Provider **Press**

Provider information

March 2018 / Vol. 23, No. 1

BlueCross BlueShield Minnesota

QUALITY INITIATIVES AT BLUE CROSS

The Quality Department at Blue Cross works on a variety of quality improvement projects throughout the year. Quality efforts are focused on improvement of Healthcare Effectiveness Data and Information Set (HEDIS®) scores, as well as other quality initiatives mandated by agencies such as the Department of Human Services (DHS) and the Centers for Medicare and Medicaid Services (CMS).

These efforts are designed around best practice guidelines and are aimed at educating subscribers on the importance of preventive screenings and regular wellness exams, as well as treatment of some chronic illnesses. For subscribers with suspected "gaps" in care, outreach is conducted in a variety of ways: text messaging, email, mailings, or interactive voice response (IVR) calls. In addition to general education regarding preventive care and management of chronic conditions, subscribers are often directed to contact their primary care provider to schedule needed appointments.

Our clinical consultant team is also available to provide information and answer any questions related to HEDIS or other quality projects. Please feel free to contact Shantele Gillmann, RN in the Quality Department at **(651) 662-7380** if you have questions, concerns or ideas for improving quality of care.

We appreciate your partnership as we work toward the common goal of improving the health of our subscribers.

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.

Inside preview

FYI

PUBLICATIONS AVAILABLE ONLINE

The following is a list of Quick Points and Bulletins published from January to February 2018 that are available online at **providers.bluecrossmn.com**. Bulletins are currently mailed to all participating providers affected by the information; however, later this year, Blue Cross will cease mailing Bulletins and instead post them on our website. This change further supports ease of access and administrative efficiency for providers and Blue Cross, and it helps reduce the use of paper to be environmentally friendly. Quick Points are available only on our website unless noted otherwise in the bottom left corner of the publication.

QUICK POINTS	TITLE
QP1-18	Transition of Care Management Features for New Medicare Advantage Prescription Drug Plans
QP2-18	Pharmacy Benefit Exclusion for Luxturna
QP3-19	Pharmacy Benefit Exclusion for Helixate FS
QP4-18	Remember to Request Subscribers ID Cards
QP5-18	Quality Initiatives at Blue Cross
QP6-18	Updated Commercial PA Request Form and PA List for Early Intensive Behavioral Intervention Services
QP7-18	Disclosure of Ownership Form
QP8-18	Effective January 1, 2018 FEP Standard Option Subscriber SNF Benefit
QP9-18	New Drug-Related Pharmacy Step Therapy (ST) Program- Ophthalmic Antihistamine
QP10-18	Routes of Administration Pharmacy Benefits Exclusion
QP11-18	Qualified Medicare Beneficiary Program Changes
QP12-18	Pharmacy Benefit Exclusion for Ryplazim
QP13-18	Pharmacy Benefit Exclusion for Parasabiv
QP14-18	Pharmacy Benefit Exclusion for Fasenra
BULLETINS	**TITLE**
P1-18	New Drugs, Aimovig, Fremanezumab and Galcanezumab Will Require PA
P2-18	New Medical Drug PA Requirement for Voretigene Neparvovec (Luxturna)
P3-18	New Drug-Related PA Criteria: Inhaled Antibiotics Duplicate Therapy
P4-18	Change to Medical Policy IV-126 Sacroiliac Fusion
P5-18	New Medical-Drug Related PA Requirements for Yescarta and Kymriah
P6-18	Addition of Drug to Self-Administered Oncology PA with QL Program
P7-18	Addition of Drug to Doxycycline/Minocycline
P8-18	Changes to PA for Hip Arthroplasty, Hip Resurfacing and Knee Arthroplasty for Commercial and Government Programs Lines of Business
P9-18	Update: Centurion Moving to Blue Cross for Claim Administration Services

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

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

Over the past few months, Blue Cross has worked to make this process easier for providers and introduced 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 have a specific PA form. We created 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"
  - There is also a link to the new forms from Availity. Select "Forms" in Payor Spaces.

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

PROVIDER MANUAL UPDATES

The following is a list of Blue Cross provider manuals that have been updated from January to February 2018. As a reminder, provider manuals are available online at **providers.bluecrossmn.com**. To view the manuals, select "Forms & publications," then "manuals." Updates to the manuals are documented in the "Summary of changes" section of the online manuals.

MANUAL NAME: CHAPTER NUMBER AND TITLE	CHANGE
Provider Policy and Procedure Manual: Chapter 11, Coding Policies and Guidelines, Pharmacy Services section	Completely reformatted and more detailed information added regarding PA process.

2018 HOLIDAY SCHEDULE

Provider services will be closed on the following days in 2018:

Monday, May 28

Wednesday, July 4

Monday, September 3

Thursday, November 22

Friday, November 23

Monday, December 24

Tuesday, December 25

Except for 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.

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

IDENTIFIED CLAIMS PROCESSING ISSUES GRID

Blue Cross and Blue Shield of Minnesota and Blue Plus (Blue Cross) began migrating to a new operating system on November 1, 2015, and continues to migrate lines of business to this new system. As a result of moving to a new operating system, Blue Cross has identified a number of claims processing issues and is working to resolve them.

To alert providers to these identified issues, and to decrease providers' administrative burden of calling Provider Services or submitting appeals for these known issues, Blue Cross has published a grid of high impact identified issues on the Blue Cross provider website at **providers.bluecrossmn.com**. This grid is updated on the first day of each month and if there are significant changes, the grid is also updated the middle of the month.

A link to the grid is located on the Operating Model Transition page:

1. Go to **providers.bluecrossmn.com**
2. Under "Tools and Resources", click "Operating System Transition"
3. A link to the grid will be provided under the heading "Identified Claims Processing Issues"

The grid provides:

- An issue ID
- A description of the issue
- A resolution status
- The issue start date
- The date edits were corrected in the system (the process date when claims should be processing correctly)
- Whether Blue Cross will reprocess claims automatically (recovery process)
- The date when reprocessing begins
- The date when reprocessing is complete

If a provider has attributed a claim denial or underpayment to an issue listed in the grid, but the claim isn't reprocessed by Blue Cross via the recovery process, appeals will be accepted for review for 90 days after the "Reprocessing Complete Date." The Issue ID and description must be included on the appeals cover sheet to prevent the appeal from being rejected for untimely submission.

QUALITY IMPROVEMENT

MINNESOTA'S CHLAMYDIA EPIDEMIC

Centers for Disease Control (CDC) report that 2016 is the third year in a row that saw increased rates of Sexually Transmitted Diseases (STDs). In 2016 there were 1,598,354 cases of chlamydia reported to the CDC, but it is estimated that over 2.8 million cases have occurred throughout the 50 states and District of Columbia. Many cases go unreported because screenings are not done for chlamydia infection, which is typically asymptomatic.

The Minnesota Department of Health (MDH) has a broad-based, multifaceted approach to decrease the upward trend of Chlamydia. MDH is an active member in the Minnesota Chlamydia Partnership (MCP), along with Minnesota healthcare organizations and community groups, such as Community Restoring Youth Sexual Health (CRUSH), who promote awareness, education, and low to no-cost STD screening. CRUSH is an organization of professionals, youth leaders, and community members. Please visit their website at http://crush.com for more information and help get their message out - ***'Chlamydia – Not Knowing Spreads It – GET TESTED.'***

2018 MINNESOTA ANNUAL STD TESTING DAY is April 25, 2018

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.

