thrive. MEMBER INFORMATION, PROVIDER SUPPORT

Blue Cross and Blue Shield of Minnesota is pleased to announce thrive., a quarterly newsletter designed specifically for our Medicare members. thrive. was launched late in 2015 and is filled with relevant, easy-to-digest health information — empowering readers to achieve their best health. thrive. articles are written for our Medicare members and provide educational topics such as the importance of preventive screenings, managing chronic conditions, medication related tips, etc.

Members are encouraged to talk with their providers about what screenings make sense for them, how they have been feeling physically and mentally, and what concerns they have about managing their own or a loved one’s chronic conditions.

Go to bluecrossmn.com/star-ratings-program to download a copy of thrive.

FYI

UPDATE TO BLUE CROSS’ FAX NUMBER FOR MINNESOTA PREGNANCY ASSESSMENT FORM

The fax number to submit the Minnesota Pregnancy Assessment Form (MPAF) has changed as of January 1, 2016. Submissions of the MPAF should be sent to the new fax number of 651-662-2064.

2ND ANNUAL MINNESOTA STI TESTING DAY, APRIL 12, 2016

In an effort to promote testing and heighten awareness for STD/STI Awareness Month, the second annual STI Testing Day will be observed in Minnesota on April 12, 2016. The observance is led by the Community Restoring Urban Youth Sexual Health (CRUSH) in partnership with the Minnesota Chlamydia Partnership (MCP).

Chlamydia remains Minnesota’s number one reported infectious disease with a record high 19,897 cases reported in 2014. Teens and young adults between the ages of 15 and 24 have the highest rates of chlamydia, particularly from those communities experiencing social, economic and health-related inequalities.

Additional testing sites and raised awareness are needed for this observance. Teen friendly clinics that can offer a no-cost or low cost STD/STI testing and treatment, should consider participating. Any Minnesota clinics interested in participating and publicizing can find additional information on the website at http://www.crushsti.com/.
PUBLICATIONS AVAILABLE ONLINE

The following is a list of Quick Points and Bulletins published from December 2015 to February 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**

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<td>QP33-15</td>
<td>Common Carrier and Special Transportation Providers Billing Code for Parking Fees or Tolls</td>
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<td>New Operating System Provider Eligibility and Benefit Transaction Differences</td>
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<td>New Prior Authorization Criteria for Addyi™ (fibanserin)</td>
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<td>Prior Authorization Requirements for a New Drug, Entresto (sacubitril/valsartan)</td>
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<td>P58-15</td>
<td>Prior Authorization Requirements for a New Drug, Grazoprevir/Elbasvir</td>
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<td>P10-16</td>
<td>New Drug-Related Prior Authorization Criteria for Gattex</td>
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PROVIDER MANUAL UPDATES

The following is a list of Blue Cross provider manuals that have been updated from December 2015 to February 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.

<table>
<thead>
<tr>
<th>MANUAL NAME</th>
<th>CHAPTER NUMBER AND TITLE</th>
<th>SUMMARY OF CHANGES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Provider Policy and Procedure Manual</td>
<td>Chapter 3, Quality Improvement</td>
<td>Clinical Practice Guidelines</td>
</tr>
</tbody>
</table>
| Blue Plus Manual | Chapter 3, Government Programs | • Public Programs Special Benefits  
• All New Care Coordination Delegation Guidelines  
• Child Injury Prevention Topic: added ICD-10 Coding |

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

APPEAL CONTACT INFORMATION
When submitting an appeal, sometimes we need to contact you for clarification or questions on your appeal. We would appreciate your help by providing a contact name, phone number, address and if possible, a fax number.

CODE EDITS UPDATE REMINDER
Blue Cross’ coding edits are not updated and loaded at the same time as the coding changes are available. While we are reviewing potential edits at this time, until implemented, coding edits will not be applied to the new 2016 codes. This does not mean that the codes are invalid. All new HCPCS/CPT codes effective January 1, 2016, have been loaded to our claims system.

Once the new and revised edits are implemented, all claims submitted after the implementation date of the update, regardless of service date, will be processed according to that updated version or instituted edit.

POS 19 EFFECTIVE DATE
The Medicare Place of Service (POS) codes for Professional Claims list was updated August 6, 2015. The new POS 19 was on that list but the date a POS code is added to the grid is not the effective date for that POS. The submission effective date is January 1, 2016. If the POS 19 is submitted with a date of service prior to 1/1/2016 the claim will be rejected. The entire narrative from the Medicare document is as follows:

<table>
<thead>
<tr>
<th>POS 19</th>
<th>Off Campus-Outpatient Hospital</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>A portion of an off-campus hospital provider based department which provides diagnostic, therapeutic (both surgical and nonsurgical), and rehabilitation services to sick or injured persons who do not require hospitalization or institutionalization. <em>(Effective January 1, 2016)</em></td>
</tr>
</tbody>
</table>

