat/cold treatment, and appropriate non-steroidal anti-inflammatory agents (NSAIDS)/ muscle relaxants);
    2. Recurrent or chronic intertrigo between the pendulous breast and the chest wall;
    3. Persistent shoulder grooving;
    4. Neurologic symptoms associated with brachial plexus pressure (e.g., numbness or tingling of the shoulder, arm, or hand).

  AND

  - B. The weight of breast tissue estimated to be removed must equal or exceed one of the following:
    1. 300 grams per breast or 600 grams from both breasts for women with height less than 5'2" or weight less than 120 lbs.
    2. 400 grams per breast or 800 grams from both breasts for women with height greater than or equal to 5'2" and weight between 120 lbs. and 180 lbs.
    3. 600 grams per breast or 1,200 grams from both breasts for women with height greater than or equal to 5'2" and weight greater than 180 lbs.

  AND

  - C. Documentation of a preoperative mammogram that was negative for cancer during the year prior to surgery for women 40 years of age or older.
- Liposuction is considered INVESTIGATIVE as a primary (i.e., stand alone) surgical procedure for breast reduction.

Infusion or Injection of Vitamins and/or Minerals

- Pre-Certification/Pre-Authorization: No.
- Infusion or injection of vitamins and/or minerals may be considered MEDICALLY NECESSARY when BOTH of the following criteria are met:
  - A. The individual has been diagnosed with ONE of the following conditions:
    1. A vitamin and/or mineral deficiency that has been confirmed by laboratory serum analysis; OR
    2. A medical condition requiring acute treatment or prophylaxis in the presence of well-recognized sequelae with a vitamin and/or mineral, including but not limited to the following:
       a. Coagulopathy or reversal of anticoagulation
       b. Alcohol withdrawal syndrome
       c. Wernicke's encephalopathy
       d. Refeeding syndrome
       e. Anorexia nervosa or bulimia nervosa

  AND

  - B. Oral administration is less effective, not feasible, or not appropriate.
- Infusion or injection of vitamins and/or minerals is considered INVESTIGATIVE for all other indications not addressed by

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the criteria above, including but not limited to the following:

A. Nutritional supplementation in the absence of a vitamin and/or mineral deficiency
B. Disease prevention
C. Mental health disorders
D. Substance-related disorders
E. Chronic fatigue syndrome
F. Fibromyalgia

Policies inactivated

Hematopoietic Stem-Cell Transplantation for Breast Cancer (NOTE: This policy has been combined with the policy on Hematopoietic Stem-Cell Transplantation for Miscellaneous Solid Tumors in Adults, II-123)

Hematopoietic Stem-Cell Transplantation for Epithelial Ovarian Cancer (NOTE: This policy has been combined with the policy on Hematopoietic Stem-Cell Transplantation for Miscellaneous Solid Tumors in Adults, II-123)

Policies Effective: 11/18/13 Notification Posted: 09/26/13

Policies developed

None

Policies revised

Single Nucleotide Polymorphism (SNP) Breast Cancer Risk Assessment

- Pre-Certification/Pre-Authorization: Not applicable.
- Testing for one or more single nucleotide polymorphism (SNP) is considered INVESTIGATIVE as a method of estimating individual patient risk for developing breast cancer due to a lack of evidence demonstrating its impact on improved health outcomes. These include but are not limited to the OncoVue® and BREVAGen™ breast cancer tests and tests offered directly to consumers.

Rituximab

- Pre-Certification/Pre-Authorization: No.
- Rituximab may be considered MEDICALLY NECESSARY for the following.
  A. Oncologic Indications
     1. Non-Hodgkin's lymphoma (NHL) (e.g. AIDS-related B-cell lymphoma, Burkitt's lymphoma, B-cell lymphoma; high- grade B-cell lymphoma, chronic lymphocytic leukemia/small lymphocytic lymphoma, diffuse large B-cell lymphoma, follicular lymphoma and nodal marginal zone lymphoma, gastric mucosa-associated lymphoid tissue (MALT) lymphoma, lymphoblastic lymphoma, mantle cell lymphoma, non-gastric MALT lymphoma, post-transplant lymphoproliferative disorders, primary cutaneous B-cell lymphoma, and splenic marginal zone lymphoma)
     2. Acute lymphocytic leukemia
     3. Chronic lymphocytic leukemia (CLL)
     4. Central nervous system cancer – metastatic and primary lesions
     5. Hairy cell leukemia

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6. Hodgkin's lymphoma
7. Waldenström macroglobulinemia