Here are ways we at Blue Cross Support Chlamydia Screening:

- ***Provider Toolkit*** - Blue Plus, along with UCare, HealthPartners, and Hennepin Health, represent a collaborative effort in supporting the Minnesota Chlamydia Partnership. This collaborative developed and annually updates a provider toolkit which is available on the Stratis Health website – Quality Improvement Program page. This helpful guide contains a wealth of resource links and documents to help you, the provider, have that meaningful conversation with your young patients. Please visit the Stratis website at http://www.stratishealth.org/index.html and download the manual.
- ***Member Incentive*** - Blue Advantage PMAP or Blue Plus MinnesotaCare offers female members ages 16-24 years, a $25 reward card for completing a Chlamydia screening and submitting a voucher. If your patients have questions about these vouchers they may call Blue Cross at **(651) 662-5545** or **1-800-711-9862**, 8 a.m. to 5 p.m. Monday through Friday. TTY users call 711 or look online at https://bluecrossmn.com.
- ***Gap in Care Reports*** - The Health Management Quality department can send you a 'gap in care' report for your attributed members to support your outreach efforts. Contact Sheila Dalen, RN at sheila.dalen@bluecrossmn.com or your Blue Cross Clinical Consultant to inquire about these reports.

Thank you for the quality of care you provide to our subscribers!

UTILIZATION MANAGEMENT CLINICAL CRITERIA

Upon request, any Blue Cross practitioner may review the clinical criteria used to evaluate an individual case. Medical and behavioral health policies are available for your use and review on our website at **providers.bluecrossmn.com**.

HEALTH LITERACY

MAKING A CASE FOR HEALTH LITERACY

"Improving Health and the Bottom Line: The Case for Health Literacy by Stan Hudson, MA, CDFT; R.V. Rikard, Ph.D.; Ioana Staiculescu, MPH, CDFT, and Karen Edison, MD

Health literacy refers to one's ability to find, know, and use health information to make daily choices that impact one's health. According to the authors, health literacy is not just the right thing to do for the patient, it is also the right thing to do to make sure we control costs and improve quality. Health literacy is a vital tool supporting the movement away from the current business model where providers make money when patients use more health care to one in which providers will make the most money when they keep people in better health and out of the hospital. The commissioned paper by the Roundtable on Health Literacy, Health and Medicine Division of the National Academies of Sciences, Engineering, and Medicine, was presented as part of their November workshop focusing on building the case for health literacy. The mission of the Roundtable is to inform, inspire, and activate a wide variety of stakeholders to support the development, implementation, and sharing of evidence-based health literacy practices and policies. The goal is to improve the health and well-being of all people.

- Building the Case for Health Literacy: A Workshop (11/15/17) – link below – watch the presentations, get PowerPoints and access the report under "attachments."
  http://www.nationalacademies.org/hmd/Activities/PublicHealth/HealthLiteracy/2017-NOV-15.aspx

Key Elements of Building the Case for Health Literacy

The importance of integrating and addressing health literacy falls into two primary categories:

a) ***The business case***, which includes health literacy's impact on cost, quality, behavior, access, and patient experience, and

b) ***The ethical case***, which includes health literacy's impact on health equity, as well as the legal/regulatory case.

Throughout the paper, Hudson and team have highlighted supporting evidence on the impact of health literacy both from the business and ethical cases. For example:

- First time colonoscopy patients who watched an education video had significantly lower anxiety scores the day of the procedure and as a result required 18% less sedation medication and had a 14% decrease in procedure time (The Beryl Institute, 2015).
- Interventions to increase health literacy and self-efficacy provide greater improvements in hemoglobin A1c, glucose, and total cholesterol (M. Kim, Kim,

(continued on next page)

QUALITY IMPROVEMENT

Han, Huh, & Nguyen, 2013) and regularly taking diabetic medication (Al Sayah, Majumdar, Williams, Robertson, & Johnson, 2013; Hofer et al., 2017; Y. Lee et al., 2016).

- An initiative using education classes, a teach-back call, and interactive voice response calls led to reductions in drinking sugar-sweetened beverages resulting in small but significant decreases in BMI (Zoellner et al., 2016).

The studies and techniques reviewed show clearly the impact of health literacy and the need for greater adoption of these principles and best practices across the health industry.

- To read the paper, use the link below: http://www.nationalacademies.org/hmd/~/media/Files/Activity%20Files/PublicHealth/HealthLiteracy/Commissioned%20Papers%20-Updated%202017/Hudson%20et%20al%202017%20Improving%20health%20and%20the%20bottom%20line%20%20the%20case%20for%20health%20literacy.pdf

You are invited to join the next Roundtable online meeting.

The topic will be **Health Literacy and Older Adults: Reshaping the Landscape** on March 13th at 8 AM EST. Be sure to save the link above.

PROVIDERS PERSPECTIVE ON CONTINUITY AND COORDINATION OF CARE

Keeping care coordinated across multiple care providers can be challenging. As a part of our ongoing efforts to improve continuity and coordination of care for our members, Blue Cross and Blue Shield of Minnesota (Blue Cross) gathers feedback from our network of providers on their perspectives of how well medical care is coordinated. To accomplish this, Blue Cross sponsored a telephonic survey to measure the Blue Cross provider network experience with continuity and coordination of care for their patients across the care delivery system.

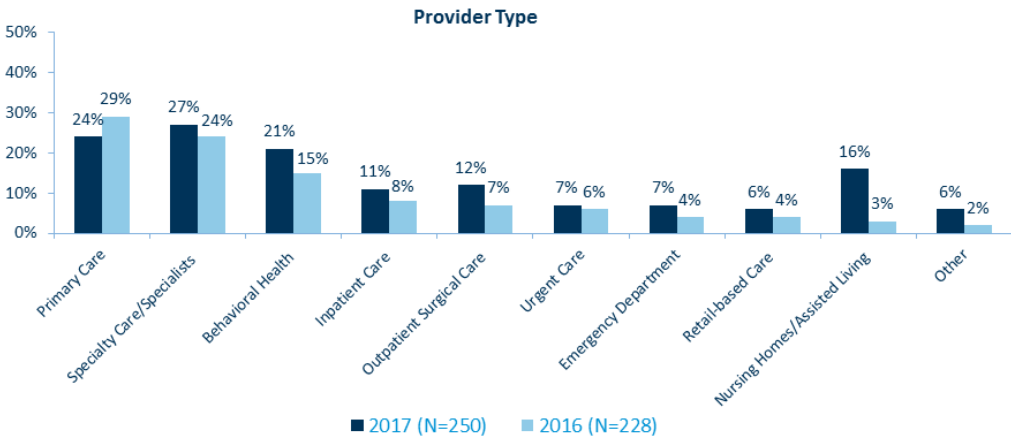
Blue Cross conducted the survey of a random selection of contracted providers between October 11, 2017 and November 6, 2017. Qualified respondents included the Quality Director, Medical Director, or Clinical Director at a facility. If those titles weren't available, someone with a clinical background and knowledgeable about continuity and coordination of care was interviewed. **A total of 250 telephone surveys were completed.** The total for completed surveys is consistent with the past two years survey results.