FYI WHO TO CONTACT

<table>
<thead>
<tr>
<th>HELPFUL PHONE NUMBERS</th>
</tr>
</thead>
<tbody>
<tr>
<td>BLUELINE (voice response unit)</td>
</tr>
<tr>
<td>BlueCard® member benefits or eligibility</td>
</tr>
<tr>
<td>FEP® (voice response unit)</td>
</tr>
<tr>
<td>Availity</td>
</tr>
<tr>
<td>Provider services</td>
</tr>
</tbody>
</table>

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.
PHARMACY SECTION

PHARMACY UPDATES FOR QUARTER 1, 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 evaluates 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 January 1, 2016:

<table>
<thead>
<tr>
<th>ADDITIONS TO FlexRx FORMULARY</th>
<th>REMOVALS FROM FlexRx FORMULARY</th>
</tr>
</thead>
<tbody>
<tr>
<td>ARNUNITY ELLIPTA</td>
<td>MESTINON TIMESPAN</td>
</tr>
<tr>
<td>BENICAR, BENICAR HCT</td>
<td>NEXIUM CAPS</td>
</tr>
<tr>
<td>BREO ELLIPTA</td>
<td>VIEKIRA PAK</td>
</tr>
<tr>
<td>DAKLINZA</td>
<td>ZYVOX TABS</td>
</tr>
<tr>
<td>NOVOEIGHT</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ADDITIONS TO GenRx FORMULARY</th>
<th>REMOVALS FROM GenRx FORMULARY</th>
</tr>
</thead>
<tbody>
<tr>
<td>CRESTOR</td>
<td>MESTINON TIMESPAN</td>
</tr>
<tr>
<td>DAKLINZA</td>
<td>VIEKIRA PAK</td>
</tr>
<tr>
<td>NOVOEIGHT</td>
<td>ZYVOX TABS</td>
</tr>
</tbody>
</table>

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

Drug Formulary Exclusions

Effective January 1, 2016, Blue Cross and Blue Shield of Minnesota implemented selected drug coverage exclusions in nine drug categories. This may mean that coverage of these drugs will be excluded depending on the member’s prescription drug benefit. The drug categories with selected exclusions are:

<table>
<thead>
<tr>
<th>Category</th>
<th>Exclusions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Androgens and Anabolic Steroids</td>
<td>Doxycycline/Minocycline</td>
</tr>
<tr>
<td>Glucose Test Strips</td>
<td>Growth Hormones</td>
</tr>
<tr>
<td>Sedative/Hypnotics</td>
<td>Insulin</td>
</tr>
<tr>
<td>Nasal Steroids</td>
<td>Topical Acne Antibiotics</td>
</tr>
<tr>
<td>Topical Retinoids</td>
<td></td>
</tr>
</tbody>
</table>

In all cases, there are formulary alternatives to the excluded drugs. The complete list of excluded drugs can be found at:

https://www.myprime.com/content/dam/prime/memberportal/forms/2015/FullyQualified/Other/ALL/BCBSMN/COMMERCIAL/MNFLEXRX/MN_Drug_Exclusion_List.pdf
PHARMACY UPDATE FOR QUARTER 1, 2016

**Utilization Management Updates**

**Quantity Limits**

Effective January 1, 2016, Blue Cross and Blue Shield of Minnesota implemented additional quantity limits depending on the member's prescription drug benefit. Programs in this update include new quantity limits for:

<table>
<thead>
<tr>
<th>Category</th>
<th>Drugs</th>
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<tbody>
<tr>
<td>Alzheimer's medications</td>
<td>Anti-emetics</td>
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<td>BPH drugs</td>
<td>DPP4s</td>
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<tr>
<td>HAE drugs</td>
<td>Insulin</td>
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<tr>
<td>Nasal steroids</td>
<td>Niacin extended-release</td>
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<tr>
<td>Topical NSAIDs</td>
<td>Transdermal fentanyl</td>
</tr>
<tr>
<td>Antidepressants</td>
<td>ARBs</td>
</tr>
<tr>
<td>Biologics for rheumatoid arthritis/psoriasis/Crohn's</td>
<td>Cystic fibrosis</td>
</tr>
<tr>
<td>Migraine</td>
<td>MS</td>
</tr>
<tr>
<td>Statins</td>
<td>Oral oncology drugs</td>
</tr>
</tbody>
</table>

**Prior Authorization**

New prior authorization programs for Addyi (effective February 1, 2016), Catena, drisapersen, eteplirsen, obeticholic acid, Translarna, and Uptravi (will be effective February 1, 2016 or upon drug launch).

