

QUALITY IMPROVEMENT - BEST PRACTICES IN CARE TRANSITIONS

The Institute of Medicine identified care coordination as a priority area for improving health care quality, effectiveness, safety and efficiency within the care delivery system. The Agency for Healthcare Research and Quality supports this by stating, well-designed, targeted care coordination that is delivered to the right people can improve outcomes for everyone: patients, providers, and payers. Blue Cross encourages our network of providers to adopt best practices to improve continuity and coordination of care, especially during care transitions. This article summarizes a literature review conducted by the Center for Healthcare Research & Transformation (published January 2014) exploring best practices in care transitions and successful programs that reduced readmissions and overall costs.

The Center for Healthcare Research & Transformation (CHRT) found six program elements described as best practices in the academic literature reviewed. CHRT reports these best practices create a strong foundation for high-quality, cost-saving care transitions and have potential for the greatest impact on high-risk patients, especially those with modifiable risks like diabetes and obesity.

The program elements are:

- Comprehensive discharge planning
- Complete and timely communication of information
- Medication reconciliation
- Patient/Caregiver education using the “teach back” method
- Open communication between providers
- Prompt follow-up visit with an outpatient provider after discharge

To learn more about the individual components included in each of the best practice elements listed above and successful programs, check out CHRTS’s full report titled: [Care Transitions: Best Practices and Evidence-based Programs.](#)

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. Issues are published in March, June, September and December. Below is the URL (select “provider press” from the “Select a Category” drop down option): https://www.bluecrossmn.com/Page/mn/en_US/forms-and-publications.

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FYI

PUBLICATIONS AVAILABLE ONLINE

The following is a list of Quick Points and Bulletins published from June to August 2017 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 |
|--------------|--|
| QP13-17 | Pharmacy Benefit Update – Evzio Exclusion |
| QP14-17 | McKesson Interqual Criteria Update |
| QP15-17 | New Pre-Authorization Forms Revision |
| QP16-17 | Contract Renewal Overlapping with Termination Notices for Interpreter Agencies |
| QP17-17 | Pharmacy Benefit Update-AirDuo Resplick |
| QP18-17 | Reminder Regarding PCA Assessment Requests |
| QP19-17 | Durable Medical Equipment Cures Act |
| QP20-17 | Searching Eligibility and Benefits |
| QP21-17 | New Pre-Authorization Forms for Bariatric Surgery, Lumbar Fusion and Percutaneous Facet Joint Denervation |
| QP22-17 | New Medical Drug Management Process and Medical Drug Policies |
| QP23-17 | New Pre-Authorization Form for Reduction Mammoplasty |
| BULLETINS | TITLE |
| P29-17 | New Drug-Related Prior Authorization (PA) Criteria: Erythropoietins |
| P30-17 | New Drug-Related Prior Authorization (PA) Criteria: Topical Retinoids |
| P31-17 | New Drug-Related Prior Authorization (PA) Criteria: Thrombopoietin Receptor Agonists |
| P32-17 | Minnesota Senior Health Options Model of Care Requirement |
| P33-17 | Revised Reimbursement Policy for Anesthesia Services: Anesthesia |
| P34-17 | Addition of Drug to the Amitiza, Linzess, and Trulance Prior Authorization Program |
| P35-17 | Addition of Drug to the Substrate Reduction Therapy Prior Authorization with Quantity Limit Program |
| P36-17 | Addition of Drug to Vesicular Monoamine transporter 2 Inhibitors Prior Authorization with Quantity Limit Program |
| P37-17 | Update to Attachment B: Definition of Outpatient Health Services Categories |
| P38-17 | New Drug-Related Prior Authorization for Xolair |
| P39-17 | Concurrent Review for Inpatient Hospital Services at Select Facilities |
| P40-17 | New Prior Authorization Requirements for Immunomodular Drugs |
| P41-17 | PCA Agencies Requirements |
| P42-17 | Addition of Drugs to Self-Administered Oncology Prior Authorization with Quantity Limit Program |
| P43-17 | New Drug-Related Prior Authorization for Symbicort |
| P44-17 | New Drug-Related Prior Authorization with Quantity Limit Criteria: Opioid, Buprenorphine Concurrent Therapy |
| P45-17 | New Drug-Related Prior Authorization with Quantity Limit Criteria: Concurrent Opioids with Buprenorphine |
| P46-17 | Addition of Drug to Self-Administered Oncology Prior Authorization with Quantity Limit Program |
| P46-17 | Requirement to Submit National Drug Codes |

FYI

MEMBER RIGHTS AND RESPONSIBILITIES

Blue Cross is committed to treating its members in a way that respects their rights, while maintaining an expectation of their individual responsibilities. All Blue Cross members have certain rights concerning their care and treatment, and responsibilities as a member, such as following agreed upon instructions for care, or supplying information needed to provide care. A complete listing of Member Rights and Responsibilities can be found online at bluecrossmn.com by entering “member rights” in the search field. Questions or requests for a paper copy may be directed to Lisa K. at **(651) 662-2775**.

FYI

REMINDER: MEDICARE REQUIREMENTS FOR REPORTING PROVIDER DEMOGRAPHIC CHANGES

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 this link: <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**.

FYI WHOM 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. | |

FYI

PROVIDER MANUAL UPDATES

The following is a list of Blue Cross provider manuals that have been updated from June to August 2017. 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, Public Programs Sub-sections | Various updates to Transportation Services |
| Blue Plus Manual | Chapter 3, Government Programs | Various updates based on Provider Bulletins |
| Provider Policy and Procedure Manual | Chapter 2, Provider Agreements | Updates to Responsibilities of Participating Providers |
| Provider Policy and Procedure Manual | Chapter 4, Medical Management | Updates to Introduction and Pre-Admission Notification Requirement |
| Provider Policy and Procedure Manual | Chapter 8, Claims Filing | Community Mental Health Center |
| Provider Policy and Procedure Manual | Chapter 10, Appeals | Updates to Post Services Claims Appeals |

FYI

PRE-AUTHORIZATION/PRE-APPROVAL FORMS SPECIFIC TO SELECT MEDICAL POLICIES

Over the next few months, Blue Cross will, gradually, introduce new pre-authorization/pre-approval (PA) fax or mail forms that are specific to medical services and specialty drugs that require pre-authorization. Not all medical policies that require pre-authorization will have a specific PA form. We will create forms to support specific medical policies that generate the most questions on what clinical information to include with the pre-authorization request. The goal in creating the new PA forms is to reduce the number of interactions needed to obtain information in order to complete the medical necessity review.