B. Non-Cancer Indications
1. FDA Approved:
   a. In combination with methotrexate for the treatment of adults with moderately-to severely-active rheumatoid arthritis who have had an inadequate response to one or more tumor necrosis factor (TNF) antagonist therapies
   b. In combination with glucocorticoids for the treatment of adults with granulomatosis with polyangiitis (GPA or Wegener's granulomatosis) or microscopic polyangiitis (MPA)
2. Non-FDA approved
   a. Autoimmune hemolytic anemia (AIHA)
   b. Idiopathic or immune thrombocytopenic purpura (ITP)
   c. In combination with glucocorticoids and plasma exchange for the treatment of adults with thrombotic thrombocytopenic purpura (TTP)

- The use of rituximab for treatment of all other conditions is considered INVESTIGATIVE due to a lack of published clinical evidence establishing the role of rituximab in the treatment of these conditions.

Hyperbaric Oxygen Therapy

- Pre-Certification/Pre-Authorization: No.
- Systemic Hyperbaric Oxygen Therapy

A. Use of systemic hyperbaric oxygen therapy may be considered MEDICALLY NECESSARY in the treatment of the following conditions:
1. Decompression sickness;
2. Acute carbon monoxide/smoke/cyanide inhalation;
3. Arterial gas embolism;
4. Gas gangrene;
5. Chronic refractory osteomyelitis;
6. Necrotizing soft tissue infections;
7. Crush injury with acute traumatic ischemia;
8. Radiation necrosis;
9. Compromised skin grafts or flaps;
10. Non-healing diabetic wounds of the lower extremities when ALL the following criteria are met:
   a. Patient has type I or type II diabetes and a lower extremity wound due to diabetes; and
   b. Patient has a wound classified as Wagner grade 3 or higher; and
   c. Patient has no measurable signs of healing after 30 days of an adequate course of standard wound therapy
11. Thermal burns, acute (second and third degree);
12. Profound anemia with exceptional blood loss: only when blood transfusion is impossible or must be delayed;
13. Pre- and post- treatment for patients undergoing dental surgery (not implant-related) of an irradiated jaw.

B. All other uses of systemic hyperbaric oxygen therapy are considered INVESTIGATIVE due to a lack of evidence demonstrating an impact on improved health outcomes. Those indications include, but are not limited to:
1. Autism spectrum disorders,
2. Bisphosphonate-related osteonecrosis of the jaw;

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3. Cerebral palsy;
4. Herpes zoster;
5. Acute ischemic stroke,
6. Motor dysfunction associated with stroke;
7. Traumatic brain injury;
8. Vascular dementia.

- Topical Hyperbaric Oxygen Therapy
  Use of topical hyperbaric oxygen therapy for ALL indications is considered INVESTIGATIVE due to a lack of evidence demonstrating an impact on improved health outcomes.

Testing of Fetal Nucleic Acids in Maternal Blood for Detection of Fetal Aneuploidy

- Pre-Certification/Pre-Authorization: No.
- Testing of cell-free fetal nucleic acids in maternal blood may be considered MEDICALLY NECESSARY in pregnant women when ALL of the following criteria are met:
  A. Singleton pregnancy;
  AND
  B. Member is at high risk of carrying a child with trisomy 13, 18, or 21 defined as one or more of the following:
    1. Maternal age 35 years or older at delivery
    2. History of prior pregnancy with a trisomy
    3. Parental balanced Robertsonian translocation with increased risk of fetal trisomy 13 or trisomy 21
    4. Fetal ultrasonographic findings indicating an increased risk of aneuploidy (e.g., nuchal translucency)
    5. Positive test results for aneuploidy (e.g., first trimester, sequential, or integrated screen, or a quadruple screen)
- Testing of cell-free fetal nucleic acids in maternal blood is considered INVESTIGATIVE for all other indications including but not limited to:
  A. Testing in women with one or more of the following:
    1. At average risk of carrying a child with Down syndrome or other trisomy; or
    2. Under age 35 at delivery; or
    3. With twin, triplet, or higher order pregnancy.
  B. As part of a routine prenatal laboratory assessment
  C. Testing for any indication other than trisomy 13, trisomy 18, or trisomy 21

Positron Emission Tomography (PET)

- Pre-Certification/Pre-Authorization: No.
- NOTE: Previous separate medical policies on different applications of PET (cardiac, oncologic, and miscellaneous) have been combined into this policy.
- Cardiac Applications
  A. Positron emission tomography (PET) or positron emission tomography/computed tomography (PET/CT) may be considered MEDICALLY NECESSARY for the following indications:
    1. Myocardial perfusion assessment and diagnosis of coronary artery disease in patients with either of the following indications:
      a. Indeterminate SPECT; OR

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b. The patient's body type or physique is expected to lead to an indeterminate SPECT (e.g., BMI ≥ 35 kg/m2, chest wall deformity, breast implant)

2. Myocardial viability assessment in patients with severe left ventricular dysfunction, as a technique to determine candidacy for cardiac surgery.
3. Suspected cardiac sarcoidosis assessment in patients with a medical contraindication to magnetic resonance imaging (MRI) (e.g., patients with pacemakers, automatic implanted cardioverter-defibrillators, or other metal implants).

