Provider Press

Provider information

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BlueCross BlueShield Minnesota

BLUE CROSS CONTRACTS WITH SECURECARE TO MANAGE ITS CHIROPRACTIC NETWORK

Effective October 1, 2016, Blue Cross and Blue Shield of Minnesota (Blue Cross) will no longer hold direct contracts with Chiropractors. Blue Cross has contracted with SecureCare (SCC) to administer certain components of its Chiropractic network, including:

- Network Management
- Contract Management
- Communications
- Provider Relations
- Credentialing
- Provider Education

Providers who wish to continue servicing Blue Cross subscribers at the in-network level after September 30, 2016, must register and contract with SCC by June 30, 2016, to ensure there are no gaps in their participation status. Providers who have completed the contracting process and signed a participation agreement with SCC prior to June 30, 2016, will be considered an in-network provider for Blue Cross members through SCC.

Providers who are currently participating in the Blue Cross Chiropractic network should have received a welcome packet from SCC that included information on contracting, credentialing, and a log in ID that allows you to access SCC's online portal.

Both Blue Cross and SCC are organizations dedicated to the development and recognition of your practice and profession. Some key features of the SCC relationship include:

- Review by licensed peer providers
- Provider report cards
- Continued access to Blue Cross subscribers
- Access to a state-of-the-art EDI platform
- Best practices and quality improvement programs

You may learn more about SCC at: www.securecarecorp.com. If you have any questions about this relationship, please contact Blue Cross provider services at **(651) 662-5200** or **1-800-262-0820**.

FYI

NEED HELP UNDERSTANDING OUR NETWORKS?

Blue Cross has published two guides to help providers identify and understand our products. The Commercial Network Guide provides details regarding commercial products, including our narrow networks, and the Medicare Product Guide provides details about our Medicare products. Both guides are located on our website at **providers.bluecrossmn.com** under the "Education Center" section. The Medicare product guide is available under "Medicare Education" and the Commercial Network Guide has its own section in the Education Center.

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 March 2016 to May 2016 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
QP6-16	April 2016 HCPCS Code Updates
QP7-16	Inquiring and Updating Pre-Admission Notification Submissions on the Availity Web Portal
QP8-16	Optician Contracting and Eyewear Overview
QP9-16	PCCs Will No Longer Be Listed on Minnesota Health Care Programs Subscriber ID Cards
QP10-16	Operating System Remit Differences – Subscriber Payments
QP11-16	New BlueRide Email Notification Option for Skilled Nursing Facilities
BULLETINS	**TITLE**
P13-16	Personal Care Assistance (PCA) Services Liability Insurance Requirements
P14-16	Addition of Lazanda® to Existing Drug-Related Prior Authorization with Quantity Limit Program
P15-16	Place of Service 53 will be Changed to a Facility Place of Service
P16-16	Blue Cross Contracts with SecureCare to Manage the Chiropractic Network
P17-16	Non-Emergency Medical Transportation Services NETStudy Background Check Requirement
P18-16	Reminder: Pre-Certification and Concurrent Review Requirements for Medicare Skilled Nursing Facility Services for SecureBlue (MSHO) Subscribers
P19-16	Chiropractic Services for Platinum Blue (Cost) Subscribers
P20-16	Addition of Uptravi and Adempas to Existing Drug Related Prior Authorization Program
P21-16	Reminder: Pre-Certification and Concurrent Review Requirements for Medicare Skilled Nursing Facility Services for SecureBlue (MSHO) Subscribers
P22-16	Pricing Order Change When Bilateral and Multiple Surgery Reduction occur on the Same Claim

WE ARE REACHING FOR THE STARS!

Blue Cross and Blue Shield of Minnesota (Blue Cross) is committed to partnering with providers and members to improve clinical outcomes for the Medicare beneficiaries we jointly serve. As part of our ongoing efforts, Blue Cross will be encouraging members to discuss all of their preventive care with their providers, and offering members a Visa gift card for completing the screening.

Blue Cross will also be partnering with Home Access Health (HAHC) to provide a FIT CHEK colon cancer screening kit and/or a urine collection kit and/or a finger stick blood collection kit (A1c test kit) to members not currently up to date with their colon cancer or diabetes screenings. You will be hearing more about this initiative and others in the coming months. For more information on the specific rewards available, please reference the Provider Star Ratings website under "Tools and Resources" on the provider home page:

https://www.bluecrossmn.com/healthy/public/personal/home/providers/star-ratings-program

FYI

PROVIDER MANUAL UPDATES

The following is a list of Blue Cross provider manuals that have been updated from March 2016 to May 2016. 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 11, Coding Policies and Guidelines, Coding section	Content change to: Preventive Services Required Under the Patient Protection and Affordable Care Act (PPACA)
Provider Policy and Procedure Manual	Chapter 8, Claims Filing	Content change to: Public Programs Claims Filing Exception
Blue Plus Manual	Chapter 2, Blue Plus Members	Added ICD-10 codes
Provider Policy and Procedure Manual	Chapter 4, Health Management	Chapter name changed to Health Management (previously Integrated Health Management)
Provider Policy and Procedure Manual	Chapter 5, Health Care Options	Deleted Healthy Start Prenatal Support as a topic and added Maternity Management

2016 HOLIDAY SCHEDULE

Provider services will be closed on the following days in 2016:

Monday, May 30

Monday, July 4

Monday, September 5

Thursday, November 24

Friday, November 25

Monday, 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 Friday.

CODING CORNER

JULY HCPCS UPDATE

There will be new HCPCS codes added July 1, 2016. HCPCS codes are now posted under "Other Codes Effective July 1, 2016" on the CMS website at:

https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/HCPCS-Quarterly-Update.html

A Provider Quick Points will be published with details and the new codes before the effective date.

CODING CORNER

UNITS FOR PATHOLOGY AND LAB SERVICES

Surgical pathology codes 88300-88309 specifically instruct that a "unit of service is the specimen". CPT further includes a definition as: "A specimen is defined as tissue(s) that is (are) submitted for individual and separate attention, requiring individual examination and pathologic diagnosis."

Based on this instruction these pathology codes may be submitted with more than one unit, as appropriate. However, units for other lab codes must be reported based on the code definition. As noted in our reimbursement policy (RP - General Coding - 009 – Maximum Units Per Day) as well as the MN Uniform companion guide, section **A.3.4.2. Units (basis for measurement):**

> The number of units is the number of services performed and reported per service line item as defined in the code description unless instructed differently in this appendix.
>
> The following are clarifications/exceptions:
>
> - Report one unit for all services without a measure in the description.
> - Report the number of units as the number of services performed for services with a measure in the description. For example, one unit equals:
>   - "per vertebral body;"
>   - "each 30 minutes;"
>   - "each specimen;"
>   - "15 or more lesions;"
>   - "initial."

CHECK OUT OUR REIMBURSEMENT POLICIES

Have you checked out our individual reimbursement policy documents on the provider "Tools and Resources" section of the Blue Cross website (**providers.bluecrossmn.com**)? We have been moving existing policies from Chapter 11 of the Blue Cross Provider Policy and Procedure Manual (PPPM) to the website since June 1, 2015, and will be releasing even more policies in May.

Once most policies are moved the current information described in Chapter 11 of the PPPM will be removed with a reference to the Blue Cross website for additional policy detail.

As a reminder, the policies listed in the PPPM and Reimbursement Policies are contractually binding as part of the overall Provider Service Agreement between Blue Cross and Providers.

UNLISTED CODE REMINDER

Unlisted codes are an effective and valid way to report services or procedures where there is no other code that defines that service or procedure. However, the use of any unlisted code will be subject to review.

The following must be considered if you submit a code that is by definition unlisted, not otherwise classified or not elsewhere classified:

- A narrative and/or documentation must be submitted describing the service or item.
- The unit submitted for any unlisted code will always be one (1).

Your unlisted code and charge will be denied/ rejected if:

- We find there is a definitive code available.
- Documentation/narrative is not furnished.
- The unit is over one (1).