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/MN_FlexRx_UM_Updates.pdf](https://www.myprime.com/content/dam/prime/memberportal/forms/2015/FullyQualified/Other/ALL/BCBSMN/COMMERCIAL/MN_FlexRx_UM_Updates.pdf)

**GenRx**

[https://www.myprime.com/content/dam/prime/memberportal/forms/2015/FullyQualified/Other/ALL/BCBSMN/COMMERCIAL/MN_GenRx_UM_Updates.pdf](https://www.myprime.com/content/dam/prime/memberportal/forms/2015/FullyQualified/Other/ALL/BCBSMN/COMMERCIAL/MN_GenRx_UM_Updates.pdf)

For tools and resources regarding Pharmacy please visit our website at [blucrossmn.com](http://blucrossmn.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.blucrossmn.com](http://providers.blucrossmn.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.
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
QUALITY IMPROVEMENT

CLINICAL PRACTICE GUIDELINES

Blue Cross believes that the use of clinical practice guidelines is a key component of Quality Improvement. Each year, Blue Cross’ Clinical Practice Quality Committee (a designee of the Quality Council) approves the adoption of select guidelines that are used to support various programs and initiatives. The guidelines do not substitute for sound clinical judgement; however, they are intended to assist clinicians in understanding key processes for improvement efforts.

For the complete list of Clinical Practice Guidelines with hyperlinks please refer to Chapter 3 of the Blue Cross Provider Policy and Procedure Manual. To access the manual, go to providers.bluecrossmn.com and select “Forms and Publications” then “Manuals.”

Please note, some treatment and management options recommended in clinical practice guidelines may not be covered benefits under a Blue Cross and Blue Shield of Minnesota and Blue Plus (Blue Cross) member’s health plan.

Recommended Sources

Blue Cross recognizes several sources for Clinical Practice Guidelines for a variety of areas of clinical practice; including, but not limited to the sources noted below:

- USPSTF: U.S. Preventive Services Task Force
  http://www.uspreventiveservicestaskforce.org/BrowseRec/Index/browserecommendations

- HRSA: Health Resources and Services Administration
  http://www.hrsa.gov/index.html

- ICSI: Institute for Clinical Systems Improvement
  https://www.icsi.org/guidelines__more/

Specific guidelines:

Specific guidelines recommended by Blue Cross include the following:

- Behavioral Health
  - Diagnosis, Evaluation, and Treatment of Attention-Deficit/Hyperactivity Disorder in Children and Adolescents (AAP)
  - Treatment of adults with major depressive disorder (APA, ICSI)

- Non-Preventive Acute or Chronic Conditions
  - Prevention and management of Diabetes (ADA)
  - Diagnosis and management of Asthma (NHLBI)

- Preventive Care Guidelines
  - Preventive Services for Adults (USPSTF)
  - Preventive Services Children and Adolescents (USPSTF)
  - Routine Prenatal Care (USPSTF)

Questions concerning Clinical Practice Guidelines can be directed to Abby Linn, Accreditation Analyst, Quality and Health Outcomes at (651) 662-8943. A copy of the clinical practice guidelines with hyperlinks is also available by calling Abby Linn.
REMININDER: 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:

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 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: 01/18/16   Notification Posted: 11/24/15

Policies developed
None

Policies revised

Preimplantation Genetic Testing

• 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, Huntington’s disease); or
      4. One partner is a known carrier of a single X-linked disorder (e.g., Fragile X syndrome, hemophilia A).

• Preimplantation genetic diagnosis as an adjunct to IVF is considered INVESTIGATIVE in ALL situations other than those specified above.

• Preimplantation genetic screening as an adjunct to IVF 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., HLA typing in the absence of a documented history of a known inherited disorder, such as Fanconi anemia).

Intravenous Human Epidermal Growth Factor Receptor 2 (HER2)-Targeted Agents

• Trastuzumab (Herceptin®)
  A. Trastuzumab may be considered MEDICALLY NECESSARY for treatment of ANY of the following cancers:
     1. Breast cancer, when BOTH of the following criteria are met:
         a. Patient has breast cancer or leptomeningeal metastases from breast cancer; AND
b. HER2 overexpression or HER2 amplification in the tumor tissue has been confirmed by ONE of the following HER2 test results:
   i. Immunohistochemistry (IHC) assay is 3+; or
   ii. In situ hybridization (ISH) assay shows an average HER2 copy number ≥6.0 signals/cell; or
   iii. ISH assay shows a HER2/chromosome 17 enumeration probe (CEP17) ratio ≥2.0.

2. Gastric, esophageal, and gastroesophageal junction cancer, when BOTH of the following criteria are met:
   a. Patient has advanced or metastatic gastric, esophageal, or esophagogastric junction adenocarcinoma; AND
   b. HER2 overexpression or HER2 amplification in the tumor tissue has been confirmed by ONE of the following HER2 test results:
      i. IHC assay is 3+; or
      ii. ISH assay shows an average HER2 copy number ≥6.0 signals/cell; or
      iii. ISH assay shows a HER2/CEP17 ratio ≥2.0.

3. Non-small cell lung cancer (NSCLC), when BOTH of the following criteria are met:
   a. Patient has NSCLC; AND
   b. HER2 mutation in the tumor tissue has been confirmed by genetic testing.