B. PET or PET/CT is considered INVESTIGATIVE for all other cardiac applications, due to a lack of evidence demonstrating an impact on improved health outcomes.

- Oncologic Applications

A. Initial Treatment Strategy:

1. PET or PET/CT may be considered MEDICALLY NECESSARY as an Initial Treatment Strategy (Diagnosis and Staging) for known or suspected malignancy when the following criteria are met:
   a. One (1) PET or PET/CT for solitary pulmonary nodule. myeloma, and all solid malignant tumors (except those listed below as INVESTIGATIVE) when the test is needed to determine the location and/or extent of the suspected or proven malignancy in order to make at least one of the following determinations:
      - Whether or not the patient is an appropriate candidate for an invasive diagnostic or therapeutic procedure;

      OR
      - The optimal anatomic location for an invasive procedure; OR
      - The anatomic extent of malignancy, when recommended therapy reasonably depends on the extent of malignancy

   AND
   b. Other standard imaging modalities (e.g., CT, MRI, or ultrasound) are either not indicated or are unable to conclusively provide the required information.
2. PET or PET/CT is considered INVESTIGATIVE as an Initial Treatment Strategy (Diagnosis and Staging) for all other non-solid primary tumors and the following solid primary malignant tumors:
   a. Prostate
   b. Kidney
   c. Bladder, urinary
   d. Basal and squamous cell skin cancers

B. Subsequent Treatment Strategy

1. PET or PET/CT may be considered MEDICALLY NECESSARY as a Subsequent Treatment Strategy (Restaging and Monitoring) for known or suspected malignancies when the following criteria are met:
   a. PET or PET/CT for myeloma and all solid primary malignant tumors (except those listed below as INVESTIGATIVE) when the test is performed after completion of initial therapy for malignancy and the imaging results are required to assess therapeutic success, in order to establish the need for any subsequent therapy, by determining at least one of the following:
      - Presence or extent of residual disease; or
      - Presence or extent of recurrent disease; or
      - Presence or extent of metastasis; or
      - Other assessment of tumor response

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AND

b. Other standard imaging modalities (e.g., CT, MRI, or ultrasound) are either not indicated or unable to conclusively provide the required information.

2. PET or PET/CT is considered INVESTIGATIVE when used as a Subsequent Treatment Strategy (Restaging and Monitoring) for all other non-solid primary tumors and the following solid primary malignant tumors:
   a. Prostate
   b. Kidney
   c. Bladder, urinary
   d. Basal and squamous cell skin cancers
   e. Small cell lung
   f. Pancreas
   g. Solitary pulmonary nodule

C. PET or PET/CT for early treatment response assessment, also referred to as interim PET, (i.e., involving comparison of PET images before treatment and at some interval during the initial course of treatment) is considered INVESTIGATIVE due to a lack of evidence demonstrating an impact on improved health outcomes.

D. PET or PET/CT as a surveillance tool for patients with cancer or with a history of cancer when there are no new or worsening symptoms, physical findings, lab tests, or other imaging tests suggesting recurrence or progression of malignancy is considered INVESTIGATIVE due to a lack of evidence demonstrating an impact on improved health outcomes.

- Miscellaneous Applications

A. PET or PET/CT may be considered MEDICALLY NECESSARY for the following indications:
   1. Localization of epileptic seizure focus in patients with complex partial epileptic seizures who are candidates for resections of a suspected epileptogenic focus and who:
      a. Have not responded to standard medical treatment; AND
      b. Have undergone conventional techniques for seizure localization which suggested, but did not conclusively determine, seizure focus.
   2. Diagnosis of chronic osteomyelitis.

B. PET or PET/CT is considered INVESTIGATIVE for the diagnosis or evaluation of all other non-cardiac and non-oncologic conditions or disorders not identified in III.A.1 or III.A.2, including but not limited to all behavioral health disorders.