PHARMACY SECTION

PHARMACY UPDATES FOR QUARTER 2, 2016

Drug Formulary Changes

As part of our continued efforts to evaluate and update our formularies, Blue Cross and Blue Shield of Minnesota and Blue Plus evaluate drugs on a regular basis. This evaluation includes a thorough review of clinical information, including safety information and utilization. Based on our most recent review, the following BRAND name drugs have been added to or removed from drug formularies effective April 1, 2016:

ADDITIONS TO FlexRx FORMULARY	REMOVALS FROM FlexRx FORMULARY
BRILINTA	ACTONEL
IRESSA	ATELVIA
IXINITY	DIBENZYLINE
LONSURF	GLYBURIDE
NOXAFIL	METIPRANOLOL
ODOMZO	NAMENDA
PRENATAL VIT PLUS LOW IRON	ORAP
ORKAMBI	PULMICORT
THIOTEPA	TARGRETIN
UNITUXIN	
ADDITIONS TO GenRx FORMULARY	**REMOVALS FROM GenRx FORMULARY**
BRILINTA	BEAU RX
IRESSA	DIBENZYLINE
IXINITY	INDOMETHACIN SODIUM
LONSURF	LEXUSS 210
NOXAFIL	METHYLENE BLUE
ODOMZO	MORPHINE SULFATE
PRENATAL VIT PLUS LOW IRON	PULMICORT
ORKAMBI	RECEDO
THIOTEPA	TARGRETIN
UNITUXIN	

The complete list of formulary changes can be found at:

FlexRx -
https://www.myprime.com/content/dam/prime/memberportal/forms/2015/FullyQualified/Other/ALL/BCBSMN/COMMERCIAL/MNFLEXRX/MN_FlexRx_Formulary_Update.pdf

GenRx –
https://www.myprime.com/content/dam/prime/memberportal/forms/2015/FullyQualified/Other/ALL/BCBSMN/COMMERCIAL/MNGENRX/MNSM_Formulary_Update.pdf

PHARMACY SECTION

UTILIZATION MANAGEMENT UPDATES

Blue Cross and Blue Shield of Minnesota implemented additional Quantity Limits and/or Prior Authorizations depending on the member's prescription drug benefit. Programs in this update include new Quantity Limits (QL) or Prior Authorizations (PA) for:

March 1, 2016

GRASTEK	PA	QL
ORALAIR tabs	PA	QL
ORALAIR starter pack	PA	QL
RAGWITEK	PA	QL

April 1, 2016

ALECENSA	PA	QL
AZENASE		QL
BELBUCA		QL
COTELLIC	PA	QL
ESBRIET	PA	QL
GATTEX	PA	
GENVOYA		QL
HETLIOZ	PA	QL
JUXTAPID	PA	QL
KORLYM	PA	QL
KYNAMRO	PA	QL
MYALEPT	PA	
NATPARA	PA	QL
NINLARO	PA	QL
OFEV	PA	QL
RAYOS	PA	
RESTASIS	PA	
SEEBRI NEOHALER		QL
TAGRISSO	PA	QL
TRESIBA		QL
UTIBRON NEOHALER		QL
VARUBI		QL

PA = Prior Authorization QL = Quantity Limit

In addition, information on upcoming changes to the Nuvigil/ armodafinil, Provigil/modafinil Prior Authorization/ Quantity Limit program is included below:

June 1, 2016

- Nuvigil/armodafinil, Provigil/ modafinil Prior Authorization/ Quantity Limit will be inactivated for the Commercial lines of business
- Nuvigil/armodafinil, Provigil/ modafinil Prior Authorization/Quantity Limit will continue for Medicaid
- The medical policy database will be updated to reflect these changes

A complete listing of all utilization management updates can be found at:

FlexRx -
https://www.myprime.com/content/dam/prime/memberportal/forms/2015/FullyQualified/Other/ALL/BCBSMN/COMMERCIAL/MNFLEXRX/MN_FlexRx_UM_Updates.pdf

(continued on next page)

PHARMACY SECTION

UTILIZATION MANAGEMENT UPDATES - continued

GenRx -
https://www.myprime.com/content/dam/prime/memberportal/forms/2015/FullyQualified/Other/ALL/BCBSMN/COMMERCIAL/MNGENRX/MNSM_GenRx_UM_Updates.pdf

For tools and resources regarding Pharmacy please visit our website at **bluecrossmn.com** and select "Shop Plans" and "Prescription Drugs." Tools include our formulary updates (by formulary list) and frequently asked questions.

Formulary updates are completed quarterly and posted online for review. These updates can be found by selecting the "Search a Drug List" link under the "Prescription Drugs" section and then selecting the applicable formulary listing.

Additional information regarding Pharmacy is also located in the Provider Policy and Procedure Manual. To access the manual go online to **providers.bluecrossmn.com** and select "Forms and Publications" then "Manuals." Topics in the manual include, but are not limited to, formulary exceptions, quantity limits and step therapy.

CODING CORNER

ICD-10 UPDATES

The freeze on updates to the ICD-10 codes ends this year so all of the accumulated and approved code changes will become effective October 1, 2016. There are lists online of the upcoming changes from ICD meetings up to March 2016. However, there may be additional changes in the official addenda once posted.

As of March there are over 1,900 ICD-10-CM (diagnosis) changes including about 351 revised and 313 deleted codes. The codes are posted on the Centers for Disease Control and Prevention National Center for Health Statistics website.

ICD-10-PCS (procedure) has about 3,651 new codes and 487 revised. The list of proposed new and revised codes for ICD-10-PCS is available on the CMS.gov website.

FYI WHO TO CONTACT

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.	
For phone numbers, fax numbers and addresses for Care Management programs and services please refer to the Provider Policy and Procedure Manual, Chapter 1 "How to Contact Us" section.	

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 Medical 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 Outcomes Dept.
R472
P.O. Box 64179
St. Paul, MN 55164-0179

FYI

REMINDER: MEDICARE REQUIREMENTS FOR REPORTING PROVIDER DEMOGRAPHIC CHANGES

This is a reminder of the Medicare requirements for reporting provider demographic changes. This information was previously published on October 2, 2015, in Provider Bulletin P41-15.

Blue Cross and Blue Shield of Minnesota (Blue Cross) has continually collaborated with providers in an effort to ensure accurate information is provided in all provider directories.

In accordance with Medicare requirements, Blue Cross is required to maintain accurate provider network directories for the benefit of our Subscribers. Blue Cross is hereby notifying all providers to submit a form to us when any of the following changes occur:

- Accepting new patients
- Demographic address and phone changes
- Office hours or other changes that affect availability
- Tax ID changes
- Practitioner additions or terminations
- Branch additions

Forms location
Based on what change has occurred, submit the appropriate form located on our website at **providers.bluecrossmn.com**. Select "Administrative Updates" in the "What's Inside" section to obtain instructions on completing the various forms or access the link below:
https://www.bluecrossmn.com/healthy/public/personal/home/providers/admin-updates.

How do we submit changes?
Send the appropriate form via fax as indicated below:
Fax: **651-662-6684, Attention: Provider Data Operations**

Questions?
If you have questions, please contact provider services at **(651) 662-5200** or **1-800-262-0820**.

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:
Under "Medical Policy and Pre-Certification/Authorization Router," 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 Tools & Resources), and then read and accept the Blue Cross Medical Policy Statement. You have now navigated to the Blue Cross and Blue Shield of Minnesota Medical Policy web page.

Click on the "+" (plus) sign next to "Medical and Behavioral Health Policies."

- The "Upcoming Medical Policy Notifications" 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.
- The "Medical and Behavioral Health Policies" section lists all policies effective at the time of your inquiry.
    - Note: On November 1, 2015, Blue Cross and Blue Shield of Minnesota began migrating subscribers from our legacy operating system to our new operating system. Subscriber migration will continue over the next few years with the goal of having all subscribers migrated to the new operating system by the end of 2018. During the migration, there will be two sets of medical policies: one for migrated subscribers (new operating system) and one for non-migrated subscribers (legacy operating system). Please follow the instructions on the web page to select the applicable medical policy based upon the member's migration status. This change was previously communicated in the Provider Bulletin entitled "Medical Policies on the New Operating System Effective November 1, 2015" (P-32-15), which published September 9, 2015.

Click on the "+" (plus) sign next to "Utilization Management."

- The Pre-Certification/Pre-Authorization lists identify various services, procedures, prescription drugs, and medical devices that require pre-certification/pre-authorization. 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

Policies Effective: 04/18/16 Notification Posted: 02/26/16

Policies developed

None

Policies revised

Advanced Therapies for Pharmacological Treatment of Pulmonary Hypertension

- Advanced Therapies for Pharmacological Treatment of Pulmonary Arterial Hypertension (PAH; WHO Group 1)

A. Advanced therapies for PAH may be considered MEDICALLY NECESSARY for patients who meet ALL of the following criteria:

1. Mean pulmonary artery pressure greater than 25 mm Hg; AND
2. Pulmonary capillary wedge pressure, left atrial pressure, or left ventricular end-diastolic pressure less than or equal to 15 mm Hg; AND
3. Pulmonary vascular resistance greater than 3 Wood units; AND
4. Confirmation of PAH by complete right heart catheterization; AND
5. Exclusion of significant chronic hypoxemic lung disease or chronic thromboembolic disease; AND
6. A negative response to acute pulmonary vasodilator testing OR a contraindication to calcium-channel antagonists.