B. Trastuzumab is considered INVESTIGATIVE for patients who do not meet the medical necessity criteria listed above.

• Pertuzumab (Perjeta®)
  A. Pertuzumab may be considered MEDICALLY NECESSARY for treatment of cancer when ALL of the following criteria are met:
     1. Patient has breast cancer; AND
     2. HER2 overexpression or HER2 amplification in the tumor tissue has been confirmed by ONE of the following HER2 test results:
        a. IHC assay is 3+; or
        b. ISH assay shows an average HER2 copy number ≥6.0 signals/cell; or
        c. ISH assay shows a HER2/CEP17 ratio ≥2.0.
     AND
     3. Used in combination with trastuzumab and a taxane (e.g., paclitaxel or docetaxel).

B. Pertuzumab is considered INVESTIGATIVE for patients who do not meet the medical necessity criteria listed above.

• Ado-Trastuzumab Emtansine (Kadcyla®)
  A. Ado-trastuzumab emtansine may be considered MEDICALLY NECESSARY for treatment of cancer when ALL of the following criteria are met:
     1. Patient has metastatic or recurrent breast cancer; AND
     2. HER2 overexpression or HER2 amplification in the tumor tissue has been confirmed by ONE of the following HER2 test results:
        a. IHC assay is 3+; or
        b. ISH assay shows an average HER2 copy number ≥6.0 signals/cell; or
c. ISH assay shows a HER2/CEP17 ratio ≥2.0.

AND

3. Previously treated with trastuzumab and a taxane (e.g., paclitaxel or docetaxel), separately or in combination.

B. Ado-trastuzumab emtansine is considered INVESTIGATIVE for patients who do not meet the medical necessity criteria listed above.

Surgical Treatment of Gender Dysphoria

• Criteria for All Surgical Treatment

Surgical treatment of gender dysphoria may be considered MEDICALLY NECESSARY when all of the following diagnostic criteria are met in addition to criteria for specific surgeries listed in sections II and III: 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, and

3. Has the ability to recognize and diagnose co-existing mental health concerns and to distinguish these from gender dysphoria; and


AND

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
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important areas of functioning.

• Breast Surgery

A. Mastectomy and creation of a male chest in female-to-male members may be considered MEDICALLY NECESSARY when criteria IA and IB and the following criteria are met:

1. The member is at least 18 years of age (legal age of majority in Minnesota). Requests for breast surgery for a member younger than 18 years of age will be reviewed by medical director; and

2. Persistent, well-documented gender dysphoria; and

3. Capacity to make a fully informed decision and to give consent to treatment; and

4. If significant medical or mental health concerns are present, they must be reasonably well-controlled.

Note: Hormone therapy is not a prerequisite for mastectomy for female-to-male members. The Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People Version 7 from the World Professional Association for Transgender Health (WPATH) state the following: “Chest surgery in FtM (female-to-male) patients could be carried out (before age of majority) preferably after ample time of living in the desired gender role and after one year of testosterone treatment. The intent of this suggested sequence is to give adolescents sufficient opportunity to experience and socially adjust in a more masculine gender role, before undergoing irreversible surgery. However, different approaches may be more suitable, depending on an adolescent’s specific clinical situation and goals for gender identity expression.”

B. Breast augmentation (e.g., implants/lipofilling) may be considered MEDICALLY NECESSARY in male-to-female members when criteria IA and IB and the following criteria are met:

1. The member is at least 18 years of age (legal age of majority in Minnesota). Requests for breast surgery for a member younger than 18 years of age will be reviewed by medical director; and

2. Persistent, well-documented gender dysphoria; and

3. Capacity to make a fully informed decision and to give consent to treatment; and

4. If significant medical or mental health concerns are present, they must be reasonably well-controlled.

Note: Hormone therapy is not a prerequisite for breast augmentation for male-to-female members. The Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People Version 7 from the World Professional Association for Transgender Health (WPATH) state the following: “Although not an explicit criterion, it is recommended that MtF (male-to-female) patients undergo feminizing hormone therapy (minimum 12 months) prior to breast augmentation surgery. The purpose is to maximize breast growth in order to obtain better surgical (aesthetic) results.”

C. Documentation Requirements

1. One letter of recommendation must be provided to a health plan representative from a qualified mental health professional. The letter must address all of the following:

   a. The member’s general identifying characteristics; and

   b. Results of the member’s psychosocial assessment, including any diagnoses; and

   c. The duration of the mental health professional’s relationship with the member including the type of evaluation and therapy or counseling to date; and

   d. An explanation that the criteria for surgery have been met, and a brief description of the clinical rationale for supporting the member’s request for surgery; and
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e. A statement about the fact that informed consent has been obtained from the member; and
f. A statement that the mental health professional is available for coordination of care and welcomes a phone call to establish this.

2. The health plan and the physician responsible for breast removal or augmentation must receive this letter and recommendations for surgery and the surgical treatment must be authorized by the health plan prior to its occurrence. If the providers are working within a multidisciplinary specialty team, the letters may be sent only to the health plan with documentation of the information in the member’s chart.