Continuous or Intermittent Glucose Monitoring in Interstitial Fluid

- Pre-Certification/Pre-Authorization: No.
- Criteria for intermittent (e.g. 72 hour) monitoring, continuous glucose monitoring, and continuous glucose monitoring during pregnancy have not changed. The following investigative uses have been added or changed.
- Investigative Uses
  - Use of an artificial pancreas system, including but not limited to closed-loop monitoring devices with low-glucose suspend (LGS) features, are considered INVESTIGATIVE.
  - Remote glucose monitoring (e.g., mySentry™) is considered INVESTIGATIVE.

Policies inactivated

Magnetoencephalography / Magnetic Source Imaging

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Skilled Nursing Facility (SNF) Care
Home Health Care
Testing for Common Genetic Variants to Predict Risk of Non-Familial Breast Cancer (NOTE: This policy has been combined with the policy on Single Nucleotide Polymorphism (SNP) Breast Cancer Risk Assessment, VI-32)
Positron Emission Tomography (PET): Cardiac Applications (NOTE: This policy has been combined with the policy on Positron Emission Tomography (PET), V-27)
Positron Emission Tomography (PET): Oncologic Applications (NOTE: This policy has been combined with the policy on Positron Emission Tomography (PET), V-27)
Positron Emission Tomography (PET): Miscellaneous Applications (NOTE: This policy has been combined with the policy on Positron Emission Tomography (PET), V-27)

Policies Effective: 12/16/13 Notification Posted: 10/24/13

Policies developed

None

Policies revised

Preimplantation Genetic Testing

- Pre-Certification/Pre-Authorization: Yes.
- Preimplantation genetic diagnosis as an adjunct to in vitro fertilization (IVF) may be considered MEDICALLY NECESSARY in ANY of the following situations:
  A. Detection of a structural chromosomal abnormality in an embryo when one of the partners is known to harbor a balanced or unbalanced chromosomal translocation; or
  B. Detection of a specific inherited single genetic disorder in an embryo when:
     1. Both partners are known carriers of a single gene autosomal recessive disorder (e.g., cystic fibrosis, ß-thalassemia); or
     2. One partner is a known carrier of a single gene autosomal recessive disorder (e.g., cystic fibrosis, ß-thalassemia) and the partners have one biological offspring that has been diagnosed with that recessive disorder; or
     3. One partner is a known carrier of a single gene autosomal dominant disorder (e.g., Marfan syndrome, myotonic dystrophy); or
     4. One partner is a known carrier of a single X-linked disorder (e.g., Fragile X syndrome, hemophilia A).
- Preimplantation genetic screening as an adjunct to IVF, when one or both partners do not meet the criteria above, is considered INVESTIGATIVE in ALL situations, including but not limited to the following:
  A. Recurrent implantation failure; or
  B. Maternal age greater than 35 years; or
  C. Recurrent pregnancy loss.
- Preimplantation genetic testing as an adjunct to IVF is considered NOT MEDICALLY NECESSARY for the sole purpose of either of the following:
  A. Nonmedical gender selection (i.e., gender selection for observable, nonmedical characteristics or traits in the absence of a documented history of an X-linked disorder, such as Fragile X syndrome or hemophilia A); or
  B. Human leukocyte antigen (HLA) typing to identify a potential donor for a future stem cell or organ transplant (i.e.,

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HLA typing in the absence of a documented history of a known inherited disorder, such as Fanconi anemia).

Sclerotherapy for Varicose Veins of the Lower Extremities

- Pre-Certification/Pre-Authorization: No.
- Sclerotherapy may be considered MEDICALLY NECESSARY for initial or follow-up treatment of varicose tributaries, accessory or perforator veins when BOTH A and B are met:
  - A. Results of duplex ultrasound of the deep and superficial venous system performed while patient is standing documents all of the following:
    1. Venous diameter of target vessel is between 3 mm and 6 mm;

    AND
    2. Documented reflux of accessory or tributary veins of >0.5 seconds or at least 0.35 seconds if perforator veins are treated;