B. The following advanced therapies for PAH may be considered MEDICALLY NECESSARY when used as monotherapy for patients diagnosed with PAH (as described in section A above):

1. Epoprostenol (Flolan® or Veletri®) continuous intravenous infusion;
2. Treprostinil (Remodulin®) continuous subcutaneous or intravenous infusion;
3. Treprostinil (Tyvaso®) inhalation via nebulizer;
4. Treprostinil (Orenitram™) extended-release oral;
5. Iloprost (Ventavis®) inhalation via nebulizer;
6. Selexipag (Uptravi®) oral;
7. Bosentan (Tracleer®) oral;
8. Ambrisentan (Letairis®) oral;
9. Macitentan (Opsumit®) oral;
10. Sildenafil (Revatio®) oral or intravenous injection;
11. Tadalafil (Adcirca®) oral;
12. Riociguat (Adempas®) oral.

C. Combination therapy (i.e., two or more advanced therapies) for patients diagnosed with PAH (as described in section A above) may be considered MEDICALLY NECESSARY when ONE of the following conditions are met:

1. Ambrisentan (Letairis®) and tadalafil (Adcirca®) will be used as first-line treatment for PAH; OR
2. The patient has failed to demonstrate an adequate response to monotherapy and BOTH of the following:
   a. Drugs are from different therapeutic classes, excluding the combination of a soluble guanylate cyclase

MEDICAL AND BEHAVIORAL HEALTH POLICY UPDATE

inhibitor (e.g., riociguat [Adempas®]) and a phosphodiesterase type 5 inhibitor (e.g., sildenafil [Revatio®] or tadalafil [Adcirca®]), which are contraindicated as combined treatment; AND

b. Each drug may be considered medically necessary for the treatment of PAH (as described in section B above).

D. All other combination therapy (i.e., two or more advanced therapies) for PAH is considered INVESTIGATIVE as first-line treatment.

- Advanced Therapies for Pharmacological Treatment of Non-PAH Pulmonary Hypertension (PH; WHO Groups 2-5)

A. The use of riociguat may be considered MEDICALLY NECESSARY for the treatment of chronic thromboembolic pulmonary hypertension (CTEPH; WHO Group 4) in patients with ONE of the following conditions:

1. Persistent or recurrent pulmonary hypertension after surgical thrombectomy; OR
2. Inoperable CTEPH.

B. The use of riociguat is considered INVESTIGATIVE for the treatment of all other non-PAH pulmonary hypertension conditions, including but not limited to:

1. Pulmonary hypertension associated with left heart diseases (WHO Group 2);
2. Pulmonary hypertension associated with lung diseases and/or hypoxemia (including chronic obstructive pulmonary disease) (WHO Group 3);
3. Miscellaneous conditions (i.e., sarcoidosis, histocytosis X and lymphangiomatosis) (WHO Group 5)

C. The use of epoprostenol, treprostinil, iloprost, selexipag, bosentan, ambrisentan, macitentan, sildenafil, or tadalafil is considered INVESTIGATIVE for the treatment of non-PAH pulmonary hypertension conditions, including but not limited to:

1. Pulmonary hypertension associated with left heart diseases (WHO Group 2);
2. Pulmonary hypertension associated with lung diseases and/or hypoxemia (including chronic obstructive pulmonary disease) (WHO Group 3);
3. Pulmonary hypertension due to chronic thrombotic and/or embolic disease (WHO Group 4);
4. Miscellaneous conditions (i.e., sarcoidosis, histocytosis X and lymphangiomatosis) (WHO Group 5)

- Other Advanced Therapies
  The use of tadalafil 10 mg (Cialis®) and vardenafil 10 mg (Levitra®) is considered INVESTIGATIVE for the treatment of PAH (WHO Group 1) and non-PAH pulmonary hypertension (WHO Groups 2-5).

Transmucosal Fentanyl for Cancer-Related Pain

- Use of transmucosal fentanyl (i.e., Actiq®, fentanyl lozenges, Fentora®, Abstral®, Subsys®, Lazanda®) may be considered MEDICALLY NECESSARY for management of breakthrough cancer pain in patients who meet ALL of the following criteria:
  - Age 18 years or older (Actiq®, fentanyl lozenges, Fentora®, Abstral®, Subsys®, or Lazanda®) OR 16 years or older (Actiq® or fentanyl lozenges); AND
  - Already receiving around-the-clock opioid therapy for underlying persistent cancer pain; AND
  - Currently tolerant to opioid therapy for underlying persistent cancer pain. Patients considered opioid tolerant are those taking at least 60 mg oral morphine daily, at least 25 mcg transdermal fentanyl hourly, at least 30 mg oral oxycodone daily, at least 8 mg oral hydromorphone daily, at least 25 mg oral oxymorphone daily, or an equianalgesic dose of another opioid for a week or longer.

MEDICAL AND BEHAVIORAL HEALTH POLICY UPDATE

- Use of transmucosal fentanyl is considered NOT MEDICALLY NECESSARY for all other indications, including but not limited to treatment of acute, postoperative, or non-cancer-related pain.

Policies inactivated:

BRAF Mutation Analysis
Spinal Fusion: Thoracic

Policies Effective: 05/16/16 Notification Posted: 03/29/16

Policies developed

None

Policies revised

Botulinum Toxin

- The use of botulinum toxin (A or B serotypes) may be considered MEDICALLY NECESSARY for any of the following indications:

A. Cervical dystonia (spasmodic torticollis) to decrease the severity of abnormal head position and neck pain*

B. Strabismus* or blepharospasm including benign essential blepharospasm or VII (facial) nerve disorders in patients 12 years of age and above*

C. Upper or lower limb spasticity*

D. Dystonia/spasticity in patients with any of the following diseases of the central nervous system:
   1. Focal dystonias:
      a. Focal upper limb dystonia (e.g., organic writer's cramp)
      b. Oromandibular dystonia (e.g., orofacial dyskinesia, Meige syndrome)
      c. Laryngeal dystonia (adductor spasmodic dysphonia)
      d. Idiopathic (primary or genetic) torsion dystonia
      e. Symptomatic (acquired) torsion dystonia
   2. Spastic conditions:
      a. Cerebral palsy
      b. Spasticity related to stroke
      c. Acquired spinal cord or traumatic brain injury
      d. Hereditary spastic paraplegia
      e. Spastic hemiplegia
      f. Neuromyelitis optica
      g. Multiple sclerosis or Schilder's disease

E. Esophageal achalasia in patients who have not responded to dilation therapy or who are considered poor surgical candidates

MEDICAL AND BEHAVIORAL HEALTH POLICY UPDATE

F. Sialorrhea (drooling) associated with Parkinson's disease

G. Chronic anal fissure

H. Prevention (treatment) of chronic migraine headache in the following situations*

1. Initial 6-month trial in adult patients, when ALL of the following criteria are met:
   a. Migraine headaches lasting at least 4 hours on at least 15 days per month; AND
   b. Migraine headaches for at least 3 months; AND
   c. Symptoms persist despite adequate trials of at least 2 agents from different classes of medications used in the treatment of chronic migraine headaches (e.g. antidepressants, antihypertensives, and antiepileptics).

   NOTE: Patients who have contraindications to preventive medications are not required to undergo a trial of these agents.
2. Continuing treatment beyond 6-months, when ONE of the following criteria are met:
   a. Migraine headache frequency reduced by at least 7 days per month compared to pre-treatment level; OR
   b. Migraine headache duration reduced at least 100 hours per month compared to pre-treatment level.

I. Urinary incontinence due to detrusor overactivity associated with a neurologic condition [e.g., spinal cord injury (SCI), multiple sclerosis (MS)] in adults who have an inadequate response to or are intolerant of an anticholinergic medication.*

J. Overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency, in adults who have an inadequate response to or are intolerant of an anticholinergic medication.*

* FDA-approved indication for at least one of the agents.