The forms may be revised or withdrawn at any time as business needs, utilization management, or medical policy changes occur.

Where do I find the new forms?

- Go to providers.bluecrossmn.com
- Select Forms & Publications under the News & Updates section
- Select the forms category "precertification/preauthorization/notification"

Provider Quick Points will be issued with each of the new pre-authorization/pre-approval forms.

2017 HOLIDAY SCHEDULE

Provider services will be closed on the following days in 2017:

Monday, September 4

Thursday, November 23

Friday, November 24

Monday, December 25

With the exception of the dates stated above, representatives answering the provider services numbers are available to assist you 7 a.m. to 6 p.m. Monday through Friday.

PHARMACY SECTION

PHARMACY UPDATES FOR QUARTER 3, 2017

Pharmacy 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 (Blue Cross) 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 July 1, 2017.**

| ADDITIONS TO FlexRx FORMULARY | ADDITIONS TO GenRx FORMULARY |
|--------------------------------|--------------------------------|
| BAVENCIO | BAVENCIO |
| ENTRESTO | ENTRESTO |
| INVOKAMET XR | INVOKAMET XR |
| KISQALI | KISQALI |
| LEVOLEUCOVORIN IV INJ 175 MG | NALOXONE HCL PREFILLED SYRINGE |
| LUMIGAN | STELARA IV SOLN |
| NALOXONE HCL PREFILLED SYRINGE | VYVANSE CHEW TAB |
| STELARA IV SOLN | |
| VIMPAT | |
| VYVANSE CHEW TAB | |

| REMOVALS FROM FlexRx FORMULARY | REMOVALS TO GenRx FORMULARY |
|--|--|
| AZILECT | CONCERTA |
| BANZEL | DEPOCYT |
| BENICAR | EMEND CAP 80 MG And THERAPY PACK 80 & 125 MG |
| BENICAR HCT | EPZICOM |
| CELONTIN | EVZIO |
| CONCERTA | OXYCODONE/IBUPROFEN |
| DEPOCYT | SEROQUEL XR TAB 400 MG |
| DIFFERIN | TAMIFLU CAPS |
| DILANTIN-125 | TENCON |
| EMEND CAP 80 MG and THERAPY PACK 80 & 125 MG | VAGIFEM |
| EPZICOM | |
| EVZIO | |
| HYDROXYZINE PAMOATE | |
| ONFI | |
| OXYCODONE/IBUPROFEN | |
| PEGANONE | |
| SEROQUEL XR TAB 400 MG | |
| TAMIFLU CAPS | |
| TENCON | |
| VAGIFEM | |
| ZETIA | |

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PHARMACY SECTION

PHARMACY UPDATES FOR QUARTER 3, 2017 (cont. from previous page)

Drug Formulary Changes

The complete list of formulary changes for the following formularies can be found at:

FlexRx Formulary –

https://www.myprime.com/content/dam/prime/memberportal/forms/2017/FullyQualified/Other/ALL/BCBSMN/COMMERCIAL/MNFLEXRX/MN_FlexRx_Formulary_Update.pdf

GenRx Formulary –

https://www.myprime.com/content/dam/prime/memberportal/forms/2017/FullyQualified/Other/ALL/BCBSMN/COMMERCIAL/MNGENRX/MNSM_Formulary_Update.pdf

The complete drug list for the following formularies can be found at:

BasicRx Formulary –

https://www.myprime.com/content/dam/prime/memberportal/forms/2017/FullyQualified/Other/ALL/BCBSMN/COMMERCIAL/MNHIMBSCRX/MN_HIM_BasicRx_Drug_List_2017.pdf

KeyRx Formulary – KeyRx is a new drug formulary available for commercial health insurance plans.

https://www.myprime.com/content/dam/prime/memberportal/forms/2017/FullyQualified/Other/ALL/BCBSMN/COMMERCIAL/MNFINR/MN_KeyRx_Drug_List.pdf

PHARMACY BENEFIT EXCLUSION

Due to their route of administration, the following drugs are no longer covered under the pharmacy drug benefit, but may be covered and processed under the medical drug benefit. For drugs that require a prior authorization under the medical benefit, failure to obtain authorization prior to service will result in a denied claim and payment.

| DRUG NAME | Medical Prior Authorization Required | Pharmacy Benefit Exclusion Effective Date |
|---------------------|--------------------------------------|---|
| BENLYSTA | YES | 4/1/2017 |
| epoprostenol sodium | YES | |
| FLOLAN | YES | |
| REMODULIN | YES | |
| REVATIO IV SOLN | YES | |
| sildenafil IV soln | YES | |
| SPRINRAZA | YES | |
| SYNAGIS | YES | |
| VELETRI | YES | |
| BRINEURA | TO BE DETERMINED | 5/1/2017 |
| RADICAVA | TO BE DETERMINED | 7/1/2017 |
| RITUXAN HYCELA | TO BE DETERMINED | |

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PHARMACY SECTION

PHARMACY BENEFIT EXCLUSION (continued from previous page)

Effective July 24, 2017, Blue Cross will no longer cover AirDuo Respiclick under the pharmacy benefit plan for the commercial lines of business. Members must use a medication alternative that is covered under the pharmacy benefit plan or pay full price for continued use of their current medication. A summary of the excluded medication and preferred pharmacy formulary alternative can be found below.

| Excluded Medication | Preferred Alternative Medication |
|---------------------|---|
| AirDuo Respiclick | Fluticasone/Salmeterol Inhaler Authorized Generic |

PHARMACY UTILIZATION MANAGEMENT (UM) UPDATE

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

New UM Programs for April 2017

| BRAND NAME (generic name - if available) | Requirement | | |
|--|-------------|--|--|
| DUPIXENT | PA | | |
| EMFLAZA | PA | | |

New UM Programs for May 2017

| BRAND NAME (generic name - if available) | Requirement | | |
|--|-------------|--|--|
| INGREZZA | PA | | |

New UM Programs for July 2017

| BRAND NAME (generic name - if available) | Requirement | | |
|--|-------------|----|----|
| ENTRESTO | PA | QL | |
| L-GLUTAMINE, pharmaceutical grade | PA | | |
| SOLQUA | | QL | ST |
| XULTOPHY | | QL | ST |