• Genital surgery
A. Hysterectomy and salpingo-oophorectomy in female-to-male members and orchiectomy in male-to-female members may be considered MEDICALLY NECESSARY when criteria IA and IB and the following criteria are met:
   1. The member is at least 18 years of age (legal age of majority in Minnesota); and
   2. Persistent, well-documented gender dysphoria; and
   3. Capacity to make a fully informed decision and to give consent to treatment; and
   4. If significant medical or mental health concerns are present, they must be reasonably well-controlled; and
   5. The member has completed 12 continuous months of hormonal therapy as appropriate to the member’s gender goals, unless hormones are not clinically indicated for the individual.
B. Metoidioplasty or phalloplasty in female-to-male members and vaginoplasty in male-to-female members may be considered MEDICALLY NECESSARY when criteria IA and IB and the following criteria are met:
   1. The member is 18 years of age or older; and
   2. Persistent, well-documented gender dysphoria; and
   3. Capacity to make a fully informed decision and to give consent to treatment; and
   4. If significant medical or mental health concerns are present, they must be reasonably well-controlled; and
   5. The member has completed 12 continuous months of hormonal therapy as appropriate to the member’s gender goals, unless hormones are not clinically indicated for the individual; and
   6. The member has completed 12 continuous months of living in a gender role that is congruent with their gender identity.

C. Documentation Requirements
   1. Two letters of recommendation from licensed mental health professionals have been obtained; one must be from a licensed doctoral level clinical psychologist or a psychiatrist.
   2. Both letters must include all of the information listed in IIC.
   3. These letters must be presented to the health plan and to the surgeon prior to genital surgery. If the providers are working within a multidisciplinary specialty team, the letters may be sent only to the health plan with documentation of the information in the member’s chart.

• Other Surgical Procedures
Surgical procedures to alter the gender-specific appearance of a member who has undergone or is planning to undergo gender reassignment surgery, include but are not limited to:
• Facial hair removal
• Blepharoplasty
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- Face lift
- Facial bone reconstruction
- Rhinoplasty
- Liposuction
- Reduction thyroid chondroplasty

These procedures are subject to contract definitions for medical necessity or cosmetic surgery benefits, unless otherwise specified in the benefit chart.

Nonpharmacologic Treatment of Acne
- The following may be considered MEDICALLY NECESSARY for treatment of active acne that is resistant to pharmacologic treatments:
  A. Intralesional injections of corticosteroids; and
  B. Chemical exfoliation, including epidermal chemical peels.
- The following treatments for active acne are considered INVESTIGATIVE due to the lack of clinical evidence demonstrating their impact on improved health outcomes:
  A. Cryotherapy/cryosurgery;
  B. Dermabrasion;
  C. Photodynamic therapy;
  D. Laser therapy, including pulsed dye laser therapy;
  E. Light therapy, including red, blue or violet light therapy and intense pulsed light therapy; and
  F. Thermal therapy devices.
- Treatment for acne scarring and other cosmetic effects of acne is considered COSMETIC including, but not limited to, the following treatments:
  A. Dermabrasion;
  B. Laserabrasion;
  C. Cryotherapy/cryosurgery;
  D. Photodynamic therapy; and
  E. Epidermal and dermal chemical peels

Policies inactivated:
None

Policies Effective: 03/21/16   Notification Posted: 01/28/16

Policies developed

Measurement of Serum Antibodies to Infliximab and Adalimumab
- Measurement of antibodies to infliximab, either alone or as a combination test that includes the measurement of serum infliximab levels, is considered INVESTIGATIVE due to a lack of clinical evidence demonstrating an impact on improved health outcomes.
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- Measurement of antibodies to adalimumab, either alone or as a combination test that includes the measurement of serum adalimumab levels, is considered INVESTIGATIVE due to a lack of clinical evidence demonstrating an impact on improved health outcomes.

Policies Revised

Infliximab

- Use of infliximab may be considered MEDICALLY NECESSARY for the following indications:
  
  A. Rheumatoid Arthritis
     1. Patient is an adult with moderately to severely active rheumatoid arthritis; AND
     2. Failure, intolerance, or contraindication to at least one non-biologic disease-modifying antirheumatic drug (DMARD); AND
     3. Used in combination with methotrexate; AND
     4. Patient is NOT currently being treated with any other biologic immunomodulators; AND
     5. Prescribed by or after consultation with a rheumatologist.

  B. Crohn’s disease
     1. Patient is 6 years of age or older with moderately to severely active Crohn’s disease; AND
     2. Failure, intolerance, or contraindication to conventional therapy (e.g., aminosalicylates such as sulfasalazine, immunosuppressants such as 6-mercaptopurine, azathioprine, or methotrexate, or intravenous steroids for hospitalized patients); AND
     3. Patient is NOT currently being treated with any other biologic immunomodulators; AND
     4. Prescribed by or after consultation with a gastroenterologist.