- Retreatment with botulinum toxin is considered NOT MEDICALLY NECESSARY for all indications, including prevention of migraine headache, if the original treatment was determined to be not medically necessary.
- The use of all botulinum toxin agents is considered COSMETIC for the treatment of glabellar lines or wrinkles and other indications solely to improve appearance.
- All other uses of botulinum toxin are considered INVESTIGATIVE including, but not limited to:

A. Bell's palsy

B. Benign prostatic hyperplasia

C. Chronic low back pain

D. Chronic motor tic disorder, and tics associated with Tourette syndrome (motor tics)

E. Depressive disorders

F. Detrusor sphincteric dyssynergia

G. Essential tremor

H. Facial wound healing

I. Gastroparesis

J. Headaches, except as noted above for prevention (treatment) of chronic migraine headache

K. Hirschsprung's disease

L. Internal anal sphincter (IAS) achalasia

M. Interstitial cystitis

MEDICAL AND BEHAVIORAL HEALTH POLICY UPDATE

N. Joint pain
O. Lateral epicondylitis
P. Mechanical neck disorders
Q. Myofascial pain syndrome
R. Neuropathic pain after neck dissection
S. Pain after hemorrhoidectomy or lumpectomy
T. Prevention of pain associated with breast reconstruction after mastectomy
U. Raynaud's disease/Raynaud's phenomenon
V. Sialorrhea (drooling), unless secondary to Parkinson's disease
W. Tinnitus
X. Trigeminal neuralgia

- The use of assays to detect antibodies to botulinum toxin is considered INVESTIGATIVE due to a lack of evidence demonstrating an impact on improved health outcomes.

Tumor Treatment Fields Therapy

- Tumor treatment fields (TTF) therapy may be considered MEDICALLY NECESSARY for patients who meet ALL of the following criteria:

A. History of histologically confirmed glioblastoma (World Health Organization grade IV astrocytoma); and
B. Recurrence of glioblastoma in the supratentorial region of the brain has been histologically or radiologically confirmed; and
C. After surgery, radiation and chemotherapy, or patient is not a candidate for these treatments.

- Tumor treatment fields (TTF) therapy is considered INVESTIGATIVE for all other indications including, but not limited to treatment of other malignancies (e.g., cancers of the breast, lung, ovaries, pancreas, melanoma and solid tumor brain metastases). There is a lack of evidence demonstrating an impact on improved health outcomes for treatment of conditions other than recurrent glioblastoma.

Immune Globulin Therapy

- INTRAVENOUS IMMUNE GLOBULIN

The use of intravenous immune globulin may be considered MEDICALLY NECESSARY in the treatment of the following conditions:

A. Primary Immunodeficiencies
   1. X-linked agammaglobulinemia (XLA or Bruton's agammaglobulinemia);
   2. Common variable immune deficiency (CVID) when the following criteria are met:
      a. Significant and recurrent infections (e.g., recurrent pneumonias, frequent episodes of bacterial sinusitis, and not just isolated chronic sinusitis); AND
      b. Onset of symptoms after two (2) years of age; AND
      c. Abnormally low serum levels of IgM and/or IgA (2 standard deviations below the age-adjusted mean); AND
      d. Abnormally low serum levels of IgG, as demonstrated by ONE of the following:
         i. Total serum IgG level < 400mg/dL; OR

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ii. At least 2 standard deviations below the normal age-adjusted mean;

AND

e. A demonstrated impaired response to immunization with protein AND/OR polysaccharide antigens:

i. For protein antigens: Serum antibody titers to tetanus and/or diphtheria should be obtained before immunization with tetanus and/or diphtheria vaccine and then three to four weeks after immunization. An abnormal response is defined as less than a four-fold rise in antibody titer

ii. For polysaccharide antigens: Serum antibody titers to pneumococcus should be obtained before immunization and then three to six weeks after immunization with a polyvalent pneumococcal polysaccharide vaccine (such as Pneumovax). An abnormal response is defined as less than a four-fold rise in titer;

AND

f. Exclusion of other possible causes of hypogammaglobulinemia.

3. IgG subclass deficiencies

a. Significant and recurrent infections (e.g., recurrent pneumonias, frequent episodes of bacterial sinusitis, and not just isolated chronic sinusitis); AND

b. Abnormally low levels of one or more IgG subclasses (2 standard deviations below the age-adjusted mean) in patients with normal levels of total IgG and IgM; AND

c. A demonstrated impaired response to immunization with protein AND/OR polysaccharide antigens:

i. For protein antigens: Serum antibody titers to tetanus and/or diphtheria should be obtained before immunization with tetanus and/or diphtheria vaccine and then three to four weeks after immunization. An abnormal response is defined as less than a four-fold rise in antibody titer

ii. For polysaccharide antigens: Serum antibody titers to pneumococcus should be obtained before immunization and then three to six weeks after immunization with a polyvalent pneumococcal polysaccharide vaccine (such as Pneumovax). An abnormal response is defined as less than a four-fold rise in titer.

4. X-linked immunodeficiency with hyper IgM;

5. Immunodeficiency with thrombocytopenia and eczema (Wiscott-Aldrich syndrome);

6. Hyperimmunoglobulin E syndrome;

7. Severe combined immune deficiency (SCID);

8. Cellular immunodeficiency with immunoglobulins (Nezelof syndrome);

9. Thymic hypoplasia (DiGeorge's syndrome);

10. Ataxia telangiectasia (Louis-Bar syndrome)

B. Secondary Immunodeficiencies

1. Pediatric human immunodeficiency virus (HIV infection);

2. Acquired hypogammaglobulinemia due to:

a. Chronic lymphocytic leukemia;

b. Multiple myeloma;

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c. Waldenstrom's macroglobulinemia (lymphoplasmacytic lymphoma);

d. Post-CD20 therapy, with recurrent infections

C. Hematologic Disorders

1. Idiopathic thrombocytopenic purpura (ITP);
2. Neonatal alloimmune thrombocytopenia - as antenatal treatment in women who have previously had an infant with alloimmune thrombocytopenia or as neonatal treatment for the infant;
3. Warm antibody autoimmune hemolytic anemia, refractory to cortocosteroids and splenectomy;
4. Pure red cell aplasia due to parvovirus B19;
5. Hemolytic disease of the fetus and newborn (erythroblastosis fetalis)

D. Rheumatic and Inflammatory Disorders

1. Kawasaki disease (mucocutaneous lymph node syndrome);
2. Dermatomyositis that has not responded to treatment with prednisone and immunosuppressant therapy (e.g., azathioprine, methotrexate);
3. Polymyositis that has not responded to treatment with prednisone and immunosuppressant therapy (e.g., azathioprine, methotrexate)

E. Neurologic Disorders

1. Acute inflammatory demyelinating polyneuropathy (Guillain-Barré syndrome);
2. Chronic inflammatory demyelinating polyneuropathy (CIDP);
3. Myasthenia gravis
   a. Myasthenic crisis (i.e., an acute episode of respiratory muscle weakness);
   b. Myasthenia gravis in patients with chronic debilitating disease (e.g., restricted daily activities and symptomatic at rest or worse) despite treatment with cholinesterase inhibitors, or complications from or failure of steroids and /or azathioprine;
4. Multifocal motor neuropathy in patients with conduction block and anti-GM1 antibodies.
5. Stiff-person syndrome (Moersch-Woltman syndrome), after incomplete response to conventional therapy (e.g., benzodiazepines, baclofen)

F. Organ and Stem-Cell Transplantation

1. Prior to solid organ transplantation, for treatment of patients at high risk of antibody-mediated rejection, including highly sensitized patients and those receiving an ABO incompatible organ;
2. Following organ transplantation, for treatment of antibody-mediated rejection;
3. Following hematopoietic stem-cell transplantation, for treatment of related immunodeficiencies.