Changes to Existing UM Programs Effective 7/1/17

| BRAND NAME (generic name - if available) | Requirement | | |
|---|-------------|----|----|
| ARYMO ER | | QL | |
| EUCRISA | | | ST |
| ketorolac tabs | | QL | |
| KISQALI | PA | QL | |
| lidocaine ointment 5% | PA | QL | |
| REPATHA 140 mg/mL pre-filled syringe or auto-injector | PA | QL | |
| SELZENTRY 25 mg | | QL | |
| SELZENTRY 75 mg | | QL | |
| SYNJARDY XR 25-1000 mg | | QL | |
| SYNJARDY XR 5-1000 mg, 10-1000 mg, 12.5-1000 mg | | QL | |
| VYVANSE chew tabs | | QL | |

UTILIZATION MANAGEMENT STATEMENT

Utilization Management (UM) decision making is based only on appropriateness of care and service and on existing coverage provisions. Blue Cross does not compensate providers, practitioners or other individuals making UM decisions for denial of coverage or services. We do not offer incentives to decision makers to encourage denial of coverage or services that would result in less than appropriate care or under-utilization of appropriate care and services.

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PHARMACY SECTION

PHARMACY UTILIZATION MANAGEMENT (UM) UPDATE (continued)

New UM Programs Effective 8/1/17

| BRAND NAME (generic name - if available) | Requirement | | |
|--|-------------|----|--|
| ARANESP | PA | | |
| BUPHENYL | PA | | |
| EPOGEN | PA | | |
| JUBLIA | PA | QL | |
| KERYDIN | PA | QL | |
| LAMISIL (terbinafine) tab | PA* | QL | |
| LAMISIL granules packet | PA | QL | |
| MIRCERA | PA | | |
| ONMEL | PA | QL | |
| PENLAC (ciclopirox) | PA* | QL | |
| PROCRIT | PA | | |
| PROMACTA 12.5 mg, 25 mg | PA | QL | |
| PROMACTA 50 mg, 75 mg | PA | QL | |
| RAVICTI | PA | | |
| SPORANOX (itraconazole) cap | PA* | QL | |
| SPORANOX 10 mg/mL oral solution | PA | QL | |

Changes to Existing UM Programs Effective 8/1/17

| BRAND NAME (generic name - if available) | Requirement | | |
|--|-------------|-------|--|
| AUSTEDO | PA | QL | |
| BERINERT | PA | QL ** | |
| CERDELGA | PA | QL | |
| CINRYZE | PA | QL ** | |
| FIRAZYR | PA | QL ** | |
| glecaprevir/pibrentasvir (brand name not yet known) | PA | | |
| KALBITOR | PA | QL ** | |
| RUCONEST | PA | QL ** | |
| sofosbuvir/velpatasvir/voxilaprevir (brand name not yet known) | PA | | |
| TRULANCE | PA | | |

New UM Programs Effective 9/1/17

| BRAND NAME (generic name - if available) | Requirement | | |
|--|-------------|--|--|
| XOLAIR | PA | | |

PA=Prior Authorization; QL=Quantity Limit;

ST=Step Therapy

*PA currently in place; **QL currently in place;

***ST currently in place

‡Generic available – the generic is also subject to prior authorization or step therapy

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PHARMACY SECTION

PHARMACY UTILIZATION MANAGEMENT (UM) UPDATE (continued)

Additional UM Updates for Medicaid Lines of Business

- The Inhaled Corticosteroid Prior Authorization was implemented, **effective July 1, 2017**. Quantity limits were previously implemented and remain in place.
- The Retinoids (Topical) Prior Authorization will be implemented, effective **August 1, 2017**.

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

FlexRx –

https://www.myprime.com/content/dam/prime/memberportal/forms/2017/FullyQualified/Other/ALL/BCBSMN/COMMERCIAL/MNFLEXRX/MN_FlexRx_UM_Updates.pdf

GenRx –

https://www.myprime.com/content/dam/prime/memberportal/forms/2017/FullyQualified/Other/ALL/BCBSMN/COMMERCIAL/MNGENRX/MNSM_GenRx_UM_Updates.pdf

BasicRx –

https://www.myprime.com/content/dam/prime/memberportal/forms/2017/FullyQualified/Other/ALL/BCBSMN/COMMERCIAL/MNHIMBSCRX/MN_Exh_GenRx_UM_Updates.pdf

MEDICAL DRUG UTILIZATION MANAGEMENT (UM) UPDATE

Blue Cross updated existing medical drug policies and implemented new medical drug policies, including some with prior authorization (PA) requirements. Details are outlined below.

| MEDICAL DRUG POLICY | UPDATE/CHANGE | EFFECTIVE DATE | PRODUCTS IMPACTED |
|--|---|----------------|---------------------|
| II-016 Botulinum Toxins (Botox, Dysport, Myobloc, Xeomin) | Existing policy drug dosing grid updated; PA requirement continued | 7/17/17 | Commercial |
| II-152 Belimumab (Benlysta) | Existing policy updated to include dosing grid guidelines; PA requirement continued | 7/17/17 | Commercial |
| II-171 Nusinersen (Spinraza) | New policy with PA requirement | 6/19/17 | Commercial/Medicaid |
| II-172 Eteplirsen (Exondys 51) | New policy | 7/17/17 | Commercial |
| II-173 Accepted Indications for Medical Drugs Which are not Addressed by a Specific Medical Policy | New policy | 7/31/17 | Commercial/Medicaid |

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PHARMACY SECTION

MEDICAL DRUG UTILIZATION MANAGEMENT (UM) UPDATE (cont.)

| MEDICAL DRUG POLICY | UPDATE/CHANGE | EFFECTIVE DATE | PRODUCTS IMPACTED |
|---|--------------------|----------------|---------------------|
| II-174 Evaluation Process for New FDA-Approved Medical Drugs or Medical Drug Indications) | New policy | 7/31/17 | Commercial/Medicaid |
| MHCP - Immunomodulator Drugs | New PA requirement | 8/28/17 | Medicaid |

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.

Similar Pharmacy Management for the Federal Employee Program (FEP) members can be found on the Fepblue.org website. FEP members have a different PBM (Caremark) and will have different formulary list and procedures for prior authorizations and quantity limits than listed above. This information can be found by scrolling down to "Pharmacy Benefits" and selecting "Finding out more."