    AND
    3. Absence of reflux at the saphenofemoral and saphenopopliteal junctions or surgical ligation and division or endovenous ablation of a refluxing saphenofemoral and/or saphenopopliteal junction has been successfully performed.
  - B. Varicose veins with one or more of the following:
    1. A single significant hemorrhage from a ruptured superficial varicosity, especially if transfusion was required; or
    2. More than one episode of minor hemorrhage from a ruptured superficial varicosity or after a single episode of hemorrhage if a varix remains in an area prone to trauma such as the pretibial area; or
    3. Venous ulcer (open or healed); or
    4. Two or more episodes of superficial symptomatic thrombophlebitis or persistent and symptomatic superficial thrombophlebitis that is unresponsive to conservative therapy including use of prescribed pressure gradient stockings of at least 3 months and NSAIDs if not contraindicated; or
    5. Symptoms characterized by severe, persistent pain, swelling or heaviness and throbbing that interfere with activities of daily living after conservative therapy including prescribed pressure gradient stockings for at least 3 months has not improved symptoms.
- Sclerotherapy is considered INVESTIGATIVE for the following due to a lack of evidence regarding effect on health outcome:
  - A. Treatment of great or small saphenous veins
  - B. Sole treatment of isolated tributary, accessory, or tributary veins without concurrent or prior successful treatment of saphenous veins
  - C. Treatment of veins < 3 mm or > 6 mm in diameter
  - D. Treatment of veins in the presence of peripheral arterial disease.
- Sclerotherapy of spider veins, telangiectasias and asymptomatic varicosities is considered COSMETIC.

Sacroiliac Joint Fusion

- Pre-Certification/Pre-Authorization: Yes.
- Sacroiliac joint fusion, performed by an open procedure, may be considered MEDICALLY NECESSARY for ANY of the following indications:
  - A. Adjunct to sacrectomy or partial sacrectomy for treatment of sacral tumors;

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B. Adjunct to the medical treatment of sacroiliac joint infection (e.g., osteomyelitis, pyogenic sacroiliiitis);
C. Treatment of severe traumatic injuries associated with pelvic ring fracture.

- Sacroiliac joint fusion, performed by an open procedure, is considered INVESTIGATIVE for all other indications including, but not limited to:
  A. Mechanical lower back pain;
  B. Sacral insufficiency fractures.
- Minimally invasive or percutaneous sacroiliac joint fusion procedures are considered INVESTIGATIVE for all indications due to a lack of evidence demonstrating an impact on improved health outcomes.

Intravitreal Angiogenesis Inhibitors for Treatment of Retinal and Choroidal Vascular Conditions

- Pre-Certification/Pre-Authorization: No.
- Pegaptanib (Macugen)
  A. Intravitreal injections of pegaptanib may be considered MEDICALLY NECESSARY as a treatment of neovascular (wet) age-related macular degeneration.
  B. The use of pegaptanib for treatment of all other conditions is considered INVESTIGATIVE.
- Aflibercept (Eylea)
  A. Intravitreal injections of aflibercept may be considered MEDICALLY NECESSARY for treatment of the following conditions:
     1. Neovascular (wet) age-related macular degeneration
     2. Macular edema following central retinal vein occlusion
  B. The use of aflibercept for treatment of all other non-neoplastic conditions is considered INVESTIGATIVE.
- Ranibizumab (Lucentis)
  A. Intravitreal injections of ranibizumab may be considered MEDICALLY NECESSARY for treatment of the following conditions:
     1. Neovascular (wet) age-related macular degeneration
     2. Macular edema following retinal vein occlusion
     3. Diabetic macular edema
     4. Proliferative diabetic retinopathy as an adjunctive treatment to vitrectomy or photocoagulation
     5. Choroidal neovascularization due to angioid streaks, central serous chorioretinopathy, choroidal rupture or trauma, idiopathic choroidal neovascularization, multifocal choroiditis, pathologic myopia, presumed ocular histoplasmosis syndrome or uveitis
  B. The use of ranibizumab for treatment of all other conditions is considered INVESTIGATIVE.
- Bevacizumab (Avastin)
  A. Intravitreal injections of bevacizumab may be considered MEDICALLY NECESSARY for treatment of the following conditions:
     1. Neovascular (wet) age-related macular degeneration
     2. Macular edema following retinal vein occlusion
     3. Diabetic macular edema
     4. Proliferative diabetic retinopathy as an adjunctive treatment to vitrectomy or photocoagulation
     5. Choroidal neovascularization due to angioid streaks, central serous chorioretinopathy, choroidal rupture or trauma, idiopathic choroidal neovascularization, multifocal choroiditis, pathologic myopia, presumed ocular histoplasmosis

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syndrome, or uveitis
6. Neovascular glaucoma
7. Rubeosis (i.e., neovascularization of the iris)
8. Retinopathy of prematurity