(continued on next page)

QUALITY IMPROVEMENT

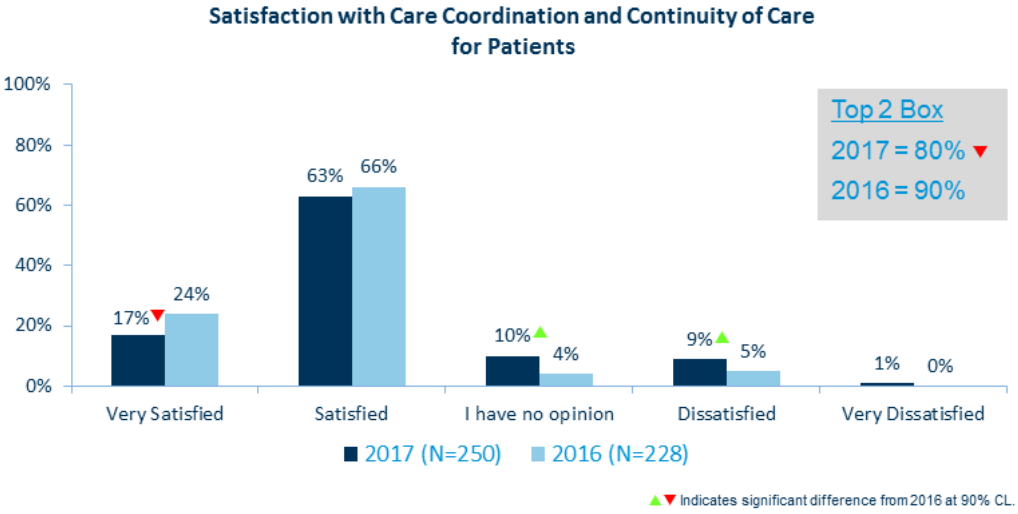
RESPONDENTS REPRESENT A MIX OF PRACTICE TYPES

The survey sample shows an increase in the percentage of nursing home/assisted living providers responding. In addition, only 18% of providers surveyed report being part of an integrated care delivery system. This is down from over 40% in 2016.



EIGHTY PERCENT (80%), OVERALL SATISFACTION WITH THE CONTINUITY AND COORDINATION OF CARE REMAINS HIGH AMONG PROVIDERS

While overall satisfaction with continuity and coordination of care remains high among providers with 80% being at least satisfied, this is a significant decrease from the 90% rate reported in the 2016 survey. Significant decreases in overall satisfaction are reported for the following provider types: primary care, nursing homes/assisted living, retail-based and specialists.

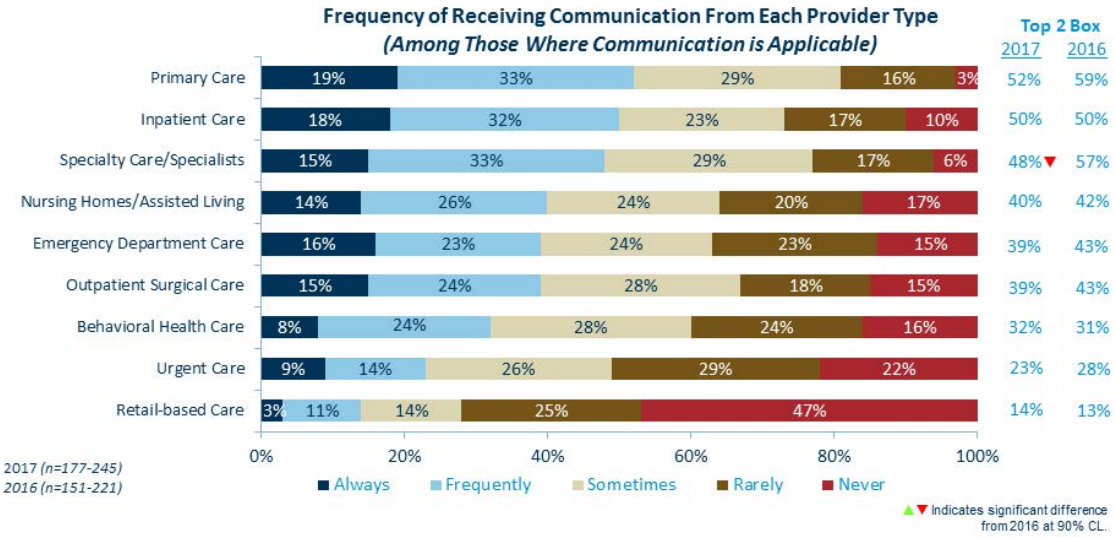


(continued on next page)

QUALITY IMPROVEMENT

FREQUENCY OF RECEIVING COMMUNICATION SHIFTED SLIGHTLY DOWN, BUT NOT SIGNIFICANTLY FOR MOST

Respondents are most likely to "always" or "frequently" receive communication about their patients from Primary Care, Inpatient Care, and Specialty Care/Specialists. However, frequency of receiving communication from Specialty Care/Specialists decreased significantly from 2016, moving from 57% to 48%. Communication is rarely received from Retail-based Care.

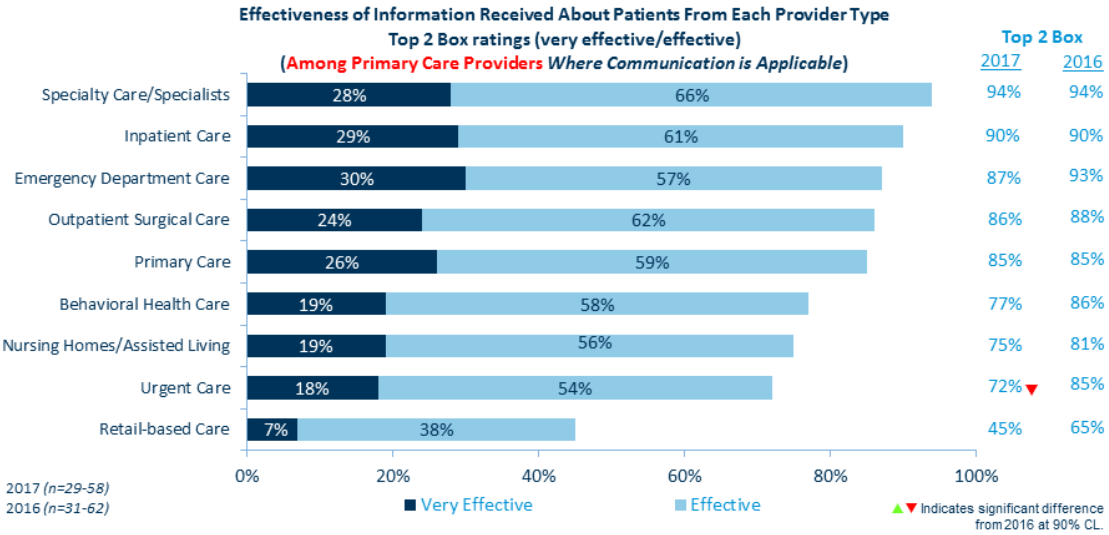


(continued on next page)

QUALITY IMPROVEMENT

COMMUNICATION RECEIVED FROM VARIOUS CARE TYPES SEEN AS EFFECTIVE BY PRIMARY CARE

Among Primary Care providers, at least 90% find information from Specialty Care/ Specialists and Inpatient Care providers to be highly effective. Results also show a significant decrease in effectiveness for information received from Urgent Care settings. In fact, 43% of Inpatient Care providers report that re-admissions have gone down because of information/communication sharing between their practice and Primary Care providers.