QUALITY IMPROVEMENT

BETTER CARE THROUGH QUALITY IMPROVEMENT

Every year, Blue Cross reviews the care delivered to our subscribers. This review determines the goals for the quality program. The program currently has many goals to improve health services. Making sure our subscribers receive preventive services and health screenings; making sure people with health problems, like heart disease, receive treatment; and improving the customer service experience are just a few of the goals in the program. More detailed information is available about Blue Cross' process and outcomes in meeting quality improvement goals related to subscriber care and service. You can see more information about our quality improvement program at bluecrossmn.com. Enter "quality improvement program" in the search field. If you are unable to access the website, please contact Lisa at **(651) 662-2775** to request information about the Quality Improvement Program to be mailed to your office.

HEALTH LITERACY

HEALTH LITERACY – EFFECTIVE COMMUNICATION IS KEY

There are many definitions used for health literacy and as the field continues to evolve, we are likely to see even more appear.

Health Literacy is...

"... the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions."
(Healthy People)

"... the use of a wide range of skills that improve the ability of people to act on information in order to live healthier lives. These skills include reading, writing, listening, speaking, numeracy, and critical analysis, as well as communication and interaction skills."
(Calgary Charter)

"... a patient's ability to obtain, understand and act on health information and the capacity of health care providers and health care systems to communicate clearly, educate about health and empower patients."
(Minnesota Health Literacy Partnership)

Regardless of the definition you prefer, clear and effective communication is at the center of health literacy. It doesn't matter what the mode of communication is, consumers want information that is easy to read, understand, and use. It is the job of health professionals and care advocates to help bridge the divide between medical terminology and plain language so that everyone can understand what to do and why to do it.

In 2012, Minnesota Community Measurement began reporting patient experience of care measures utilizing patient responses to the Clinician & Group – Consumer Assessment of Healthcare Providers and Systems (CG-CHAPS) survey. The [2016 Health Care Quality Report](#) shows across all respondents, the overall top box average for *How Well Providers Communicate With Patients* was 83%. The score represents a composite result for the following 4 questions:

- How often did this provider explain things in a way that was easy to understand?
- How often did this provider listen carefully to you?
- How often did this provider show respect for what you had to say?
- How often did this provider spend enough time with you?

Explaining things in a way that is easy to understand or using plain language when talking with patients is one of the best ways to improve health literacy within your practice. In Minnesota, our rates are strong, but there is still work to be done. The Minnesota Health Literacy Partnership has a new [campaign](#) focused on plain language. The [campaign](#) is available on their website. Consider using the materials and ideas to promote awareness of health literacy and the use of plain language as a best practice within your setting.

By working together to improve communication at all levels of care, hopefully our rates for *How Well Providers Communicate With Patients* will continue to rise.

QUALITY IMPROVEMENT

QUALITY OF CARE COMPLAINT REPORT

Article Five of the Blue Plus provider contract outlines the complaint procedure for primary care clinics. MN Rules 4685.1110 and 4685.1700-1900 outline the requirements of complaint collection and analysis of quality of care complaints for the Health Plan. Blue Plus requires providers to report these complaints quarterly. Reporting is required, even if there were no complaints during the reporting period.

Complaints should be submitted via secure email in a report format (e.g. excel, csv).

Required data elements for the report are as follows:

- Member ID Number
- Patient Name
- Patient Date of Birth
- Date of Service / Incident
- Date Complaint Received by Provider
- Practitioner Named in Complaint
- Location of Service / Incident
- Summary of Complaint
- Categorizations Used to Classify Complaint
- Summary of Outcome / Resolution, including date

Submit report via secure email to: Quality.of.Care.Mailbox@bluecrossmn.com

FYI

ADDITION OF DRUGS TO THE SELF-ADMINISTERED ONCOLOGY PRIOR AUTHORIZATION WITH QUANTITY LIMIT PROGRAM

Effective October 1, 2017, Blue Cross and Blue Shield of Minnesota and Blue Plus (Blue Cross) will be adding a prior authorization (PA) with quantity limit (QL) requirement for the following products:

| PHARMACY PRIOR AUTHORIZATION PROGRAM | DRUG NAME | QUANTITY LIMIT (PER 30 DAYS) |
|---------------------------------------|---------------------|------------------------------|
| Self-Administered Oncology PA with QL | ALUNBRIG | 180 TABLETS |
| Self-Administered Oncology PA with QL | RYDAPT | 240 CAPSULES |
| Self-Administered Oncology PA with QL | ZEJULA | 90 CAPSULES |
| Self-Administered Oncology PA with QL | KISQALI FEMARA PACK | 91 TABLETS |

Products Impacted

This PA program applies to commercial lines of business **and** the following Minnesota Health Care Programs:

- Blue Advantage Prepaid Medical Assistance Program (PMAP)
- Minnesota Senior Care Plus (MSC+)
- MinnesotaCare

New PA criteria will be posted by September 1, 2017, and may be accessed using the Blue Cross provider link.

- Access providers.bluecrossmn.com
- Under Tools and Resources, select Medical policy, then acknowledge the Acceptance statement
- Select Utilization Management
- Select Pharmacy Utilization Management Programs

CoverMyMeds prior authorization request service

As a reminder, CoverMyMeds (CMM) is a free service to providers which allows quick and easy submission of PA requests. Experience with CMM by other plans has demonstrated marked reductions in physician office call-backs regarding PA requests, after CMM is implemented. PA requests may also continue to be faxed to their review destination external to the CMM portal, as is the current practice.

You may access CMM at www.covermymeds.com. Select Help (top right of the web page) to view FAQs and Support tutorials (3-5 minutes), including live online chat support to help you get started. You will need to open a CMM account to submit requests using the portal.

For more information regarding this refer to Provider Bulletin P42-17, which was published on August 3, 2017.

FYI

CHLAMYDIA SCREENING

The American Academy of Family Physicians and the American Academy of Pediatrics recommends screening all sexually active females 24 years of age and younger for Chlamydia.

Blue Cross continues to participate, along with other health plans, in promoting Chlamydia screening in members 24 years of age and younger. In 2016 communities and student volunteer organizations across Minnesota sponsored events such as the National STD Testing Day at North Minneapolis; "Pee for Pizza" parties and "Chlamydia is Not a Flower" education at St. Paul Community College; creation of a youth peer education group called the "Check Yo' Self Crew" at the High School of Recording Arts; and numerous other events in collaboration with Minnesota's Chlamydia Partnership.¹ While the screening rates in Minnesota are rising slowly, in part because of heightened awareness of sexually-transmitted diseases, more can be done.