G. Dermatologic Disorders

1. Autoimmune Mucocutaneous Blistering Diseases, for treatment of the following conditions in patients with severe, progressive disease despite treatment with conventional medical therapy (e.g., corticosteroids, azathioprine, cyclophosphamide):
   a. Pemphigus vulgaris;
   b. Pemphigus foliaceus;

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c. Bullous pemphigoid;
d. Mucous membrane pemphigoid;
e. Bullous systemic lupus erythematosus (SLE);
f. Epidermolysis bullosa acquisita

2. Toxic epidermal necrolysis (TEN)

- SUBCUTANEOUS IMMUNE GLOBULIN

The use of subcutaneous immune globulin (SCIg) therapy may be considered MEDICALLY NECESSARY for the treatment of primary immunodeficiencies (FDA-labeled indications), including the following:

A. Congenital agammaglobulinemia;
B. Severe combined immunodeficiency (SCID);
C. Wiskott-Aldrich syndrome;
D. X-linked agammaglobulinemia (XLA);
E. Common variable immune deficiency (CVID) when the following criteria are met:
1. Significant and recurrent infections (e.g., recurrent pneumonias, frequent episodes of bacterial sinusitis, and not just isolated chronic sinusitis); AND
2. Onset of symptoms after two (2) years of age; AND
3. Abnormally low serum levels of IgM and/or IgA (2 standard deviations below the age-adjusted mean); AND
4. Abnormally low serum levels of IgG, as demonstrated by ONE of the following:
a. Total serum IgG level < 400mg/dL; OR
b. At least 2 standard deviations below the normal age-adjusted mean;
AND
5. A demonstrated impaired response to immunization with protein AND/OR polysaccharide antigens:
a. For protein antigens: Serum antibody titers to tetanus and/or diphtheria should be obtained before immunization with tetanus and/or diphtheria vaccine and then three to four weeks after immunization. An abnormal response is defined as less than a four-fold rise in antibody titer
b. For polysaccharide antigens: Serum antibody titers to pneumococcus should be obtained before immunization and then three to six weeks after immunization with a polyvalent pneumococcal polysaccharide vaccine (such as Pneumovax). An abnormal response is defined as less than a four-fold rise in titer;
AND
6. Exclusion of other possible causes of hypogammaglobulinemia.

- INVESTIGATIVE INDICATIONS

The use of intravenous immune globulin OR subcutaneous immune globulin is considered INVESTIGATIVE in ALL other circumstances, including the following conditions:

A. Chronic fatigue syndrome;
B. Multiple sclerosis (relapsing-remitting and chronic, progressive);
C. Recurrent fetal loss;

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D. Chronic sinus infections *(unless the sinus infection is a symptom of one of the primary immunodeficiencies listed above. Chronic sinus infection is common in most primary immunodeficiencies listed, especially antibody deficiency with normal or near-normal immunoglobulins);

E. Inclusion body myositis;

F. Asthma;

G. POEMS syndrome (polyneuropathy, organeomegaly, endocrinopathy, monoclonal gammopathy, and skin changes);

H. Autistic spectrum disorders;

I. PANDAS (Pediatric Autoimmune Neuropsychiatric Disorders Associated with Streptococcal Infections);

J. Fisher syndrome;

K. Opsoclonus-myoclonus;

L. Postpolio syndrome.

Testing of Circulating Tumor Cells or Cell-Free Tumor DNA

- Testing of circulating tumor cells or cell-free (circulating) tumor DNA in the blood is considered INVESTIGATIVE in all situations including but not limited to screening asymptomatic individuals, and in the diagnosis or management of patients with cancer due to a lack of evidence demonstrating an impact on improved health outcomes.

Ventricular Assist Devices and Total Artificial Hearts

- Implantable Ventricular Assist Devices

A. Implantable ventricular assist devices with FDA approval may be considered MEDICALLY NECESSARY as a bridge to recovery in patients with a potentially reversible condition, including but not limited to:

1. Cardiogenic shock;
2. Cardiomyopathy;
3. Myocarditis;
4. Following cardiac surgery when the patient cannot be weaned from cardiopulmonary bypass.

B. Implantable ventricular assist devices with FDA approval may be considered MEDICALLY NECESSARY as a bridge to heart transplantation in adults who meet one of the following criteria:

1. The patient is currently listed as a heart transplantation candidate and is not expected to survive until a donor heart can be obtained; OR
2. The patient is undergoing evaluation to determine candidacy for heart transplantation.

C. Implantable ventricular assist devices with FDA approval, including humanitarian device exemptions, may be considered MEDICALLY NECESSARY as a bridge to heart transplantation in children and adolescents who meet one of the following criteria:

1. The patient is currently listed as a heart transplantation candidate and is not expected to survive until a donor heart can be obtained; OR
2. The patient is undergoing evaluation to determine candidacy for heart transplantation.

D. Implantable ventricular assist devices with FDA approval may be considered MEDICALLY NECESSARY as destination therapy in patients with end-stage heart failure who are ineligible for heart transplantation and who meet one of the following criteria:

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1. Symptoms of New York Heart Association (NYHA) class IV heart failure for ≥60 days; OR
2. Symptoms of NYHA class III/IV for at least 28 days and dependent on intra-aortic balloon pump for ≥14 days or IV inotropic agents, with two failed weaning attempts.

E. All other uses of implantable ventricular assist devices are considered INVESTIGATIVE, including but not limited to the use of non-FDA approved ventricular assist devices, due to a lack of evidence demonstrating an impact on improved health outcomes.

- Percutaneous Ventricular Assist Devices

A. Percutaneous ventricular assist devices (pVADs) are considered INVESTIGATIVE for all indications, due to a lack of evidence demonstrating an impact on improved health outcomes.

- Total Artificial Hearts

A. Total artificial hearts, used in accordance with their FDA approval, may be considered MEDICALLY NECESSARY as a bridge to heart transplantation for patients with biventricular failure who are currently listed as heart transplantation candidates.

B. All other uses of total artificial hearts are considered INVESTIGATIVE, including but not limited to the use of total artificial hearts as destination therapy and the use of non-FDA approved total artificial hearts, due to a lack of evidence demonstrating an impact on improved health outcomes.

Oscillatory Devices for the Treatment of Cystic Fibrosis and Other Respiratory Disorders in the Home

- The use of high-frequency chest wall oscillation (HFCWO) devices in the home setting may be considered MEDICALLY NECESSARY as an alternative to chest physiotherapy for airway clearance in patients with a diagnosis of cystic fibrosis.
- The use of high-frequency chest wall oscillation (HFCWO) devices in the home setting may be considered MEDICALLY NECESSARY for airway clearance when standard chest physiotherapy (i.e., postural drainage, percussion and vibration, and cough) has failed or cannot be performed for patients with the following conditions:

A. Chronic bronchiectasis confirmed by high resolution computed tomography (CT) and which is characterized by:

1. Daily productive cough for at least 6 continuous months; or
2. Exacerbations occurring more than 2 times per year which require antibiotic therapy.

B. Chronic neuromuscular disorder in patients who have the ability to cough and have experienced pulmonary complications (e.g., pneumonia or other significant worsening of pulmonary function), Examples of chronic neuromuscular disorders include but are not limited to:

1. multiple sclerosis
2. cerebral palsy
3. hereditary muscular dystrophy
4. spinal muscular atrophy
5. myotonic disorders
6. quadriplegia
7. acid maltase deficiency
8. paralysis of the diaphragm
9. post-polio
10. anterior horn cell disease

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- Other applications of HFCWO devices are considered INVESTIGATIVE including but not limited to use:
  A. As an adjunct to chest physiotherapy
  B. In other lung diseases, such as chronic obstructive pulmonary disease (COPD), in the absence of a confirmed diagnosis of bronchiectasis
  C. In chronic neuromuscular disorders not meeting the criteria above
- The use of intrapulmonary percussive ventilation devices is considered INVESTIGATIVE in the treatment of chronic pulmonary diseases, including but not limited to cystic fibrosis, bronchiectasis, and neuromuscular disorders in the home setting.