  C. Fistulizing Crohn’s Disease
     1. Patient is an adult with fistulizing Crohn’s disease; AND
     2. Patient is NOT currently being treated with any other biologic immunomodulators; AND
     3. Prescribed by or after consultation with a gastroenterologist.

  D. Ankylosing Spondylitis
     1. Patient is an adult with active ankylosing spondylitis; AND
     2. Failure, intolerance, or contraindication to at least two nonsteroidal anti-inflammatory drugs (NSAIDs); AND
     3. Patient is NOT currently being treated with any other biologic immunomodulators; AND
     4. Prescribed by or after consultation with a rheumatologist.

  E. Psoriatic Arthritis
     1. Patient is an adult with active psoriatic arthritis; AND
     2. Failure, intolerance, or contraindication to at least one non-biologic DMARD; AND
     3. Patient is NOT currently being treated with any other biologic immunomodulators; AND
     4. Prescribed by or after consultation with a rheumatologist, dermatologist, or other physician with expertise in treating psoriatic arthritis.
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F. Plaque Psoriasis
   1. Patient is an adult with moderate to severe plaque psoriasis with EITHER of the following:
      a. Greater than 5% of body surface area with plaque psoriasis; OR
      b. Less than or equal to 5% body surface area with plaque psoriasis involving sensitive areas or areas that would
         significantly impact daily functioning (e.g., palms, soles of the feet, head/neck, or genitalia).
         AND
   2. Failure, intolerance, or contraindication to at least one of the following:
      a. Phototherapy (e.g., narrow or broad band ultraviolet B [UVB] or psoralen plus ultraviolet A [PUVA]); OR
      b. Systemic, non-biologic therapy (e.g., methotrexate, cyclosporine, or acitretin);
         AND
   3. Patient is NOT currently being treated with any other biologic immunomodulators; AND
   4. Prescribed by or after consultation with a dermatologist or other physician with expertise in treating moderate to
      severe plaque psoriasis.

G. Ulcerative Colitis
   1. Patient is 6 years of age or older with moderately to severely active ulcerative colitis; AND
   2. Failure, intolerance, or contraindication to conventional therapy (e.g., aminosalicylates such as sulfasalazine,
      immunosuppressants such as 6-mercaptopurine, azathioprine, or methotrexate, or intravenous steroids for
      hospitalized patients); AND
   3. Patient is NOT currently being treated with any other biologic immunomodulators; AND
   4. Prescribed by or after consultation with a gastroenterologist.

H. Juvenile Idiopathic Arthritis
   1. Patient is 2 years of age or older with moderately to severely active juvenile idiopathic arthritis; AND
   2. Failure, intolerance, or contraindication to at least one non-biologic DMARD; AND
   3. Patient is NOT currently being treated with any other biologic immunomodulators; AND
   4. Prescribed by or after consultation with a rheumatologist.

I. Non-Infectious Uveitis
   1. Patient has chronic, recurrent, treatment-refractory, or vision-threatening non-infectious uveitis; AND
   2. Failure, intolerance, or contraindication to conventional therapy (e.g., corticosteroids and immunosuppressants
      such as azathioprine, cyclosporine, or methotrexate); AND
   3. Patient is NOT currently being treated with any other biologic immunomodulators; AND
   4. Prescribed by or after consultation with an ophthalmologist.

   • All other uses of infliximab are considered INVESTIGATIVE, including but not limited to intra-articular injections and
     treatment of the following conditions, due to the lack of clinical evidence demonstrating an impact on improved health
     outcomes.
     • Age-related macular degeneration
     • Alcoholic hepatitis
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- Arthritis (other than rheumatoid arthritis, psoriatic arthritis, and juvenile idiopathic arthritis)
- Behcet syndrome
- Cancer cachexia
- Depression
- Diabetic macular edema
- Endometriosis
- Erythrodermic or exfoliative psoriasis
- Giant cell arteritis
- Graft-versus-host disease
- Hidradenitis suppurativa
- Kawasaki syndrome
- Polyarteritis nodosa
- Polymyalgia rheumatica
- Renal cell carcinoma
- Sacroiliitis
- Sarcoidosis
- Sclerosing cholangitis
- Sjogren syndrome
- Systemic lupus erythematosus
- Systemic necrotizing vasculitides
- Systemic sclerosis
- Takayasu’s arteritis
- Wegener’s Granulomatosis

Neurofeedback

- Neurofeedback is considered INVESTIGATIVE for all indications due to a lack of clinical evidence demonstrating an impact on improved health outcomes.