Here are ways you can help:

- Obtain an updated copy of the **Chlamydia Provider Toolkit** at:
http://www.stratishealth.org/pip/documents/Chlamydia_Toolkit.pdf
- Visit the **Minnesota Chlamydia Partnership** website at:
<http://www.health.state.mn.us/divs/idepc/diseases/chlamydia/mcp/index.html>
- Request a 3rd quarter 'Gaps in Care' list of our members aged 16-24 years old who are attributed to your provider group by sending an email to
Sheila.dalen@bluecrossmn.com

¹ Minnesota Chlamydia Partnership (MCP); Minnesota Department of Health,
<http://www.health.state.mn.us/mcp>

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: July 17, 2017 Notification Posted: May 26, 2017

Policies developed

Eteplirsen, II-172

Use of eteplirsen is considered **INVESTIGATIVE** for all indications, including but not limited to treatment of Duchenne muscular dystrophy, due to the lack of evidence demonstrating an impact on improved health outcomes.

Policies revised

Belimumab, II-152

I. Initial Review

Belimumab may be considered **MEDICALLY NECESSARY** when ALL of the following criteria are met:

- The patient has a diagnosis of active systemic lupus erythematosus (SLE), according to the American College of Rheumatology (ACR) classification criteria (NOTE: See classification criteria at the end of the policy); **AND**
- The patient is an adult (18 years of age or older); **AND**
- Laboratory documentation of a positive test for serum autoantibodies, using the anti-nuclear antibody (ANA) test (titer \geq 1:80) OR the anti-double stranded DNA test (concentration \geq 30 IU/mL), at two independent time points; **AND**
- ONE of the following:

1. The patient is currently receiving a stable standard of care treatment regimen for SLE with stable dosing for at least 30 days. Standard of care treatment regimens comprise any of the following drug classes, alone or in combination:

- Corticosteroids;
- Antimalarials (e.g., hydroxychloroquine);
- Non-biologic immunosuppressives (e.g., azathioprine, methotrexate, cyclosporine);

OR

2. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to ALL the standard of care drug classes listed above;

AND

- The patient is not currently being treated with other biologics or intravenous cyclophosphamide; **AND**
- The patient has not had severe active lupus nephritis (e.g., proteinuria >6 g/day, serum creatinine >2.5 mg/dL, required dialysis, or high-dose prednisone >100 mg/day) within the past 90 days; **AND**
- The patient has not had severe active central nervous system (CNS) lupus (e.g., seizures, psychosis, organic brain syndrome, cerebrovascular accident, cerebritis, or CNS vasculitis requiring therapeutic intervention) within the past 60 days; **AND**
- The patient does not have any FDA labeled contraindications to therapy (see table 1 below); **AND**
- The dose is within the FDA labeled dose (see table 2 below).

II. Renewal Review

Belimumab may be considered **MEDICALLY NECESSARY** when **ALL** of the following criteria are met:

MEDICAL AND BEHAVIORAL HEALTH POLICY UPDATE

- The patient has been previously approved for therapy through the initial review process; **AND**
- The patient has shown positive clinical response (e.g., slowing of disease progression or decrease in symptom severity and/or frequency); **AND**
- ONE of the following:
 1. The patient is currently receiving a stable standard of care treatment regimen for SLE with stable dosing at least 30 days. Standard of care treatment regimens comprise any of the following drug classes, alone or in combination:
 - Corticosteroids
 - Antimalarials (e.g., hydroxychloroquine);
 - Non-biologic immunosuppressives (e.g., azathioprine, methotrexate, cyclosporine);

OR

2. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to ALL the standard of care drug classes listed above;

AND

- The patient is not currently being treated with other biologics or intravenous cyclophosphamide; **AND**
 - The patient has not had severe active lupus nephritis (e.g., proteinuria >6 g/day, serum creatinine >2.5 mg/dL, required dialysis, or high-dose prednisone >100 mg/day) within the past 90 days; **AND**
 - The patient has not had severe active central nervous system (CNS) lupus (e.g., seizures, psychosis, organic brain syndrome, cerebrovascular accident, cerebritis, or CNS vasculitis requiring therapeutic intervention) within the past 60 days; **AND**
 - The patient does not have any FDA labeled contraindications to therapy (see table 1 below); **AND**
 - The dose is within the FDA labeled dose (see table 2 below).
- III. All other uses of belimumab are considered **INVESTIGATIVE** including SLE not meeting the criteria above, due to the lack of clinical evidence demonstrating an impact on improved health.

• Table 1. FDA Labeled Contraindications

| AGENT | FDA LABELED CONTRAINDICATIONS |
|-----------|-----------------------------------|
| Belimumab | Previous anaphylaxis to belimumab |

• Table 2. Dosing

| FDA LABELED INDICATIONS | DOSING |
|--|---|
| Systemic lupus erythematosus (SLE), autoantibody-positive in adults who are receiving standard therapy | 10 mg/kg intravenously at 2-week intervals for the first 3 doses and at 4-week intervals thereafter |

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Documentation Submission

Documentation supporting the medical necessity criteria described in the policy must be included in the prior authorization. In addition, the following documentation must also be submitted:

Initial Review

1. Clinical notes describing the diagnosis and clinical features of the diagnosis.
2. Laboratory results supporting a positive test for serum autoantibodies, including the reference range for the laboratory performing the test.
3. Clinical notes describing current and past medications for the diagnosis, including response to the medications.
4. The dose being requested, including the patient's weight. If the requested dose is higher or more frequent than the dosing guidelines provided in the table above, a clear explanation for the medical necessity of the requested dose **MUST** be submitted, including prior dosing (strength and frequency) associated with inadequate response.

Renewal Review

1. Documentation of prior approval for belimumab through the initial review process.
2. Documentation supporting positive clinical response (e.g., slowing of disease progression or decrease in symptom severity and/or frequency).
3. Clinical notes describing current and past medications for the diagnosis, including response to the medications.
4. The dose being requested, including the patient's weight. If the requested dose is higher or more frequent than the dosing guidelines provided in the table above, a clear explanation for medical necessity of the requested dose **MUST** be submitted, including prior dosing (strength and frequency) associated with inadequate response.