Policies inactivated:

Balloon Catheter Therapy for Chronic Rhinosinusitis
Oxygen
Negative Pressure Wound Therapy Pumps/Vacuum Assisted Closure of Chronic Wounds
Interferential Stimulator
Non-Powered Negative Pressure Wound Therapy System
Seat Lift Mechanisms
Positional MRI
Functional Magnetic Resonance Imaging-(fMRI)

Policies Effective: 06/20/16 Notification Posted: 04/29/16

Policies developed

Genetic Cancer Susceptibility Panels

- I. Multigene cancer susceptibility panels may be considered MEDICALLY NECESSARY when all of the following are met:
  A. Pretest genetic counseling by a cancer genetics professional independent of the laboratory performing the test documents a family history/pedigree consistent with an inherited cancer or cancer syndrome; OR an individual has tested negative (indeterminate) for a single syndrome, but personal or family history remains strongly suggestive of an inherited susceptibility; AND
  B. The genetic disorder is associated with one or more cancers; AND
  C. The risk of cancer from the genetic disorder cannot be identified through biochemical or other testing; AND
  D. Genes in the panel have a direct association with increased susceptibility for the specific cancer or cancer syndrome in question; AND
  E. Results of testing will impact the medical management of the individual (e.g., increased screening or surveillance).
- II. Multigene cancer susceptibility panels are considered INVESTIGATIVE for all other indications, including but not limited to the following, due to a lack of clinical evidence demonstrating an impact on improved health outcomes:
  A. Panel includes genes for which there is not clear evidence of a direct association with increased risk for a specific cancer or cancer syndrome. These include but are not limited to:
    - CancerNext™ Expanded

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- ColoNext™ (colon cancer)
- RenalNext™ (kidney cancer)
- GeneDx Colorectal Cancer Panel
- iGene Cancer Panel
- University of Washington ColoSeq™
- VistaSeq Hereditary Cancer Panel

B. Testing done in the absence of pretest genetic counseling by a cancer genetics professional independent of the laboratory performing the test

C. Panel is offered as a direct access (also known as direct to consumer) test

D. Panel testing in the general population as a screening tool

E. All other uses of genetic cancer susceptibility panel testing which do not meet criteria as stated above

Policies revised

Genetic Testing

- The following criteria apply to circumstances in which there is no Blue Cross Blue Shield of Minnesota medical policy that addresses genetic testing for a specific condition.
- I. Carrier Testing for Genetic Disease

  Prenatal carrier testing in adults may be considered MEDICALLY NECESSARY when the parent or prospective parent is at high risk of being a carrier of a specific genetic disorder based upon family history as defined by meeting one or more in IA and ALL of the requirements in IB.

  A. At least one of the following criteria are met:

     1. The individuals have a previously affected child with the genetic disease; OR
     2. One or both individuals have a first- or second-degree relative who is affected; OR
     3. One or both individuals have a first-degree relative with an affected offspring; OR
     4. One or both individuals is known to be a carrier of a clinically significant hereditary condition; OR
     5. One or both individuals are members of a population known to have a carrier prevalence for a particular condition that is higher than the prevalence found in the general population. These include, but are not limited to:
        a. Bloom syndrome, Canavan disease, cystic fibrosis, familial disautonomia, Fanconi anemia, Gaucher disease mucolipidosis IV, Niemann-Pick (type A) and Tay-Sachs disease in individuals of Ashkenazi Jewish descent
        b. Hemoglobinopathies in individuals of African American, Southeast Asian and Mediterranean descent

  AND

  B. ALL of the following criteria are met:

     1. The natural history of the disease is well understood and there is a reasonable likelihood that the disease is one with high morbidity in the homozygous or compound heterozygous state; AND
     2. A clinical association between the genetic marker and the disorder has been established; AND
     3. Alternative biochemical or other clinical tests to definitively diagnose carrier status are not available, or, if available, provide an indeterminate result or are individually less efficacious than genetic testing; AND

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4. Genetic testing is performed to facilitate decisions surrounding reproduction.

C. Carrier testing for genetic disease is considered INVESTIGATIVE when the criteria above are not met due to a lack of clinical evidence demonstrating its impact on improved health outcomes.

D. Expanded carrier testing panels are considered INVESTIGATIVE due to a lack of clinical evidence demonstrating its impact on improved health outcomes. These include but are not limited to the following:

- 23andMe
- Counsyl™
- GoodStart Select™
- InheriGen™
- InheriGenPlus™
- Inheritest™
- Natera Horizon™ Multi-Disease Carrier Screening
- Progenity™ nxtPanel

- II. Genetic Testing to Determine Risk of a Non-Cancer Condition

A. Genetic testing to determine future risk of a non-cancer condition may be considered MEDICALLY NECESSARY when all of the following criteria are met:

1. Pretest genetic counseling by a genetics professional independent of the laboratory performing the test documents a family history/pedigree consistent with an inherited condition or syndrome; OR an individual has tested negative (indeterminate) for a single syndrome, but personal or family history remains strongly suggestive of an inherited susceptibility; AND
2. A specific causative mutation, or set of mutations, has been established for the disorder being evaluated; AND
3. A clinical association between the genetic marker(s) and the disorder has been established; AND
4. The results of the genetic test will impact disease prevention, surveillance, or medical management of the individual.

B. Presymptomatic genetic testing to predict risk of a non-cancer condition is considered INVESTIGATIVE when the criteria above are not met. There is a lack of clinical evidence demonstrating its impact on improved health outcomes.

C. Multigene sequencing panels that include genes with no established clinical association between the genetic marker and risk for the disorder are considered INVESTIGATIVE due to a lack of evidence demonstrating an impact on improved health outcomes. Examples of these tests include but are not limited to the following:

- 23andMe
- ARUP Aortopathy Sequencing Panels
- Athena Autosomal Recessive Ataxia Evaluation Panel
- deCODE T2™
- deCODE AF™
- deCODE MI™
- deCODE Glaucoma™
- GeneDX Childhood-onset Epilepsy panel

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- GeneDX Chronic Pancreatitis Sequencing Panel
- MNG Laboratories Comprehensive Epilepsy NextGen DNA Sequencing Panel
- Pathway Genomics® Cardiac DNA Insight and Cardiac Healthy Weigh DNA Insight

D. Genetic testing of children to predict adult onset of disease is considered NOT MEDICALLY NECESSARY unless test results will guide current decisions concerning prevention and this benefit would be lost by waiting until the child has reached adulthood.

- III. Genetic Testing to Determine Cancer Susceptibility

A. Genetic Cancer Susceptibility Panels are addressed in policy VI-56;

B. Genetic Testing for Hereditary Breast and/or Ovarian Cancer Syndrome (BRCA1 and BRCA2 Genes) is addressed in policy VI-16.

- IV. Genetic Testing for Diagnosis or Disease Prognosis

A. The following tests (related genes in parentheses) may be considered MEDICALLY NECESSARY for symptomatic patients

- Alpha thalassemia (HBA1/HBA2, alpha globin 1 and alpha globulin 2)
- Bloom syndrome (BLM)
- Canavan disease (ASPA - aspartoacylase A)
- Cystic fibrosis (CFTR - cystic fibrosis transmembrane conductance regulator)
- Factor V Leiden thrombophilia (F5 - Coagulation Factor V)
- Familial dysautonomia (IKBKAP - inhibitor of kappa light polypeptide gene enhancer in B-cells, kinase complex-associated protein)
- Gaucher disease (GBA - acid beta glucosidase)
- Hemoglobin E thalassemia (Glu26Lys mutation in beta-globin)
- Mucolipidosis IV (MCOLN1- mucolipin 1)
- Myotonic dystrophy (DMPK - dystrophia myotonica protein kinase and CCHC- also known as ZNF9)
- Niemann-Pick Type A (SMPD1, sphingomyelin phosphodiesterase)
- Retinoblastoma (RB1- retinoblastoma 1)
- Sickle cell anemia (HBB - hemoglobin subunit beta)
- Spinal muscular atrophy (SMN1, SMN2)
- Tay-Sachs disease (HEXA - hexosaminidase A)
- Von Hippel-Lindau syndrome (VHL- von Hippel-Lindau tumor suppressor)

B. Genetic testing may be considered MEDICALLY NECESSARY to diagnose a genetic disorder in individuals with signs or symptoms who meet ALL of the following criteria:

1. Pretest genetic counseling by a genetics professional trained in the treatment of the suspected or diagnosed condition, independent of the laboratory performing the test, has been documented; AND
2. The genes included in the testing are directly associated with the individual's symptoms or diagnosis; AND
3. A biochemical or other test is identified but the results are indeterminate, or the genetic disorder cannot be identified through biochemical or other testing (examples of conditions for which there is biochemical testing

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available include but are not limited to serum cholesterol testing for familial hypercholesterolemia or ultrasound screening for aortic disease in Marfan syndrome); AND

4. The results of the genetic test will impact the medical management of the individual.

C. Multigene sequencing panels that include genes with no established clinical association between the genetic marker and the disorder are considered INVESTIGATIVE due to a lack of evidence demonstrating an impact on improved health outcomes. Examples of these tests include but are not limited to the following:

- Ambry Genetics Pan Cardio Panel
- Ambry Genetics Marfan, Aneurysm and Related Disorders Panel
- Baylor College of Medicine Low Bone Mass Panel
- Emory Genetic Arrythmias Sequencing Panel and Deletion/Duplication Panel
- MDx™ Health Confirm

D. Genetic testing for diagnostic purposes in individuals not meeting the above criteria is considered INVESTIGATIVE due to a lack of evidence demonstrating an impact on improved health outcomes.