B. The use of bevacizumab for treatment of all other non-neoplastic conditions is considered INVESTIGATIVE.

Hematopoietic Stem-Cell Transplantation for Acute Lymphoblastic Leukemia

- Pre-Certification/Pre-Authorization: Yes.
- Pediatric

A. Allogeneic or autologous hematopoietic stem-cell transplantation (HSCT) may be considered MEDICALLY NECESSARY to treat childhood acute lymphoblastic leukemia (ALL) in the following situations:
1. First complete remission but at high risk of relapse when the patient has ONE OR MORE of the following risk factors for relapse:
a. Poor response to initial therapy including poor response to prednisone prophase (defined as an absolute blast count of 1000/µL or greater), or poor treatment response to induction therapy at 6 weeks with high risk having ≥1% minimal residual disease measured by flow cytometry);
b. T-cell phenotype;
c. Patients with either of the following genetic abnormalities: t(9;22) or t(4;11), regardless of early response measures:

OR

2. Second or greater remission, or in patients with relapsed or refractory ALL.

- Adults

A. Allogeneic HSCT may be considered MEDICALLY NECESSARY to treat adult ALL in the following situations:
1. First complete remission but at high risk of relapse when the patient has ONE OR MORE of the following risk factors for relapse:
a. Age greater than 35 years;
b. Leukocytosis at presentation of >30,000/µL (B-cell lineage) OR >100,000/µL (T-cell lineage);
c. "Poor prognosis" genetic abnormalities, such as the Philadelphia chromosome (t(9;22));
d. Extramedullary disease;
e. Time to attain complete remission longer than 4 weeks.

OR

2. Second or greater remission, or in patients with relapsed or refractory ALL.

B. Reduced-intensity conditioning (RIC) allogeneic HSCT may be considered MEDICALLY NECESSARY as a treatment of ALL in patients who are in complete marrow and extramedullary first or second remission, and who are unable to tolerate a standard myeloablative conditioning regimen, due to the presence of co-morbid conditions (e.g., liver or kidney dysfunction, generalized debilitation, prior intensive chemotherapy, low Karnofsky Performance Status).

C. Autologous HSCT may be considered MEDICALLY NECESSARY to treat adult ALL in the absence of a suitable allogeneic donor in the following situation:
1. First complete remission but at high risk of relapse when the patient has ONE OR MORE of the following risk factors for relapse:
a. Age greater than 35 years;

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b. Leukocytosis at presentation of >30,000/µL (B-cell lineage) OR >100,000/µL (T-cell lineage);
c. "Poor prognosis" genetic abnormalities, such as the Philadelphia chromosome (t(9;22));
d. Extramedullary disease;
e. Time to attain complete remission longer than 4 weeks.

D. Autologous HSCT is considered INVESTIGATIVE to treat adult ALL for all indications EXCEPT those described in section II.C.1.

Wheelchairs

- Pre-Certification/Pre-Authorization: Yes
- Criteria for All Wheelchairs

All of the following criteria must be met for any wheelchair to be considered MEDICALLY NECESSARY:

A. The patient has a mobility limitation that significantly impairs his or her ability to participate in mobility related activities of daily living (MRADLs) appropriate to the patient's needs and abilities. These activities include toileting, dressing, personal hygiene and eating, education, working or job training. A mobility limitation is one that:
   1. Prevents the patient from accomplishing the MRADLs entirely,
   OR
   2. Places the patient at reasonably determined heightened risk of morbidity or mortality secondary to the attempts to participate in MRADLs. Weakness and fatigue alone are not considered significant impairments in the ability to participate in MRADLs.

AND

B. The patient has a mobility limitation that cannot be sufficiently resolved by use of an appropriately fitted cane or walker;

AND

C. Features of the wheelchair are based upon the patient's physical and functional capabilities and body size as assessed by a qualified professional or professionals and appropriate to the type of device requested;

AND

D. An assessment of the patient's home demonstrates that the home provides adequate access between rooms, maneuvering space and surfaces for use of the wheelchair provided.

- Criteria for manual, powered, and power-operated vehicles, customization and features, and documentation requirements have been reformatted but are not substantially changed.

Coverage of Routine Care Related to Clinical Trials

- Pre-Certification/Pre-Authorization: Yes, and should include a diagnosis, clinical history, treatment plan, and the study's sponsor and protocol ID number. This policy applies to fully insured Blue Cross Blue Shield of Minnesota and Blue Plus health plans and self-insured Minnesota health plans. Other health plans affiliated with or administered by Blue Cross (e.g., grandfathered self-insured plans) may have different benefits, and may not have to comply with the Patient Protection and Affordable Care Act (PPACA or ACA) or state of Minnesota regulations.
- Routine patient costs provided in certain clinical trials are considered ELIGIBLE for coverage for a qualified individual in the setting of an approved clinical trial for the treatment of cancer or other life-threatening conditions, with each parameter defined as follows:
  - Qualified individual is a plan member who is eligible to participate in an approved clinical trial protocol for the

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treatment of cancer or other life-threatening disease. In addition, the qualified individual must establish either:

1. A referral from a participating provider based on the provider's conclusion that the individual's participation in the trial would be appropriate; or
2. Medical and scientific information establishing that the individual's participation in the trial would be appropriate based on the individual meeting the clinical trial protocol.