Molecular Marker Evaluation of Thyroid Nodules, VI-50

- Use of the Afirma® Gene Expression Classifier may be considered **MEDICALLY NECESSARY** in cytologically indeterminate fine needle aspirates of the thyroid when **BOTH** of the following are met:
 - Patient with follicular cell neoplasm, atypia of undetermined significance (AUS) or follicular lesion of undetermined significance (FLUS); **AND**
 - Results of testing are used as an integral component of surgical decision-making in conjunction with clinical, radiographic, and cytologic features of the individual patient.
- Use of gene expression classifiers in fine needle aspirates of the thyroid not meeting criteria outlined above are considered **INVESTIGATIVE** due to the lack of clinical evidence demonstrating an impact on improved health outcomes.
- Use of mutation analysis (e.g., ThyGenX®, ThyraMIR™, ThyroSeq®, Thyroid Cancer Mutation Panel, Afirma® MTC, *BRAF*, *RAS*, *RET/PTC*, and *PAX8/PPARγ*) for molecular marker evaluation of thyroid nodules is considered **INVESTIGATIVE** due to the lack of clinical evidence demonstrating an impact on improved health outcomes.

Botulinum Toxin, II-16

- No changes were made to the medical necessity criteria; these criteria remain the same.
- Changes were made to the dosing criteria in Table 2 only; these criteria are provided below.

MEDICAL AND BEHAVIORAL HEALTH POLICY UPDATE

• Table 2. Dosing

Onabotulinum Toxin A (Botox) Dosing (1 unit = 1 billable unit)

For one or more indications, unless otherwise stated below, the maximum cumulative dose for onabotulinum toxin A (Botox®) is 400 units every 12 weeks.

| FDA LABELED INDICATIONS | MAXIMUM TREATMENT DOSE | MAXIMUM BILLABLE DOSE | MINIMUM DOSING INTERVAL |
|--|---|-----------------------|-------------------------|
| Blepharospasm | Initial: 15 units (2.5 units into each of 3 sites per affected eye) Retreatment: 30 units (5 units into each of 3 sites per affected eye). Cumulative dose in 30 days should not exceed 200 units. | 200 billable units | Every 12 weeks |
| Cervical dystonia | 300 units divided among affected muscles | 300 billable units | Every 12 weeks |
| Primary axillary hyperhidrosis | 100 units (50 units per axilla) | 100 billable units | Every 12 weeks |
| Chronic migraine prophylaxis | 155 units divided across specific head/neck muscle areas | 200 billable units | Every 12 weeks |
| Detrusor overactivity associated with a neurologic condition | 200 units | 200 billable units | Every 12 weeks |
| Overactive bladder | 100 units | 100 billable units | Every 12 weeks |
| Strabismus | Initial: 5 units per muscle Retreatment: 25 units per muscle | 100 billable units | Every 12 weeks |
| Upper limb spasticity | 400 units (both limbs) divided among affected muscles | 400 billable units | Every 12 weeks |
| Lower limb spasticity | 400 units (both limbs) divided among affected muscles | 400 billable units | Every 12 weeks |
| OFF-LABEL INDICATIONS | | | |
| Achalasia | 100 units (25 units per quadrant) | 100 billable units | Every 6 weeks |
| Chronic anal fissure | 25 units | 100 billable units | Every 12 weeks |
| Cerebral palsy (spasticity) | 200 units divided among affected muscles | 200 billable units | Every 12 weeks |

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MEDICAL AND BEHAVIORAL HEALTH POLICY UPDATE

• **Table 2. Dosing** - (continued from previous page)

| FDA LABELED INDICATIONS | MAXIMUM TREATMENT DOSE | MAXIMUM BILLABLE DOSE | MINIMUM DOSING INTERVAL |
|--|--|-----------------------|-------------------------|
| Focal limb dystonia | 20 units divided among affected muscles | 100 billable units | Every 12 weeks |
| Laryngeal dystonia (spasmodic dysphonia) | 25 units | 100 billable units | Every 12 weeks |
| Oromandibular dystonia | 100 units per muscle | 400 billable units | Every 12 weeks |
| Sialorrhea | 260 units (100 units per parotid gland and 30 units per submandibular gland) | 300 billable units | Every 12 weeks |
| Torsion dystonia | 140 units | 200 billable units | Every 12 weeks |
| Hemifacial spasm | 25 units divided among affected muscles | 100 billable units | Every 12 weeks |
| Primary palmar hyperhidrosis | 100 units (50 units per palm) | 100 billable units | Every 12 weeks |
| Other conditions (spasticity) | 400 units divided among affected muscles | 400 billable units | Every 12 weeks |

Abobotulinum Toxin A (Dysport) Dosing (5 units = 1 billable unit)

For one or more indications, unless otherwise stated below, the maximum cumulative dose for abobotulinum toxin A (Dysport®) is 1,000 units every 12 weeks.

| FDA LABELED INDICATIONS | MAXIMUM TREATMENT DOSE | MAXIMUM BILLABLE DOSE | MINIMUM DOSING INTERVAL |
|-------------------------|--|-----------------------|-------------------------|
| Cervical dystonia | Initial: 500 units divided among affected muscles Retreatment: 1,000 units divided among affected muscles | 200 billable units | Every 12 weeks |
| Upper limb spasticity | 1,000 units (both limbs) divided among affected muscles | 200 billable units | Every 12 weeks |
| Lower limb spasticity | 30 units/kg (15 units/kg per limb) or 1,000 units (both limbs), whichever is lower, divided among affected muscles | 200 billable units | Every 12 weeks |

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MEDICAL AND BEHAVIORAL HEALTH POLICY UPDATE

• **Table 2. Dosing** - (continued from previous page)

| OFF-LABEL INDICATIONS | | | |
|-----------------------------|--|--------------------|----------------|
| Blepharospasm | 240 units (120 units per eye) | 60 billable units | Every 12 weeks |
| Cerebral palsy (spasticity) | 30 units/kg divided among affected muscles | 200 billable units | Every 12 weeks |
| Hemifacial spasm | 220 units divided among affected muscles | 60 billable units | Every 12 weeks |

Rimabotulinum Toxin B (Myobloc) Dosing (100 units = 1 billable unit)

For one or more indications, unless otherwise stated below, the maximum cumulative dose for rimabotulinum toxin B (Myobloc®) is 10,000 every 12 weeks.