Blue Cross' ability to better understand gaps in providers' coordination of care experiences can ultimately help us address opportunities to improve member experience and health outcomes. The most mentioned themes around opportunities for Blue Cross to improve continuity and coordination of care were to make it easier for a provider to reach Blue Cross by phone, to improve communication and offer tips or provide articles about best practices, and to improve authorizations process.

THROUGHOUT 2018, IN THIS PROVIDER PRESS PUBLICATION, BLUE CROSS WILL PUBLISH BEST PRACTICES AND TIPS TO HELP YOU COORDINATE CARE MORE EFFICIENTLY AND EFFECTIVELY FOR YOUR PATIENTS.

Thank you for your ongoing efforts to improve continuity and coordination of care for your patients as they navigate the health care system in pursuit of better health.

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

PHARMACY SECTION

PHARMACY UPDATES FOR QUARTER 1, 2018

Pharmacy Drug Formulary Update

As part of our continued efforts to evaluate and update our formularies, Blue Cross and Blue Shield of Minnesota and Blue Plus (Blue Cross) evaluates drugs on a regular basis. This evaluation includes a thorough review of clinical information, including safety information and utilization. Blue Cross has developed several formularies based on each of our products and population requirements. A complete list of all formularies and updates can be found at the following address.

Formularies: https://www.bluecrossmn.com/healthy/public/personal/home/providers/

Under "TOOLS AND RESOURCES" select "Prescription drugs." Next, select "Search a drug list." You will be prompted to select "yes" or "no" to the question on if the member is a Medicare Part D member. Select "yes" if you wish to view formularies for Platinum Blue, SecureBlue or Medicare Advantage members. Select "no" for all other plans. Once you have selected the applicable pharmacy plan, under "helpful documents" select the documents titled "Drug list" or "Formulary updates" to review the applicable formulary.

PHARMACY UTILIZATION MANAGEMENT (UM) UPDATE

Blue Cross employs a variety of utilization management programs such as Prior Authorization, Step Therapy, and Quantity Limits. Blue Cross has implemented additional Prior Authorizations, Quantity Limits, and/or Step Therapy depending on the member's prescription drug benefit. Programs in this update include new and changes to existing Prior Authorizations (PA), Quantity Limits (QL), or Step Therapy (ST) as well as discontinuation of a ST program.

Utilization Management Program – Glucose Test Strip Step Therapy, Discontinuation Effective 12/31/17

BRAND NAME (generic name - if available)	UM Program		
Glucose test strips, all manufacturers except Bayer/ Ascensia			ST

Changes to Existing Utilization Management Programs, Effective 1/1/18

BRAND NAME (generic name - if available)	UM Program		
ARMONAIR RESPICLICK		QL	
BEVYXXA		QL	
COTEMPLA XR ODT 17.3 mg, 25.9 mg		QL	
COTEMPLA XR ODT 8.6 mg		QL	
FIASP, FIASP FLEXTOUCH		QL	
FLOLIPID 20 mg/5 mL suspension		QL	ST
FLOLIPID 40 mg/5 mL suspension		QL	ST

(continued on next page)

PHARMACY SECTION

PHARMACY UTILIZATION MANAGEMENT (UM) UPDATE (continued)

Changes to Existing Utilization Management Programs, Effective 1/1/18

BRAND NAME (generic name - if available)	UM Program		
HUMALOG JR KWIKPEN		QL	
IDHIFA	PA	QL	
LYNPARZA 100 mg, 150 mg	PA	QL	
TRELEGY ELLIPTA		QL	
TYMLOS	PA	QL	
VERZENIO	PA	QL	

New Utilization Management Program – Oral Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) Step Therapy±, Effective 1/1/18

BRAND NAME (generic name - if available)	UM Program		
ANAPROX (naproxen)			ST
ANAPROX DS (naproxen)			ST
ARTHROTEC (diclofenac/misoprostol)			ST
CAMBIA			ST
CATAFLAM (diclofenac potassium)			ST
CELEBREX (celecoxib)			ST
CLINORIL (sulindac)			ST
DAYPRO (oxaprozin)			ST
EC-NAPROSYN (naproxen)			ST
FELDENE (piroxicam)			ST
FENOPROFEN cap			ST*
FENORTHO			ST
INDOCIN			ST
KETOPROFEN cap ER 200 mg			ST*
MECLOFENAMATE			ST*
MOBIC (meloxicam)			ST
NALFON			ST*
NAPRELAN (naproxen)			ST
NAPRELAN CR (naproxen ext-release)			ST
NAPROSYN (naproxen)			ST
PONSTEL (mefenamic acid)			ST
TIVORBEX			ST
TOLMETIN			ST*
VIVLODEX			ST
VOLTAREN XR (diclofenac sodium ext-release)			ST
ZIPSOR			ST
ZORVOLEX			ST

(continued on next page)

PHARMACY SECTION

PHARMACY UTILIZATION MANAGEMENT (UM) UPDATE (continued)

New Utilization Management Program – Topical Doxepin Prior Authorization/Quantity Limit, Effective 1/1/18

BRAND NAME (generic name - if available)	UM Program		
DOXEPIN 5% cream	PA	QL	
PRUDOXIN 5% cream	PA	QL	
ZONALON 5% cream	PA	QL	

New Utilization Management Program – Biologic Immunomodulators Prior Authorization/ Quantity Limit, Effective 1/1/18

BRAND NAME (generic name - if available)	UM Program		
ACTEMRA	PA	QL	
ENBREL 25 mg/0.5mL	PA	QL	
ENBREL 25 mg/vial, kit	PA	QL	
ENBREL 50 mg/mL SureClick autoinjector	PA	QL	
ENBREL 50 mg/mL syringe	PA	QL	
CIMZIA 2x200 mg vial, kit	PA	QL	
CIMZIA 2x200 mg/mL syringe, kit	PA	QL	
CIMZIA 6x200 mg/mL syringe starter kit	PA	QL	
COSENTYX 150 mg/mL pre-filled syringe	PA	QL	
COSENTYX SENSOREADY PEN 150 mg/mL auto-injector	PA	QL	
HUMIRA 10 mg/0.2 mL syringe	PA	QL	
HUMIRA 20 mg/0.4 mL, 40 mg/0.8 mL syringe, kit	PA	QL	
HUMIRA 40 mg/0.8 mL pen, Crohn's Starter kit	PA	QL	
HUMIRA 40 mg/0.8 mL pen, kit	PA	QL	
HUMIRA 40 mg/0.8 mL pen, Psoriasis Starter kit	PA	QL	
HUMIRA 40mg/0.8 mL syringe, Pediatric Crohn's Starter kit (3 syringes)	PA	QL	
HUMIRA 40mg/0.8 mL syringe, Pediatric Crohn's Starter kit (6 syringes)	PA	QL	
KEVZARA	PA	QL	
KINERET 100 mg syringe	PA	QL	
ORENCIA 125 mg/mL (subcutaneous)	PA	QL	
ORENCIA 50 mg/0.4 mL, 87.5 mg/0.7 mL	PA	QL	
ORENCIA ClickJect autoinjector	PA	QL	
SILIQ	PA	QL	
SIMPONI	PA	QL	
STELARA 45 mg/0.5 mL	PA	QL	
STELARA 90 mg/1 mL syringe	PA	QL	
TALTZ	PA	QL	
TREMFYA	PA	QL	
XELJANZ	PA	QL	
XELJANZ XR	PA	QL	

(continued on next page)

PHARMACY SECTION

PHARMACY UTILIZATION MANAGEMENT (UM) UPDATE (continued)

New Utilization Management Program – Otezla Prior Authorization/Quantity Limit, Effective 1/1/18

BRAND NAME (generic name - if available)	UM Program		
OTEZLA 10 mg, 20 mg & 30 mg tablet starter pack (two week)	PA	QL	
OTEZLA 10 mg, 20 mg & 30 mg tablet starter pack (four week)	PA	QL	
OTEZLA 30 mg tabs	PA	QL	

Key for all the above tables:
PA=Prior Authorization; QL=Quantity Limit; ST=Step Therapy
± ST program targets brand drugs only
**Available as authorized generic or single source generic, and targeted in step therapy program*

Effective January 15, 2018

- The Hemlibra (emicizumab) Prior Authorization Program will be implemented for the Commercial and Medicaid lines of business.