Wireless Capsule Endoscopy

- I. Wireless capsule endoscopy may be considered MEDICALLY NECESSARY for ANY of the following indications:

A. Obscure gastrointestinal (GI) bleeding or iron deficiency anemia, suspected to be of small bowel origin, when evaluation by upper and lower endoscopies has been inconclusive; OR

B. Initial diagnosis in patients with suspected Crohn's disease when conventional diagnostic tests (e.g., small bowel follow-through, upper and lower endoscopy) have been inconclusive and there is no suspected or confirmed gastrointestinal obstruction, stricture, or fistulae; OR

C. Diagnostic reevaluation of patients with known Crohn's disease who remain symptomatic after treatment and there is no suspected or confirmed gastrointestinal obstruction, stricture, or fistulae; OR

D. Surveillance of the small bowel in patients with hereditary GI polyposis syndromes, including familial adenomatous polyposis and Peutz-Jeghers syndrome.

- II. The use of wireless capsule endoscopy is considered INVESTIGATIVE for all other indications, including, but not limited to:

A. Initial diagnosis or follow-up of all other intestinal conditions (e.g., irritable bowel syndrome, celiac sprue, small bowel neoplasm, Lynch syndrome, portal hypertensive enteropathy, or unexplained chronic abdominal pain);

B. Initial evaluation of acute upper GI bleeding;

C. Evaluation of the extent of involvement of known Crohn's disease or ulcerative colitis;

D. Evaluation of diseases involving the esophagus (e.g., chronic gastroesophageal reflux disease, Barrett's esophagus);

E. Evaluation of the colon including, but not limited to, detection of colonic polyps or colon cancer.

- III. Use of the patency capsule prior to wireless capsule endoscopy is considered INVESTIGATIVE due to a lack of clinical evidence demonstrating its impact on improved health outcomes.

Pressure Reducing Support Services

- I. Group 1 Pressure Reducing Support Surfaces (A4640, E0181,E0182, E0184, E0185, E0186, E0187, E0196, E0197, E0198 and E0199

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A group 1 mattress overlay or mattress may be considered MEDICALLY NECESSARY when ONE of the following criteria are met:

A. Member is completely immobile (i.e., cannot make changes in body position without assistance); OR

B. Member cannot independently make changes in body position significant enough to alleviate pressure and has at least one of the following conditions:

1. Impaired nutritional status
2. Fecal or urinary incontinence
3. Altered sensory perception
4. Compromised circulatory status

OR

C. Member has any stage pressure ulcer on the trunk or pelvis and at least one of the conditions:

1. Impaired nutritional status
2. Fecal or urinary incontinence
3. Altered sensory perception
4. Compromised circulatory status

- II. Group 2 Pressure Reducing Support Surfaces (E0193, E0277, E0371, E0372 and E0373)

A. Initial use of a group 2 pressure reducing support surface (i.e., alternating pressure and low air loss mattress and overlay) may be considered MEDICALLY NECESSARY when AT LEAST ONE of the following criteria are met:

1. Multiple stage II pressure ulcers located on the trunk or pelvis which have failed to improve over the past month and member has been on a comprehensive ulcer treatment program for at least one month including each of the following:
   a. Use of an appropriate group 1 support surface; and
   b. Regular assessment by a nurse, physician or other licensed healthcare practitioner; and
   c. Appropriate turning and positioning; and
   d. Appropriate wound care; and
   e. Appropriate management of moisture/incontinence; and
   f. Nutritional assessment and intervention consistent with the overall plan of care.

   OR

2. Large or multiple stage III (full thickness tissue loss) or stage IV (deep tissue destruction) pressure ulcer(s) on the trunk or pelvis and member cannot be positioned off the ulcer areas;

   OR

3. Myocutaneous flap or skin graft surgery for a pressure ulcer on the trunk or pelvis (within the past 60 days);and member has been on a group 2 or 3 pressure reducing support surface immediately prior to discharge from a hospital or other inpatient setting (discharge within the past 30 days);

B. Continued use of a Group 2 support surface after the initial approval for healing of stage II, III, or IV pressure ulcers may be considered MEDICALLY NECESSARY until the ulcer has healed or, if healing does not continue, there is documentation in the medical record that:

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1. Other aspects of the care plan are being modified to promote healing; AND
2. The member continues to meet medical necessity criteria for a group 2 support surface listed above.

C. Continued use of a group 2 pressure reducing support surface following a myocutaneous flap or skin graft, may be considered MEDICALLY NECESSARY for up to 60 days from the date of surgery.

- III. Group 3 Pressure Reducing Support Surfaces (E0194)

A. Initial use of a group 3 pressure reducing support surface (i.e., air-fluidized bed) may be considered MEDICALLY NECESSARY when ALL of the following criteria are met:

1. Stage III (i.e., full thickness tissue loss) or stage IV (i.e., deep tissue destruction) pressure ulcer; AND
2. Bedridden or chair-bound as a result of severely limited mobility; AND
3. In the absence of an air-fluidized bed, the member would require care in a hospital or other inpatient setting; AND
4. A documented order for the air-fluidized bed from the member's physician based upon a comprehensive assessment and evaluation of the member after completion of a course of conservative treatment designed to optimize conditions that promote wound healing. The evaluation generally must be performed within one month prior to initiation of therapy with the air-fluidized bed; AND
5. The course of conservative therapy must have been at least one month in duration without progression toward wound healing. This month of prerequisite conservative treatment may include some period in a hospital or other active inpatient setting as long as there is documentation available to verify that the necessary conservative treatment was rendered. Conservative treatment must include:
   a. Frequent repositioning of member with particular attention to relief of pressure over bony prominences (usually every 2 hours); and
   b. Use of a Group 2 support surface to reduce pressure and shear forces on healing ulcers and to prevent new ulcer formation; and
   c. Necessary treatment to resolve any wound infection; and
   d. Optimization of nutrition status to promote wound healing; and
   e. Debridement by any means, including wet-to-dry gauze dressings to remove devitalized tissue from the wound bed; and
   f. Maintenance of a clean, moist bed of granulation tissue with appropriate moist dressings protected by an occlusive covering, while the wound heals.

   AND
6. A trained adult caregiver is available to assist the member with activities of daily living (ADLs), fluid balance, dry skin care, repositioning, recognition and management of altered mental status, dietary needs, prescribed treatments, and management and support of the air fluidized bed system and its problems such as leakage; AND
7. A physician directs the home treatment regimen, and reevaluates and recertifies the need for the air-fluidized bed on a monthly basis; AND
8. All other alternative equipment has been considered and ruled out.

B. Continued use of a group 3 surface (i.e., air-fluidized bed) may be considered MEDICALLY NECESSARY when the treating physician re-certifies the following on a monthly basis:

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1. Stage III or IV pressure ulcer; AND
2. Member is bedridden or chair bound as a result of severely limited mobility; AND
3. All other alternative equipment has been considered and ruled out; AND
4. Other aspects of the care plan are being modified to promote healing.

C. After six months on a Group 3 support surface with no improvement in the member's condition, alternative treatments must be considered before additional monthly authorization.

D. An air-fluidized bed is considered NOT MEDICALLY NECESSARY under any of the following circumstances:

1. The member has co-existing pulmonary disease (the lack of back support makes coughing ineffective and dry air inhalation thickens pulmonary secretions);
2. The member requires treatment with wet soaks or moist wound dressings not protected with an impervious covering unless the member is undergoing aggressive treatment in a wound clinic and is showing measurable improvement.

Stem-Cell Therapy for Orthopedic Applications

- Stem-cell therapy is considered INVESTIGATIVE for all orthopedic applications, including but not limited to use in repair or regeneration of musculoskeletal tissue, due to a lack of evidence demonstrating an impact on improved health outcomes. Stem-cell therapy includes use of any of the following:
  - Mesenchymal stem cells (MSCs), including concentrated, engineered, or expanded MSCs;
  - Allograft bone products containing viable stem cells, including but not limited to demineralized bone matrix (DBM) with stem cells;
  - Allograft or synthetic bone graft substitutes that must be combined with autologous blood or bone marrow.