| FDA LABELED INDICATIONS | MAXIMUM TREATMENT DOSE | MAXIMUM BILLABLE DOSE | MINIMUM DOSING INTERVAL |
|-------------------------|--|-----------------------|-------------------------|
| Cervical dystonia | Initial: 5000 units divided among affected muscles Retreatment: 10,000 units divided among affected muscles | 100 billable units | Every 12 weeks |
| OFF-LABEL INDICATIONS | | | |
| Oromandibular dystonia | 100 units divided among affected muscles | 25 billable units | Every 12 weeks |
| Sialorrhea | 2,500 units (1,000 units per parotid gland and 250 units per submandibular gland) | 25 billable units | Every 12 weeks |

Incobotulinum Toxin A (Xeomin) Dosing (1 unit = 1 billable unit)

For one or more indications, unless otherwise stated below, the maximum cumulative dose for incobotulinum toxin A (Xeomin®) is 400 units every 12 weeks.

| FDA LABELED INDICATIONS | MAXIMUM TREATMENT DOSE | MAXIMUM BILLABLE DOSE | MINIMUM DOSING INTERVAL |
|-------------------------|---|-----------------------|-------------------------|
| Blepharospasm | 70 units (35 units per eye) | 100 billable units | Every 12 weeks |
| Cervical dystonia | 120 units divided among affected muscles | 200 billable units | Every 12 weeks |
| Upper limb spasticity | 400 units (both limbs) divided among affected muscles | 400 billable units | Every 12 weeks |

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MEDICAL AND BEHAVIORAL HEALTH POLICY UPDATE

Amino Acid-Based Elemental Formulas, II-69

I. Initial Review

- The use of oral amino acid-based elemental formula may be considered **MEDICALLY NECESSARY** in patients five years of age and under when **ALL** of the following criteria are met:
 - The formula contains 100% free amino acids as the protein source; **AND**
 - The patient has a definitive diagnosis, as supported by laboratory and/or diagnostic test results, of **ONE** of the following conditions:
 1. Cystic fibrosis;
 2. Amino acid, organic acid, and fatty acid metabolic and malabsorption disorders; IgE-mediated allergies to food proteins (e.g. phenylketonuria, maple syrup urine disease, homocystinuria, tyrosinemia, methylmalonic acidemia, and propionic acidemia);
 3. Food protein-induced enterocolitis syndrome;
 4. Eosinophilic esophagitis;
 5. Eosinophilic gastroenteritis;
 6. Eosinophilic colitis;
 7. Short gut syndrome; **AND**
 - The condition was diagnosed by a physician.
- The use of oral amino acid-based elemental formula may be considered **MEDICALLY NECESSARY** in children five years and under for up to 90 days when requested by a physician while actively seeking a confirmatory diagnosis and when **ALL** of the following documentation is submitted:
 - Presumptive diagnosis of one of the conditions defined in the policy statement above; **AND**
 - Patient's symptoms; **AND**
 - Minimum of three prior failed formula alternatives.

II. Renewal Review

- The use of oral amino acid-based formula may be considered **MEDICALLY NECESSARY** in children five years and under when the following documentation is submitted by a physician:
 - Improvement of the patient's symptoms while on the amino acid-based formula; **AND**
 - Definitive diagnosis of one of the conditions defined in the first policy statement under Initial Review, accompanied with supporting laboratory and/or diagnostic test results.

Policies inactivated

None

Policies Effective: July 31, 2017 Notification Posted: June 15, 2017

Policies developed

Accepted Indications for Medical Drugs Which are not Addressed by a Specific Medical Policy, II-173

- **NOTE: This policy does not apply to the following:**
 - **Medical drugs addressed by a specific medical policy utilized by Blue Cross and Blue Shield of Minnesota (Blue Cross).** (continued on next page)

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- **New FDA-approved medical drugs or medical drug indications on Blue Cross' Medical Drug Evaluation Process List (see Medical Policy II-174, Evaluation Process for New FDA-Approved Medical Drugs and Medical Drug Indications)**
- **Drugs that process under the pharmacy benefit, including but not limited to self-administered drugs and oral agents.**
- **NOTE:** FDA-approved medical drugs may require pre-authorization (PA). In the absence of a specific policy, medical drugs requiring PA will be reviewed for medical necessity according to this policy to ensure appropriate patient selection for treatment. Medical drugs requiring PA are found on Blue Cross' Pre-Certification/Pre-Authorization/Notification Lists, which can be accessed via the following steps: (1) Go to providers.bluecrossmn.com; (2) Under 'Tools and Resources' select 'Medical policy' and then acknowledge the Acceptance Statement; (3) Click on the '+' next to 'Utilization Management' and select the appropriate 'Pre-Certification/Pre-Authorization/Notification List.'

I. **Medically Accepted Indications**

Use of a medical drug may be considered **MEDICALLY NECESSARY** when the following criteria are met:

• **Non-Oncologic Indications**

1. The drug is approved by the U.S. Food and Drug Administration (FDA); **AND**
2. The drug will be used for ONE of the following non-oncologic indications:
 - An FDA-approved indication; OR
 - An off-label use supported by:
 - **TWO or more** of the following:
 - Truven Health Analytics Micromedex DrugDex® Compendium when the strength of recommendation is Class I or IIa, the strength of evidence is Category A or B, and efficacy is Class I or IIa; or
 - Elsevier/Gold Standard Clinical Pharmacology Compendium when narrative text is supportive; or
 - Wolters Kluwer Lexi-Drugs® Compendium when the level of evidence is A; or
 - American Hospital Formulary Service-Drug Information® (AHFS-DI) Compendium when narrative text is supportive;

OR

- **TWO or more** articles from major peer-reviewed medical journals (excluding case reports, letters, posters, and abstracts) that recognize the drug or combination of drugs as safe and effective for the indication for which it has been prescribed.

AND

3. The patient does not have any FDA-labeled contraindications to the drug; **AND**
4. The dose is supported by ONE of the following:
 - Drug labeling for the FDA-approved indication; or
 - Drug compendia or medical literature for the off-label indication.