Effective February 1, 2018

- The Bonjesta (doxylamine/pyridoxine ER), Diclegis (doxylamine/pyridoxyine delayed release) Prior Authorization with Quantity Limit Program will be implemented for Commercial lines of business.
- The Opioid Induced Constipation (OIC) Prior Authorization Program will be implemented for Commercial lines of business.
- The Kuvan Prior Authorization will be renamed to Phenylketonuria Prior Authorization to allow the addition of new target agents to the program.
- The Phosphodiesterase Type 5 Inhibitors Quantity Limit Program will be renamed to Erectile Dysfunction – Phosphodiesterase Type 5 Inhibitors, Topical Prostaglandin Quantity Limit Program to allow the addition of new target agents to the program.

Effective April 1, 2018

- The Inhaled Antibiotic Duplicate Therapy Prior Authorization Program will be implemented for Commercial lines of business.
- The Ophthalmic Antihistamine Step Therapy Program will be implemented for Commercial lines of business.

A detailed list of all drugs included in these programs can be found at the following address:
Utilization Management information: https://www.bluecrossmn.com/healthy/public/personal/home/providers/

Under "TOOLS AND RESOURCES" select "Prescription drugs." Next, select "Search a drug list." You will be prompted to select "yes" or "no" to the question on if the member is a Medicare Part D member. Select "yes" if you wish to view formularies for Platinum Blue, SecureBlue or Medicare Advantage members. Select "no" for all other plans. Once you have selected the applicable pharmacy plan, under "helpful documents" you will see documents titled "Utilization management." These will list all applicable drugs currently included in one of the above programs.

(continued on next page)

PHARMACY SECTION

PHARMACY UTILIZATION MANAGEMENT (UM) UPDATE (continued)

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
MEPSEVII (vestronidase alfa-vjbk) IV SOLN 10 MG/5 ML	To be determined	12/15/2017
LUXTURNA (voretigene neparvovec-rzyl) SUBRETINAL INJECTION	Yes – Effective 2/26/2018	1/15/2018

OTHER PHARMACY BENEFIT UPDATES

- **Helixate FS Will No Longer Be Covered for Commercial and Medicaid**

  Effective February 1, 2018, Helixate FS will no longer be covered. Beginning January 1, 2018, Helixate FS will no longer be manufactured. Kogenate FS will continue to be on our Commercial and Medicaid formularies and is the therapeutics equivalent to Helixate FS. Please note that both Helixate FS and Kogenate FS are manufactured by Bayer Healthcare LLC.

  Helixate FS will be available until supplies run out. Subscribers that choose to continue taking Helixate FS after February 1, 2018 will pay the full cost of the prescription.

  Affected subscribers who recently received Helixate FS will be notified of the change and directed to contact their providers to discuss covered alternative medication choices.

- **Routes of Administration Exclusion**

  Effective April 1, 2018, the following routes of administration will be excluded from the Commercial pharmacy benefit as they are more appropriately covered under the medical benefit.

  - Combination, Epidural, Hemodialysis, Intra-arterial, Intraperitoneal, Intra-articular, Perfusion, Intrapleural, Intratympanic, and Intratracheal

  Subscribers and providers impacted by this change will be notified prior to the effective date.

EXCEPTION REQUESTS

Prescribing providers may request coverage of a non-preferred drug for a Subscriber by completing the Minnesota Uniform Form for Prescription Drug Prior Authorization

(continued on next page)

PHARMACY SECTION

PHARMACY UTILIZATION MANAGEMENT (UM) UPDATE (continued)

(PA) Requests and Formulary Exceptions. Subscriber liability for non-preferred drugs is subject to the Subscriber specific benefit design. You may find this form at the address below:

Exception request: https://www.bluecrossmn.com/healthy/public/personal/home/providers/

Under "TOOLS AND RESOURCES" select "Prescription drugs." Next, select "Search a drug list." You will be prompted to select "yes" or "no" to the question on if the member is a Medicare Part D member. Select "yes" if you wish to view formularies for Platinum Blue, SecureBlue or Medicare Advantage members. Select "no" for all other plans. Once you have selected the applicable pharmacy plan on the top bar of the web page select "Forms" and then "Coverage Exception Form" or you may call provider services to obtain the documentation.

ADDITIONAL RESOURCES

For tools and resources regarding Pharmacy please visit our website at bluecrossmn.com and select "Shop Plans" and "Prescription Drugs." Tools include information on preventive drugs (if covered by plan), specialty drugs and other pharmacy programs. You will also be able search for frequently asked questions and answers. Formulary updates are completed quarterly and posted online for review.

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, claims submission and processing, 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."

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. Policies posted in November 2017 and December 2017 are effective 50 days from the date they were posted. Policies posted in January 2018 are effective 45 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: January 15, 2018 Notification Posted: November 22, 2017

Policies developed

Tisagenlecleucel, II-183

I. Tisagenlecleucel may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when **ALL** of the following criteria are met:

- Age 25 years or younger; **AND**
- Diagnosis of B-cell precursor acute lymphoblastic leukemia (ALL); **AND**
- Disease is refractory or in second or later relapse, as defined by ONE of the following:
  - Second or greater bone marrow relapse; OR
  - Any bone marrow relapse after allogeneic stem cell transplantation (SCT) and must be ≥6 months from SCT at the time of tisagenlecleucel infusion; OR
  - Primary refractory as defined by not achieving a complete response after 2 cycles of a standard chemotherapy regimen or chemorefractory as defined by not achieving a complete response after 1 cycle of standard chemotherapy for relapsed leukemia; OR
  - Patients with Philadelphia chromosome-positive ALL who are intolerant to or have failed 2 lines of tyrosine kinase inhibitor therapy (TKI), or if TKI therapy is contraindicated;

  AND
- Laboratory-confirmed CD19 tumor expression; **AND**
- Not previously treated with tisagenlecleucel; **AND**
- No FDA labeled contraindications to tisagenlecleucel; **AND**
- Screened for hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV) infection;

AND

- Does not have ANY of the following:
  - Active infection;
  - Active graft versus host disease;
  - Inflammatory disorders;
  - High pre-infusion tumor burden (>50% blasts in bone marrow);
  - Uncontrolled or accelerating tumor burden following lymphodepleting chemotherapy;
  - Unresolved serious adverse reactions from preceding chemotherapies, including pulmonary toxicity, cardiac toxicity, or hypotension.