- Life-threatening condition is defined as any disease or condition from which the likelihood of death is probable unless the course of the disease or condition is interrupted.
- Routine patient costs means items and services consistent with the coverage provided that is typically covered for an individual who is not enrolled in a clinical trial. Routine patient costs do not include:
  1. Investigational devices and services;
  2. Services provided solely to satisfy data collection and analysis needs and are not used in direct clinical management of the patient; or
  3. A service that is clearly inconsistent with widely accepted and established standards of care for a particular diagnosis.
- Approved clinical trials include Phase I through IV clinical trials that relate to the prevention, detection, or treatment of cancer or other life-threatening condition and are approved or funded by one or more of the following:
  1. The National Institutes of Health (NIH) or NIH-designated non-governmental research entity;
  2. The Centers for Disease Control and Prevention (CDC);
  3. The Agency for Health Care Research and Quality;
  4. The Centers for Medicare and Medicaid Services (CMS);
  5. Department of Defense* or Department of Veteran's Affairs*;
  6. Department of Energy*;
  7. Investigational new drug (IND) application reviewed by the Food and Drug Administration (FDA); or
  8. A drug trial that is exempt from having an investigational new drug application.

  *Either jointly with NIH or NIH-designated non-governmental research entity, CDC, Agency for Health Care Research and Delivery, or CMS OR under protocol approved by CMS

Gene Expression Profiling for the Management of Breast Cancer Treatment

- Pre-Certification/Pre-Authorization: No.
- Use of the 21-gene RT-PCR assay (i.e., Oncotype DX™) to determine recurrence risk for deciding whether or not to initiate adjuvant chemotherapy may be considered MEDICALLY NECESSARY in patients with primary, invasive breast cancer who meet ALL the following criteria:
  A. Unilateral, non-fixed tumor; and
  B. Estrogen receptor positive or progesterone receptor positive; and
  C. Human epidermal growth factor receptor 2 (HER2) negative; and
  D. Tumor size 0.6 – 1 cm with moderate/poor differentiation or unfavorable features OR tumor size larger than 1 cm; and
  E. Node negative OR no lymph nodes with micrometastases greater than 2 mm; and
  F. Patient will be treated with adjuvant endocrine therapy (e.g., tamoxifen or aromatase inhibitors).
- For patients with multiple ipsilateral primary tumors who otherwise meet the above criteria, use of the 21-gene RT-PCR assay (i.e., Oncotype DX™) may be considered MEDICALLY NECESSARY for the one tumor with the most aggressive

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histological characteristics because treatment is based on the most aggressive lesion.

- All other uses of breast cancer gene expression assays are considered INVESTIGATIVE due to a lack of evidence supporting use for any other indication. This includes, but is not limited to:
  A. Use of the 21-gene RT-PCR assay (i.e., Oncotype DX) for predicting recurrence risk in patients with positive lymph nodes or bilateral breast tumors.
  B. Use of a subset of genes from the 21-gene RT-PCR assay (i.e., Oncotype DX DCIS) for predicting recurrence risk in patients with noninvasive ductal carcinoma in situ.
  C. Use of other gene expression assays (e.g., MammaPrint®, MammoStrat™ Breast Cancer Test, Breast Cancer IndexSM, BreastOncPxTM, NexCourse® Breast IHC4, and the PAM50 Breast Cancer Intrinsic Classifier) for any indication.