Percutaneous Facet Joint Denervation

- Non-Pulsed Radiofrequency Facet Joint Denervation

A. Initial Procedure

Non-pulsed radiofrequency denervation of cervical facet joints (C2-C3 thru C7-T1 vertebrae) and lumbar facet joints (T12-L1 thru L5-S1 vertebrae) may be considered MEDICALLY NECESSARY when ALL the following criteria are met:

1. No prior spinal fusion surgery in the vertebral level being treated; AND

2. Non-radicular low back (lumbosacral) or neck (cervical) pain, suggestive of facet joint origin when evidenced by absence of nerve root compression as documented in the medical record on history, physical, and radiographic evaluations performed within the last 12 months; AND
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3. Pain has failed to respond to 3 months of conservative management with oral pain medications (e.g., non-steroidal anti-inflammatory medications, analgesics, muscle relaxants, or pharmacological therapy) AND at least one of the following therapies, within the last 6 months (as documented in the medical record):
   a. Course of physical therapy (e.g., at least 4 visits over a period of 4-6 weeks); OR
   b. Course of manipulative therapy (e.g., at least 4 visits over a period of 4-6 weeks);

AND

4. No therapeutic intra-articular injections (i.e., steroids, saline, or other substances) for a period of at least 4 weeks prior to use of a diagnostic medial branch block; AND

5. Diagnostic block with local anesthetic (no steroids or other drugs) of the facet nerve (medial branch block) or injection under fluoroscopic guidance into the facet joint has resulted in at least 50% reduction in pain for the duration of the specific local anesthetic used (e.g., generally 3-4 hours for bupivacaine and 30 minutes to 1 hour for lidocaine).

B. Repeat Procedure

Repeat non-pulsed radiofrequency denervation may be considered MEDICALLY NECESSARY when ALL of the following criteria are met:

1. Performed on the same side and at the same anatomical level of the spine as the previous procedure; AND
2. No prior spinal fusion surgery in the vertebral level being treated; AND
3. A minimum of 6 months and no more than 2 years has elapsed since the previous procedure; AND
4. Greater than 50% pain relief was obtained for at least 3 months following the previous procedure.

C. Non-pulsed radiofrequency denervation is considered INVESTIGATIVE for the treatment of chronic spinal/back pain for all uses that do not meet the criteria listed above, including but not limited to treatment of thoracic facet or sacroiliac (SI) joint pain.

• Pulsed Radiofrequency Denervation
Pulsed radiofrequency denervation is considered INVESTIGATIVE for the treatment of chronic spinal/back pain due to a lack of evidence supporting its impact on improved health outcomes.

• Other Percutaneous Techniques for Facet Joint Denervation
All other techniques for percutaneous facet joint denervation for treatment of chronic spinal/back pain are considered INVESTIGATIVE due to a lack of evidence supporting an impact on improved health outcomes. These other techniques include, but are not limited to:

A. Laser;
B. Cryodenervation.

Extracorporeal Shock Wave Treatment for Musculoskeletal Conditions and Soft Tissue Repair

• Extracorporeal shock wave treatment (ESWT) is considered INVESTIGATIVE as a treatment of the following conditions due to a lack of clinical evidence demonstrating an impact on improved health outcomes.
A. Musculoskeletal conditions including but not limited to the following:
   1. Plantar fasciitis
   2. Epicondylitis (tennis elbow)
   3. Tendinopathies, including calcific tendinitis of the shoulder, Achilles and patellar tendinitis
   4. Spasticity
   5. Stress fracture
   6. Delayed unions and nonunion of fractures
   7. Avascular necrosis of the femoral head

B. Nonhealing wounds

C. Soft tissue injury

D. Erectile dysfunction

E. Peyronie’s disease

Knee Arthroplasty (Knee Replacement)

- Total Knee Arthroplasty (Total Knee Replacement)
  Total knee arthroplasty may be considered MEDICALLY NECESSARY for ANY of the following indications:
  A. Primary and secondary tumors of the distal femur or proximal tibia; OR
  B. Displaced fractures of the distal femur or proximal tibia; OR
  C. Failed previous knee fracture fixation; OR
  D. Failed previous unicompartmental knee arthroplasty; OR
  E. Failed previous knee osteotomy; OR
  F. Advanced knee joint disease, when EITHER of the following criteria are met:
     1. Diagnostic imaging and/or arthroscopic evidence, obtained within the previous 12 months, of complete cartilage destruction (i.e., modified Outerbridge grade IV or Kellgren-Lawrence grade 4) and BOTH of the following:
        a. Moderate to severe persistent knee pain; AND
        b. Clinically significant functional limitation resulting in impaired, age-appropriate activities of daily living and diminished quality of life.
     OR
     2. Diagnostic imaging and/or arthroscopic evidence, obtained within the previous 12 months, of cartilage damage (i.e., modified Outerbridge grade III or Kellgren-Lawrence grade 3) and ALL of the following:
        a. Moderate to severe persistent knee pain despite use of BOTH of the following:
           i. Medical management with nonsteroidal anti-inflammatory agents (NSAIDS) or other analgesic medications; AND
ii. Physical therapy, including strengthening exercises: 6 week course

NOTE: If a patient is unable to complete physical therapy (PT) due to progressively worsening pain and disability, the case will be reviewed on an individual basis by an internal physician reviewer (See Documentation Submission section);

AND

b. Clinically significant functional limitation resulting in impaired, age-appropriate activities of daily living and diminished quality of life.