II. All other uses of tisagenlecleucel are considered **EXPERIMENTAL/INVESTIGATIVE** due to the lack of clinical evidence demonstrating an impact on improved health outcomes.

<u>Documentation Submission</u>

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

1. Clinical notes describing the diagnosis and clinical features of the diagnosis.
2. Clinical notes describing current and past treatments for the diagnosis, including response to the treatments.
3. Laboratory results for CD19 tumor expression.
4. Laboratory results for HBV, HCV, and HIV screening.

MEDICAL AND BEHAVIORAL HEALTH POLICY UPDATE

Bioengineered Skin and Soft Tissue Substitutes, IV-137

I. Breast reconstructive surgery following mastectomy using allogeneic acellular dermal matrix products, including but not limited to the following, is considered **MEDICALLY NECESSARY AND APPROPRIATE:**

- AlloDerm®
- AlloMax™
- AlloMend®
- DermACELL™
- DermaMatrix™
- FlexHD®
- Graftjacket®

II. Treatment of chronic, noninfected, full-thickness diabetic lower-extremity ulcers using the following tissue engineered skin substitutes may be considered **MEDICALLY NECESSARY AND APPROPRIATE:**

- AlloPatch®
- Apligraf®
- Dermagraft®
- Integra® Omnigraft Dermal Regeneration Matrix (also known as Omnigraft)

III. Treatment of chronic, noninfected, partial- or full-thickness lower-extremity skin ulcers due to venous insufficiency, which have not adequately responded following a 1-month period of conventional ulcer therapy, using the following tissue-engineered skin substitutes may be considered **MEDICALLY NECESSARY AND APPROPRIATE:**

- Apligraf®
- Oasis™ Wound Matrix

IV. Treatment of second- and third-degree burns using the following tissue-engineered skin substitutes may be considered **MEDICALLY NECESSARY AND APPROPRIATE:**

- Epicel® for the treatment of deep dermal or full-thickness burns comprising a total body surface area ≥30%
- Integra Dermal Regeneration Template™

V. Treatment of dystrophic epidermolysis bullosa using OrCel™ for mitten-hand deformity when standard wound therapy has failed may be considered **MEDICALLY NECESSARY AND APPROPRIATE.**

VI. All other uses of the bioengineered skin and soft tissue substitutes listed above are considered **EXPERIMENTAL/ INVESTIGATIONAL** for all other indications due to a lack of evidence demonstrating an impact on improved health outcomes.

VII. All other skin and soft tissue substitutes not listed above are considered **EXPERIMENTAL/INVESTIGATIONAL** for all indications due to a lack of evidence demonstrating an impact on improved health outcomes including, but not limited to:

- ACell® UBM Hydrated/Lyophilized Wound Dressing
- AlloSkin™
- AlloSkin™ RT
- Aongen™ Collagen Matrix
- Architect® ECM, PX, FX

MEDICAL AND BEHAVIORAL HEALTH POLICY UPDATE

- ArthroFlex™ (Flex Graft)
- Atlas Wound Matrix
- Avagen Wound Dressing
- AxoGuard® Nerve Protector
- Biodesign Anal Fistula Plug
- CollaCare®
- CollaCare® Dental
- Collagen Wound Dressing (Oasis Research)
- CollaGUARD®
- CollaMend™
- CollaWound™
- Collexa®
- Collieva®
- Conexa™
- Coreleader Colla-Pad
- CorMatrix®
- Cymetra™ (Micronized AlloDerm™)
- Cytal™ (previously MatriStem®)
- Dermadapt™ Wound Dressing
- DermaPure™
- DermaSpan™
- DressSkin
- Durepair Regeneration Matrix®
- Endoform Dermal Template™
- *ENDURA*Gen™
- Excellagen
- ExpressGraft™
- E-Z Derm™
- FlexiGraft®
- GammaGraft
- Graftjacket® Xpress, injectable
- Hyalomatrix®
- Hyalomatrix® PA
- hMatrix®
- Integra™ Flowable Wound Matrix
- Integra™ Bilayer Wound Matrix
- MariGen™/Kerecis™ Omega3™
- MatriDerm®
- Matrix HD™
- Mediskin®
- MemoDerm™
- Microderm® biologic wound matrix
- MicroMatrix®
- NeoForm™

MEDICAL AND BEHAVIORAL HEALTH POLICY UPDATE

- NuCel
- Oasis® Burn Matrix
- Oasis® Ultra
- Pelvicol®/PelviSoft®
- Permacol™
- PriMatrix™
- PriMatrix™ Dermal Repair Scaffold
- PuraPly™ Wound Matrix (previously FortaDerm™)
- PuraPly™ AM (Antimicrobial Wound Matrix)
- Puros® Dermis
- RegenePro™
- Repliform®
- Repriza™
- SIS Fistula Plug
- StrataGraft®
- Strattice™ (xenograft)
- Suprathel®
- SurgiMend®
- Surgisis® (including Surgisis® AFP™ Anal Fistula Plug, Surgisis® Gold™ Hernia Repair Grafts, and Surgisis® RVP™ Recto-Vaginal Fistula Plug)
- Talymed®
- TenoGlide™
- TenSIX™ Acellular Dermal Matrix
- TissueMend
- TheraForm™ Standard/Sheet
- TheraSkin®
- TruSkin™
- Veritas® Collagen Matrix
- XCM Biologic® Tissue Matrix
- XenMatrix™ AB.

Natalizumab, Il-49

I. <u>Initial Review for Multiple Sclerosis</u>

Natalizumab may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when **ALL** of the following criteria are met:

- The patient has a diagnosis of a relapsing form of multiple sclerosis (MS) (i.e., relapsing-remitting MS [RRMS], secondary-progressive MS [SPMS] with relapses, progressive-relapsing MS [PRMS]); **AND**
- ONE of the following:
  - The patient is currently receiving natalizumab; OR
  - The patient has tried and failed alemtuzumab (Lemtrada) or ocrelizumab (Ocrevus) for MS; OR
  - The patient has tried and failed at least one preferred, self-administered, disease-modifying therapy for MS (see table 1 below); OR
  - The patient has a documented intolerance, FDA-labeled contraindication, or hypersensitivity to at least one preferred, self-administered, disease-modifying therapy for MS;

MEDICAL AND BEHAVIORAL HEALTH POLICY UPDATE

AND

- The patient does not have any FDA-labeled contraindications to therapy (see table 2 below); **AND**
- Natalizumab will be used as single agent therapy, and not in combination with antineoplastic, immunosuppressant, or immunomodulatory therapy; **AND**
- The dose is within the FDA-labeled dose for the indication (see table 3 below).

II. Initial Review for Crohn's Disease

Natalizumab may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when **ALL** of the following criteria are met:

- The patient is 18 years of age or older; **AND**
- The patient has a diagnosis of moderately to severely active Crohn's disease (CD) with evidence of inflammation;

AND

- ONE of the following:
  - The patient is currently receiving natalizumab; OR
  - The patient has tried and failed at least one TNF-alpha inhibitor (e.g., adalimumab, infliximab, certolizumab pegol) AND at least one conventional agent prerequisite for CD (see table 1 below); OR
  - The patient has a documented intolerance, FDA-labeled contraindication, or hypersensitivity to BOTH a TNF-alpha inhibitor and a conventional agent for CD;

  AND
- The patient does not have any FDA labeled contraindications to therapy (see table 2 below); **AND**
- Natalizumab will not be used in combination with immunosuppressants (excluding systemic corticosteroids) (e.g., 6-mercaptopurine, azathioprine, cyclosporine, or methotrexate) or TNF-alpha inhibitors; **AND**
- The dose is within the FDA labeled dose for the indication (see table 3 below).