Policies inactivated

Deep Brain Stimulation (Applicable to Commercial and Minnesota Health Care Programs [MHCP] Products)
Natalizumab (Tysabri®) (Applicable to Commercial and Minnesota Health Care Programs [MHCP] Products)
Fetal Surgery for Prenatally Diagnosed Malformations (Applicable to Commercial and Minnesota Health Care Programs [MHCP] Products)
Injectable Clostridial Collagenase for Fibroproliferative Disorders (Applicable to Commercial and Minnesota Health Care Programs [MHCP] Products)
Wound Healing: Vacuum-Assisted Wound Therapy in the Outpatient Setting (Applicable to Commercial and Minnesota Health Care Programs [MHCP] Products)
Treatment for Severe Primary Insulin-Like Growth Factor-1 (IGF-1) Deficiency

Policies reviewed with no changes in August – October 2013:

Acupuncture
Advanced Glycation Endproducts (AGEs) Measurement by Skin Autofluorescence
Air Ambulance
Ambulatory Blood Pressure Monitoring (ABPM) (Sphygmomanometry)
Amino Acid-Based Elemental Formula
Autologous Hematopoietic Stem-Cell Transplantation for Malignant Astrocytomas and Gliomas
Biofeedback for Disorders Listed in the DSM
Bronchial Thermoplasty
Cardiac Hemodynamic Monitoring for the Management of Heart Failure in the Outpatient Setting
Computed Tomography Angiography (CTA) for Evaluation of Coronary Arteries
Computed Tomography (CT) to Detect Coronary Artery Calcification
Computerized Dynamic Posturography
Dalfampridine (Ampyra™)
Deep Brain Stimulation
Diagnosis and Treatment of Chronic Cerebrospinal Venous Insufficiency in Multiple Sclerosis
Durable Medical Equipment (DME)
Electrotherapy/Electrotherapeutic Devices
Facet Arthroplasty
Fetal Surgery for Prenatally Diagnosed Malformations

Medical and Behavioral Health Policy Update

Gene Expression Testing to Predict Coronary Artery Disease (CAD)
Gene Therapy
Genetic Testing for Congenital Long QT Syndrome
Growth Factors for Treatment of Wounds and Other Conditions
Hematopoietic Stem-Cell Transplantation for Acute Myeloid Leukemia
Hematopoietic Stem-Cell Transplantation for Autoimmune Diseases
Hematopoietic Stem-Cell Transplantation for Non-Hodgkin Lymphomas
Hematopoietic Stem Cell Transplantation for Primary Amyloidosis
Hematopoietic Stem-Cell Transplantation for Waldenström macroglobulinemia
Hyperhidrosis Treatments
Hypnotherapy
Implantable Middle Ear Hearing Aids (Semi-Implantable and Fully Implantable) for Moderate to Severe Sensorineural Hearing Loss
Injectable Clostridial Collagenase for Fibroproliferative Disorders
KRAS Mutation Analysis
Laboratory Testing to Allow Area Under the Curve (AUC) Targeted 5-Fluorouracil (5-FU) Dosing for Patients Administered 5-FU for Cancer
Laser and Photodynamic Therapy for Onychomycosis
Left Atrial Appendage Occluder Devices
Magnetic Esophageal Ring for Treatment of Gastroesophageal Reflux Disease (GERD)
Natalizumab (Tysabri®)
Non-Pharmacologic Treatment of Acne
Non-Pharmacologic Treatment of Rosacea
Ovarian and Internal Iliac Vein Embolization as Treatment for Pelvic Congestion Syndrome
Progesterone Therapy to Reduce Preterm Birth in High-Risk Pregnancies
Quantitative Electroencephalogram [QEEG] or Brain Mapping for Mental Health or Substance-Related Disorders
Secretin Infusion Therapy for Autism
Spinal Manipulation Under Anesthesia
Spinal Unloading Devices: Patient-Operated
Thermal Capsulorrhaphy
Transesophageal Endoscopic Therapies for Gastroesophageal Reflux Disease (GERD)
Vagus Nerve Stimulation
Wireless Gastric Motility Monitoring
Wound Healing: Electrostimulation and Electromagnetic Therapy
Wound Healing: Non-Contact Ultrasound Treatment
Wound Healing: Vacuum-Assisted Wound Therapy in the Outpatient Setting

Provider Press is posted on our website quarterly for business office staff of multi-specialty clinics, physicians, public health agencies, DME providers, chiropractors, podiatrists, physical therapists, occupational therapists, optometrists and behavioral health professionals/providers. Direct inquiries to:

Network Management R317
Editor: Holly Batchelder
P.O. Box 64560
St. Paul, MN 55164-0560
(651) 662-2014
toll free: 1-800-382-2000, ext. 22014

Advisors/Faith Bauer, CPC, CPC-H, CPC-P; Jeannie Harp, CPC; Janine Utecht, CPC, CPC-H, CPC-P, CPMA; and Karen Kiemele, MPH

Information in Provider Press is a general outline. Provider and member contracts determine benefits.

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For the health of all.

Network Management R317
P.O. Box 64560
St. Paul, MN 55164-0560