• Unicompartmental Knee Arthroplasty (Partial Knee Replacement)
  Unicompartmental knee arthroplasty may be considered MEDICALLY NECESSARY for the treatment of advanced knee joint disease limited to a single compartment (i.e., medial, lateral, or patellofemoral) when EITHER of the following criteria are met:

A. Diagnostic imaging and/or arthroscopic evidence, obtained within the previous 12 months, of complete cartilage destruction (i.e., modified Outerbridge grade IV or Kellgren-Lawrence grade 4) and ALL of the following:
   1. Moderate to severe persistent knee pain localized to the affected compartment (i.e., medial, lateral, or patellofemoral); AND
   2. Clinically significant functional limitation resulting in impaired, age-appropriate activities of daily living and diminished quality of life; AND
   3. Involved knee demonstrates adequate alignment and ligamentous stability

OR

B. Diagnostic imaging and/or arthroscopic evidence, obtained within the previous 12 months, of cartilage damage (i.e., modified Outerbridge grade III or Kellgren-Lawrence grade 3) and ALL of the following:
   1. Moderate to severe persistent knee pain localized to the affected compartment (i.e., medial, lateral, patellofemoral) despite use of BOTH of the following:
      a. Medical management with nonsteroidal anti-inflammatory agents (NSAIDS) or other analgesic medications; AND
      b. Physical therapy, including strengthening exercises: 6 week course
         NOTE: If a patient is unable to complete physical therapy (PT) due to progressively worsening pain and disability, the case will be reviewed on an individual basis by an internal physician reviewer (See Documentation Submission section);
         AND
   2. Clinically significant functional limitation resulting in impaired, age-appropriate activities of daily living and diminished quality of life.
   AND
   3. Involved knee demonstrates adequate alignment and ligamentous stability.
• Contralateral Knee Arthroplasty
Contralateral knee arthroplasty may be considered MEDICALLY NECESSARY for the treatment of advanced knee joint disease of the contralateral knee when there is diagnostic imaging and/or arthroscopic evidence, obtained within the previous 12 months, of complete cartilage destruction (i.e., modified Outerbridge grade IV or Kellgren-Lawrence grade 4) OR cartilage damage (i.e., modified Outerbridge grade III or Kellgren-Lawrence grade 3).

• Revision Knee Arthroplasty
Revision knee arthroplasty may be considered MEDICALLY NECESSARY for ANY of the following indications:

A. Instability, fracture, or mechanical failure of the prosthetic components or aseptic loosening; OR
B. Periprosthetic fractures; OR
C. Fracture or dislocation of the patella; OR
D. Infection of the prosthetic joint.

• Investigative Procedures
The following knee procedures are considered INVESTIGATIVE due to a lack of evidence demonstrating an impact on improved health outcomes:

A. Bicompartmental knee arthroplasty;
B. Bi-unicompartmental knee arthroplasty;
C. Unicondylar interpositional spacer.

Policies inactivated
None

Policies reviewed with no changes in November 2015 – January 2016:

Abatacept (Orencia®)
Actigraphy
Allogeneic Hematopoietic Stem-Cell Transplantation for Genetic Diseases and Acquired Anemias
Analysis of Human DNA in Stool Samples as a Technique for Colorectal Cancer Screening
Anterior Eye Segment Scanning Computerized Imaging
Axial (Percutaneous) Lumbar Interbody Fusion
Biofeedback for Disorders Listed in the DSM
Bioimpedance Spectroscopy Devices for Detection and Management of Lymphedema
Bone Morphogenetic Protein (BMP)
Communication Assist Devices
CT Colonography (Virtual Colonoscopy)
Electromagnetic Navigational Bronchoscopy
Extended Hours Skilled Nursing in the Home for Patients with Medically Complex Conditions
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Functional Neuromuscular Electrical Stimulation Devices
General Anesthesia Services for Dental Procedures
Genetic Testing and Counseling for Heritable Disorders
Genetic Testing for Familial Alzheimer’s Disease
Growth Hormone Treatment
Hematopoietic Stem-Cell Transplantation for Autoimmune Disease
Hematopoietic Stem-Cell Transplantation for Hodgkin Lymphoma
Implantation of Intrastromal Corneal Ring Segments
Left Atrial Appendage Occluder Devices
Low-Level Laser Therapy and Deep Tissue Laser Therapy
Nonpharmacologic Treatment of Rosacea
Occlusion of Uterine Arteries
Ovarian and Internal Iliac Vein Embolization as a Treatment for Pelvic Congestion Syndrome
PathfinderTG® Molecular Testing
Percutaneous Electrical Nerve Stimulation (PENS) or Percutaneous Neuromodulation Therapy (PNT)
Phototherapy in the Treatment of Psoriasis
Psychological and Neuropsychological Testing
Secretin Infusion Therapy for Autism
Spinal Cord Stimulation
Treatments for Urinary Dysfunction
Ultrasound-Guided High-Intensity Focused Ultrasound Ablation for Treatment of Prostate Cancer and Other Tumors

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