III. Renewal Review for Multiple Sclerosis or Crohn's Disease

Natalizumab may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when **ALL** of the following criteria are met:

- 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**
- The patient does not have any FDA-labeled contraindications to therapy (see table 2 below); **AND**
- ONE of the following:
  - In patients with MS, natalizumab will be used as single agent therapy, and not in combination with antineoplastic, immunosuppressant, or immunomodulatory therapy; OR
  - In patients with CD, natalizumab will not be used in combination with immunosuppressants (e.g., 6-mercaptopurine, azathioprine, cyclosporine, or methotrexate) or TNF-alpha inhibitors;

  AND
- The dose is within the FDA labeled dose for the indication (see table 3 below).

IV. All other uses of natalizumab are considered **EXPERIMENTAL/INVESTIGATIVE** due to the lack of clinical evidence demonstrating an impact on improved health outcomes.

MEDICAL AND BEHAVIORAL HEALTH POLICY UPDATE

• **Table 1. Prerequisite Agents**

FDA LABELED INDICATIONS	PREREQUISITE AGENTS
Multiple sclerosis – Relapsing forms	Teriflunomide (Aubagio) Interferon beta-1a (Avonex, Rebif) Interferon beta-1b (Betaseron) Glatiramer acetate (Copaxone, Glatopa) Fingolimod (Gilenya) Peginterferon beta-1a (Plegridy) Dimethyl fumarate (Tecfidera)
Crohn's disease	methotrexate aminosalicylates corticosteroids (including budesonide EC capsule) cyclosporine azathioprine 6-mercaptopurine metronidazole ciprofloxacin

• **Table 2. FDA-Labeled Contraindications**

AGENT	FDA LABELED CONTRAINDICATIONS
Natalizumab	Current or prior history of progressive multifocal leukoencephalopathy (PML) Hypersensitivity

• **Table 3. Dosing**

NOTE: See documentation submission requirements below if the requested dose is higher or more frequent than the dosing criteria provided in this table.

FDA LABELED INDICATIONS	DOSING
Multiple sclerosis – Relapsing forms	300 mg every 4 weeks
Crohn's disease	300 mg every 4 weeks NOTE: discontinue in patients who have not experienced therapeutic benefit by 12 weeks of induction therapy, and in patients who cannot discontinue chronic concomitant steroids within 6 months of starting therapy

<u>Documentation Submission</u>

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

Initial Review

1.Clinical notes describing the diagnosis and clinical features of the diagnosis.
2.Clinical notes describing current and past medications for the diagnosis, including response to the medications.

MEDICAL AND BEHAVIORAL HEALTH POLICY UPDATE

3.The dose being requested. 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 natalizumab 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. 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.

Alemtuzumab, Il-184

I. <u>Initial and Renewal Review for Oncologic Indications</u>

Alemtuzumab may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when **ALL** of the following criteria are met:

- The patient has a diagnosis of ONE of the following:
  - B-cell chronic lymphocytic leukemia (CLL); OR
  - Chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL); OR
  - ONE of the following T-cell lymphomas:
    - Adult T-cell leukemia/lymphoma;
    - Mycosis fungoides/sezary syndrome;
    - Peripheral T-cell lymphoma;
    - Primary cutaneous CD30+ T-cell lymphoproliferative disorders;
    - T-cell large granular lymphocytic leukemia;
    - T-cell prolymphocytic leukemia

    OR
  - Waldenstrom's macroglobulinemia/lymphoplasmacytic lymphoma.

  AND
- The patient does not have any FDA labeled contraindications to therapy (see table 2 below); **AND**
- The dose is within the FDA-labeled dose.

II. <u>Initial Review for Multiple Sclerosis</u>

Alemtuzumab may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when **ALL** of the following criteria are met:

- The patient has a diagnosis of a relapsing form of multiple sclerosis (MS) (i.e., relapsing-remitting MS [RRMS], secondary-progressive MS [SPMS] with relapses, progressive-relapsing MS [PRMS]); **AND**
- ONE of the following:
  - The patient is currently receiving alemtuzumab; OR
  - The patient has tried and failed natalizumab (Tysabri) or ocrelizumab (Ocrevus) for MS; OR
  - The patient has tried and failed at least two preferred, self-administered, disease-modifying therapies for MS (see table 1 below); OR
  - The patient has a documented intolerance, FDA-labeled contraindication, or hypersensitivity to at least two preferred, self-administered, disease-modifying therapies for MS.

  AND
- The patient does not have any FDA-labeled contraindications to therapy (see table 2 below); **AND**
- Alemtuzumab will not be used in combination with another disease-modifying therapy for MS; **AND**
- The dose is within the FDA-labeled dose for the indication (see table 3 below).

III. <u>Renewal Review for Multiple Sclerosis</u>

Alemtuzumab may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when **ALL** of the following criteria

MEDICAL AND BEHAVIORAL HEALTH POLICY UPDATE

are met:
- 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**
- The patient does not have any FDA-labeled contraindications to therapy (see table 2 below); **AND**
- Alemtuzumab will not be used in combination with another disease-modifying therapy for MS; **AND**
- The dose is within the FDA-labeled dose for the indication (see table 3 below).

IV. All other uses of alemtuzumab are considered **EXPERIMENTAL/INVESTIGATIVE** due to the lack of clinical evidence demonstrating an impact on improved health outcomes.

• Table 1. Prerequisite Agents

FDA LABELED INDICATIONS	PREREQUISITE AGENTS
Multiple sclerosis – Relapsing forms	Teriflunomide (Aubagio) Interferon beta-1a (Avonex, Rebif) Interferon beta-1b (Betaseron) Glatiramer acetate (Copaxone, Glatopa) Fingolimod (Gilenya) Peginterferon beta-1a (Plegridy) Dimethyl fumarate (Tecfidera)

• Table 2. FDA-Labeled Contraindications

AGENT	FDA LABELED CONTRAINDICATIONS
Alemtuzumab	Infection with human immunodeficiency virus (HIV)

• Table 3. Dosing for Non-Oncologic Indications

NOTE: See documentation submission requirements below if the requested dose is higher or more frequent than the dosing criteria provided in this table.

FDA LABELED INDICATIONS	DOSING
Multiple sclerosis – Relapsing forms	12 mg/day for two treatment courses: • First treatment course: 12 mg/day on 5 consecutive days (60 mg total dose) • Second treatment course: 12 mg/day on 3 consecutive days (36 mg total dose) administered 12 months after the first treatment course

Documentation Submission

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

Initial Review for Non-Oncologic Indications

1. Clinical notes describing the diagnosis and clinical features of the diagnosis.
2. Clinical notes describing current and past medications for the diagnosis, including response to the medications.
3. The dose being requested. 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.

MEDICAL AND BEHAVIORAL HEALTH POLICY UPDATE

Renewal Review for Non-Oncologic Indications

1. Documentation of prior approval for alemtuzumab 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. 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.