OR

• **Oncologic Indications**

1. The drug is approved by the U.S. Food and Drug Administration (FDA); **AND**
2. The drug will be used for ONE of the following oncologic indications:

(continued on next page)

MEDICAL AND BEHAVIORAL HEALTH POLICY UPDATE

- An FDA-approved indication; OR
- An off-label use supported by **ONE or more** of the following:
 - National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium® when the category of evidence and consensus is 1, 2A, or 2B; or
 - Truven Health Analytics Micromedex DrugDex® Compendium when the strength of recommendation is Class I, IIa, or IIb; or
 - Elsevier/Gold Standard Clinical Pharmacology Compendium when narrative text is supportive; or
 - Wolters Kluwer Lexi-Drugs® Compendium when the level of evidence is A; or
 - American Hospital Formulary Service-Drug Information® (AHFS-DI) Compendium when narrative text is supportive; or
 - **ONE or more** articles from major peer-reviewed medical journals (excluding case reports, letters, posters, and abstracts) that recognize the drug or combination of drugs as safe and effective for the indication for which it has been prescribed.

AND

3. The patient does not have any FDA-labeled contraindications to the drug; **AND**
4. The dose is supported by ONE of the following:
 - Drug labeling for the FDA-approved indication; or
 - Drug compendia or medical literature for the off-label indication.

II. Investigative Indications

All other uses of a medical drug are considered **INVESTIGATIVE** due to the lack of clinical evidence demonstrating an impact on improved health outcomes.

Evaluation Process for New FDA-Approved Medical Drugs or Medical Drug Indications, II-174

- **NOTE: This policy does not apply to the following:**
 - **Medical drugs addressed by a specific medical policy utilized by Blue Cross and Blue Shield of Minnesota (Blue Cross).**
 - **Drugs that process under the pharmacy benefit, including but not limited to self-administered drugs and oral agents.**

- **Medical Drug Evaluation Process**

Blue Cross' Medical Drug Evaluation Process involves clinical review of new FDA-approved medical drugs or medical drug indications within 6 months of FDA approval. The clinical review includes evaluation of published data to determine whether the drug or indication is medically necessary or investigative based on evidence of safety, effectiveness, and effect on health outcomes. During the Blue Cross Medical Drug Evaluation Process, new FDA-approved medical drugs or medical drug indications are considered **INVESTIGATIVE** until the evaluation process is completed.

- **Drugs and Indications Impacted by Blue Cross' Medical Drug Evaluation Process:** New FDA-approved medical drugs or medical drug indications under evaluation by Blue Cross are found on the Medical Drug Evaluation Process List, which can be accessed via the following steps: (1) Go to providers.bluecrossmn.com; (2) Under 'Tools and Resources' select 'Medical policy' and then acknowledge the Acceptance Statement; (3) Click on the '+' next to 'Medical and Behavioral Health Policies' and select 'Medical Drug Evaluation Process List.' This list will be updated and providers will be notified via a Provider Quick Point as new FDA-approved drugs and indications are added or removed from the list.

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MEDICAL AND BEHAVIORAL HEALTH POLICY UPDATE

- **NOTE:** Blue Cross may determine not to impose a Medical Drug Evaluation Process for certain new FDA-approved medical drugs or medical drug indications. In the absence of a specific medical policy, these drugs and indications may be reviewed according to Medical Policy II-173, Accepted Indications for Medical Drugs Which are not Addressed by a Specific Medical Policy.

Policies Effective: August 21, 2017 Notification Posted: June 30,17

Policies developed

Radiofrequency Ablation of Peripheral Nerves to Treat Pain, IV-130

- Radiofrequency ablation of peripheral nerves to treat pain associated with plantar fasciitis or knee osteoarthritis is considered **INVESTIGATIVE** due to a lack of evidence demonstrating an impact on improved health outcomes.

Policies revised

Transcranial Magnetic Stimulation, X-14

I. Repetitive transcranial magnetic stimulation (rTMS) may be considered **MEDICALLY NECESSARY** as a treatment of major depressive disorder when **ALL** of the following criteria have been met:

- Confirmed diagnosis of severe major depressive disorder (single or recurrent) documented by standardized rating scales that reliably measure depressive symptoms (e.g., Hamilton Rating Scale for Depression or Montgomery-Asberg Depression Rating Scale); **AND**
- 18 years of age or older; **AND**
- Any ONE of the following:
 - Failure of 4 trials of psychopharmacologic agents including 2 different agent classes (e.g., selective serotonin reuptake inhibitors [SSRIs], serotonin-norepinephrine reuptake inhibitors [SNRIs], tricyclic antidepressants [TCAs], **and** 2 augmentation trials; **OR**
 - Inability to tolerate a therapeutic dose of medication as evidenced by 4 trials of psychopharmacologic agents with distinct side effects; **OR**
 - History of response to rTMS in a previous depressive episode (at least 3 months since the prior episode);

AND

- Ongoing active psychotherapy; **AND**
- Clinical contraindication for electroconvulsive therapy (ECT) OR the patient refuses ECT; **AND**
- NONE of the following conditions are present:
 - Seizure disorder or any history of seizure with increased risk of future seizure; **OR**
 - Presence of acute or chronic psychotic symptoms or disorders (such as schizophrenia, schizophreniform or schizoaffective disorder) in the current depressive episode; **OR**
 - Acute suicidal risk, catatonia or life-threatening inanition; **OR**
 - Neurologic conditions that include epilepsy, cerebrovascular disease, dementia, increased intracranial pressure, having a history of repetitive or severe head trauma, or with primary or secondary tumors in the central nervous system (CNS); **OR**
 - Presence of an implanted magnetic-sensitive medical device located 30 centimeters or less from the TMS magnetic coil or other implanted metal items, including but not limited to a cochlear implant, implanted cardioverter defibrillator (ICD), pacemaker, vagus nerve stimulator, or metal aneurysm clips or coils, staples, or stents.

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MEDICAL AND BEHAVIORAL HEALTH POLICY UPDATE

II. Repetitive transcranial magnetic stimulation (rTMS) for treatment is considered **INVESTIGATIVE** for all other uses including but not limited to the following due to lack of evidence demonstrating an impact on health outcomes:

- Continued treatment with rTMS as maintenance therapy
- Treatment of all other psychiatric/neurologic disorders, including but not limited to bipolar disorder, schizophrenia, obsessive-compulsive disorder, or migraine headaches.

Image-Guided Minimally Invasive Decompression for Spinal Stenosis, IV-120

- Image-guided minimally invasive spinal decompression is considered **INVESTIGATIVE** due to a lack of clinical evidence demonstrating an impact on improved health outcomes.

Policies inactivated

None

There was no Medical and Behavioral Health Policy Activity for July 2017.

Policies reviewed with no changes in May 2017 and June 2017:

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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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