Implantable Cardioverter-Defibrillator

- I. Transvenous Implantable Cardioverter-Defibrillators

A. Adult Patients

1. The use of an implantable cardioverter-defibrillator (ICD) may be considered MEDICALLY NECESSARY in adults (18 years of age or older) who meet any of the following criteria:
   a. History of life-threatening clinical event (e.g. cardiac arrest) due to ventricular fibrillation (VF) or sustained ventricular tachycardia (VT) neither of which is due to reversible or transient causes; OR
   b. Spontaneous sustained VT in patients with structural heart disease; OR
   c. Spontaneous sustained VT in patients without structural heart disease, that is not amenable to other treatments; OR
   d. Syncope of undetermined origin with clinically relevant, hemodynamically significant, sustained VT or VF induced at electrophysiological study; OR
   e. Ischemic cardiomyopathy at least 40 days post MI, with left ventricular ejection fraction (LVEF) less than or equal to 30%, and are in New York Heart Association (NYHA) Class I; OR
   f. Ischemic dilated cardiomyopathy (IDCM) with NYHA Class II or III heart failure at least 40 days post MI, and measured left ventricular ejection fraction (LVEF) less than or equal to 35%; OR
   g. Non-ischemic dilated cardiomyopathy (NIDCM) with LVEF less than or equal to 35% after reversible causes have been excluded, and the response to optimal medical therapy has been adequately determined; OR

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h. Nonsustained VT due to prior MI, LVEF less than or equal to 40%, and inducible VF or sustained VT at electrophysiological study; OR

i. Hypertrophic cardiomyopathy (HCM) with one or more of the following risk factors and judged to be at high risk for sudden cardiac death (SCD) by a physician experienced in the care of patients with HCM:

- Prior cardiac arrest;
- Family history of HCM-related SCD in at least one first-degree relative younger than 50 years;
- 1 or more runs of VT at heart rates of 120 beats per minute or greater;
- Unexplained syncope within the previous 12 months inconsistent with neurocardiogenic origin;
- Abnormal blood pressure response to exercise in the presence of other SCD risk factors or modifiers;
- LV wall thickness greater than or equal to 30 mm.

2. The use of an ICD may be considered MEDICALLY NECESSARY for the prevention of sudden cardiac death (SCD) after diagnosis of any one of the following cardiac ion channelopathies and the criteria for high risk of SCD are met:

a. Long QT syndrome (LQTS), with a history of cardiac arrest or recurrent syncope while on beta blocker therapy

b. Brugada syndrome (BrS) with history of cardiac arrest; or documented spontaneous VT with or without syncope, or induced sustained VT

c. Catecholaminergic polymorphic ventricular tachycardia (CPVT) with a history of cardiac arrest, recurrent syncope, documented VT that is nonresponsive to optimal medical management or with left cardiac sympathetic denervation

d. Short QT syndrome (SQTS) with history of cardiac arrest, documented spontaneous VT with or without syncope; or family history of SCD

3. The use of an implantable cardioverter-defibrillator (ICD) is considered INVESTIGATIVE for all other indications in adults due to a lack of clinical evidence demonstrating its impact on improved health outcomes.

B. Pediatric Patients

1. The use of an implantable cardioverter-defibrillator may be considered MEDICALLY NECESSARY in children and adolescents (< 18 years of age) who meet any of the following criteria:

a. Survivors of cardiac arrest, after reversible causes have been excluded; OR

b. Symptomatic, sustained ventricular tachycardia in association with congenital heart disease in patients who have undergone hemodynamic and electrophysiologic evaluation; OR

c. Congenital heart disease with recurrent syncope of undetermined origin in the presence of either ventricular dysfunction or inducible ventricular arrhythmias; OR

d. Hypertrophic cardiomyopathy (HCM) with 1 or more of the following risk factors for sudden cardiac death (SCD) and judged to be a high risk for (SCD) by a physician experienced in the care of patients with HCM:

- Family history of HCM-related SCD in at least one first-degree relative younger than 50 years;
- LV hypertrophy based on age-specific norms;
- Unexplained syncope within the previous 12 months inconsistent with neurocardiogenic origin.

2. The use of an ICD may be considered MEDICALLY NECESSARY for the prevention of sudden cardiac death (SCD) after diagnosis of any one of the following cardiac ion channelopathies and the criteria for high risk of SCD

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are met:

a. Long QT syndrome (LQTS), with a history of cardiac arrest or recurrent syncope while on beta blocker therapy

b. Brugada syndrome (BrS) with history of cardiac arrest; or documented spontaneous VT with or without syncope or induced sustained VT

c. Catecholaminergic polymorphic ventricular tachycardia (CPVT) with a history of cardiac arrest, recurrent syncope, documented VT that is nonresponsive to optimal medical management or with left cardiac sympathetic denervation

d. Short QT syndrome (SQTS) with history of cardiac arrest, documented spontaneous VT with or without syncope; or family history of SCD

3. The use of an implantable cardioverter-defibrillator (ICD) is considered INVESTIGATIVE for all other indications in children and adolescents due to a lack of clinical evidence demonstrating its impact on improved health outcomes.

- II. Subcutaneous Implantable Cardioverter-Defibrillators

  The use of a subcutaneous implantable cardioverter-defibrillator is considered INVESTIGATIVE for ALL indications in adult and pediatric patients, due to a lack of evidence demonstrating an impact on improved health outcomes.

Policies inactivated:

Anesthesia-Assisted Opioid Withdrawal

Patient Lifts

Nebulizers

Naltrexone Extended Release Injection (Vivitrol)

In Vitro Allergy Testing

First Trimester Screening for Fetal Aneuploidy

Allergy Skin Testing

Natalizumab (Tysabri)

Policies reviewed with no changes in February 2016 - April 2016:

Autism Spectrum Disorders: Assessment

Automated Point-of-Care Nerve Conduction Tests

Bone Growth Stimulators

Breast Implant, Removal or Replacement

Cooling/Heating Devices Used in the Outpatient Setting

Cryoablation of Solid Tumors

Dynamic Spine Stabilization

Electric/Electromagnetic Stimulations for Treatment of Arthritis

Gene Expression Profiling for the Management of Breast Cancer

Gene Expression Testing for Cancers of Unknown Primary

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Gene Expression Testing to Predict Coronary Artery Disease (CAD)

Genetic Testing for FMR1 Mutations (Including Fragile X Syndrome)

Genetic Testing for Warfarin Dose

Growth Factors for Treatment of Wounds and Other Conditions

Hair Analysis

Hematopoietic Stem-Cell Transplantation for Central Nervous System (CNS) Embryonal Tumors and Ependymoma

Hematopoietic Stem-Cell Transplantation for Chronic Lymphocytic Leukemia and Small Lymphocytic Lymphoma

Hematopoietic Stem-Cell Transplantation for Chronic Myelogenous Leukemia

Hematopoietic Stem-Cell Transplantation for Miscellaneous Solid Tumors in Adults

Hematopoietic Stem-Cell Transplantation for Myelodysplastic Syndrome and Myeloproliferative Neoplasms

Hippotherapy

In Vitro Chemoresistance and Chemosensitivity Assays

Intra-Articular Hyaluronan Injections for Osteoarthritis

Intradiscal Electrothermal Annuloplasty (IDET), Percutaneous Radiofrequency Annuloplasty (PIRFT), and Intradiscal Biacuplasty

Intravenous Anesthetics for the Treatment of Chronic Pain

Islet Transplantation

Laparoscopic and Percutaneous Techniques for the Myolysis of Uterine Fibroids

Lysis of Epidural Adhesions

Metallothionein Protein (MT) Assessment and Treatment Protocol

Microwave Ablation of Solid Tumors

Mobile Cardiac Outpatient Telemetry

MRI-Guided High-Intensity Focused Ultrasound Ablation of Uterine Fibroids and Other Tumors

Multigene Expression Assays for Predicting Recurrence in Colon Cancer

Occipital Nerve Stimulation

Photodynamic Therapy for Skin Conditions

Positron Emission Mammography

Prolotherapy

Proteomics-based Testing Panels for the Evaluation of Ovarian (Adnexal) Masses

Proton Beam Radiation Therapy

Quantitative Sensory Testing

Rhinoplasty

Saliva Hormone Tests

Scintimammography/Breast-Specific Gamma Imaging/Molecular Breast Imaging

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Selected Treatments for Tinnitus

Selected Treatments for Varicose Veins of the Lower Extremities

Sleep Disorder Testing in Adults

Surface Electromyography (SEMG)

Traction Decompression of the Spine

Vestibular Evoked Myogenic Potential (VEMP) Testing

Whole Exome and Whole Genome Sequencing for the Diagnosis of Genetic Disorders

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:

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

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