Ocrelizumab, II-185

I. Initial Review for Relapsing Forms of Multiple Sclerosis

Ocrelizumab may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when **ALL** of the following criteria are met:

- The patient has a diagnosis of a relapsing form of MS (i.e., relapsing-remitting MS [RRMS], secondary-progressive MS [SPMS] with relapses, progressive-relapsing MS [PRMS]); **AND**
- ONE of the following:
  - The patient is currently receiving ocrelizumab; OR
  - The patient has tried and failed natalizumab (Tysabri) or alemtuzumab (Lemtrada) for MS; OR
  - The patient has tried and failed at least one preferred, self-administered, disease-modifying therapy for MS (see table 1 below); OR
  - The patient has a documented intolerance, FDA-labeled contraindication, or hypersensitivity to at least one preferred, self-administered, disease-modifying therapy for MS.

  AND
- The patient does not have any FDA-labeled contraindications to therapy (see table 2 below); **AND**
- For patients not currently receiving ocrelizumab, the patient has been screened for hepatitis B infection; **AND**
- Ocrelizumab will not be used in combination with another disease-modifying therapy for MS; **AND**
- The dose is within the FDA-labeled dose for the indication (see table 3 below).

II. Initial Review for Primary Progressive Forms of Multiple Sclerosis

Ocrelizumab may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when **ALL** of the following criteria are met:

- The patient has a diagnosis of a primary-progressive form of MS (PPMS); **AND**
- The patient does not have any FDA-labeled contraindications to therapy (see table 2 below); **AND**
- For patients not currently receiving ocrelizumab, the patient has been screened for hepatitis B infection; **AND**
- Ocrelizumab will not be used in combination with another disease-modifying therapy for MS; **AND**
- The dose is within the FDA-labeled dose for the indication (see table 3 below).

III. Renewal Review for Relapsing or Primary Progressive Forms of Multiple Sclerosis

Ocrelizumab may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when **ALL** of the following criteria are met:

- 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**
- The patient does not have any FDA-labeled contraindications to therapy (see table 2 below); **AND**
- Ocrelizumab will not be used in combination with another disease-modifying therapy for MS; **AND**
- The dose is within the FDA labeled dose for the indication (see table 3 below).

IV. All other uses of ocrelizumab are considered **EXPERIMENTAL/INVESTIGATIVE** due to the lack of clinical evidence demonstrating an impact on improved health outcomes.

MEDICAL AND BEHAVIORAL HEALTH POLICY UPDATE

- **Table 1. Prerequisite Agents**

FDA LABELED INDICATIONS	PREREQUISITE AGENTS
Multiple sclerosis – Relapsing forms	Teriflunomide (Aubagio) Interferon beta-1a (Avonex, Rebif) Interferon beta-1b (Betaseron) Glatiramer acetate (Copaxone, Glatopa) Fingolimod (Gilenya) Peginterferon beta-1a (Plegridy) Dimethyl fumarate (Tecfidera)

- **Table 2. FDA-Labeled Contraindications**

AGENT	FDA LABELED CONTRAINDICATIONS
Ocrelizumab	Active hepatitis B virus infection History of life-threatening infusion reaction to ocrelizumab

- **Table 3. Dosing**

NOTE: See documentation submission requirements below if the requested dose is higher or more frequent than the dosing criteria provided in this table.

FDA LABELED INDICATIONS	DOSING
Multiple sclerosis – Relapsing forms	Initial dose: 300 mg followed 2 weeks later by 300 mg Subsequent doses: 600 mg every 6 months
Multiple sclerosis – Primary progressive forms	Initial dose: 300 mg followed 2 weeks later by 300 mg Subsequent doses: 600 mg every 6 months

Documentation Submission

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

Initial Review

1. Clinical notes describing the diagnosis and clinical features of the diagnosis.
2. Clinical notes describing current and past medications for the diagnosis, including response to the medications.
3. For patients not currently receiving ocrelizumab, laboratory results for hepatitis B screening.
4. The dose being requested. 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 ocrelizumab 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. 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.

MEDICAL AND BEHAVIORAL HEALTH POLICY UPDATE

Meniscal Allografts and Other Meniscal Implants, IV-114

I. Meniscal allograft transplantation may be considered **MEDICALLY NECESSARY AND APPROPRIATE** in patients who have had a prior meniscectomy and have symptoms related to the affected side, when **ALL** of the following criteria are met:

- The patient is an adult or skeletally mature adolescent with documented closure of growth plates and not age-appropriate for total knee arthroplasty or other reconstructive knee surgery; AND
- There is disabling knee pain with activity that is refractive to conservative treatment; AND
- Diagnostic imaging and/or arthroscopic evidence obtained within the previous 12 months of minimal to absent diffuse degenerative changes in the surrounding articular cartilage (e.g., Outerbridge grade II or less, <50% joint space narrowing); AND
- There are normal knee biomechanics, or alignment and stability achieved concurrently with meniscal transplantation.

II. Meniscal allograft transplantation may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when performed in combination, either concurrently or sequentially, with treatment of articular cartilage lesions using any of the following procedures:

- Autologous chondrocyte implantation; or
- Osteochondral allografting; or
- Osteochondral autografting.

III. Use of other meniscal implants including but not limited to, collagen and polyurethane, is considered **EXPERIMENTAL/INVESTIGATIVE.**

Policies revised

Vagus Nerve Stimulation, IV-131

I. Implantable vagus nerve stimulation may be considered **MEDICALLY NECESSARY AND APPROPRIATE** for the treatment of medically refractory or intractable epileptic seizures, defined as failure of at least two antiepileptic drugs.

II. Implantable vagus nerve stimulation is considered **EXPERIMENTAL/INVESTIGATIVE** for all other indications, due to a lack of evidence demonstrating an impact on improved health outcomes. Those indications include, but are not limited to, the following:

- Chronic or recurrent depression
- Essential tremor
- Headache
- Obesity
- Fibromyalgia
- Congestive heart failure
- Tinnitus
- Traumatic brain injury (TBI)
- Post-traumatic stress disorder (PTSD)
- Upper-limb impairment due to stroke

III. Non-implantable transcutaneous vagus nerve stimulation is considered **EXPERIMENTAL/INVESTIGATIVE** for all indications due to the lack of clinical evidence demonstrating an impact on improved health outcomes.

Vagus Nerve Blocking Therapy, IV-132

Intra-abdominal vagus nerve blocking therapy is considered **EXPERIMENTAL/INVESTIGATIVE** for all indications, including but not limited to the treatment of obesity due to the lack of clinical evidence demonstrating an impact on improved health outcomes.

Injectable Bulking Agents for the Treatment of Urinary and Fecal Incontinence, IV-133

I. Use of the following periurethral bulking agents may be considered **MEDICALLY NECESSARY AND APPROPRIATE** to

MEDICAL AND BEHAVIORAL HEALTH POLICY UPDATE

treat stress urinary incontinence:
- Carbon-coated spheres (e.g., Durasphere®);
- Calcium hydroxylapatite (e.g., Coaptite®);
- Polydimethylsiloxane (e.g., Macroplastique®).

II. Use of these periurethral bulking agents as treatment for any other type of urinary incontinence is considered **EXPERIMENTAL/INVESTIGATIVE** due to the lack of clinical evidence demonstrating an impact on improved health outcomes.

III. Use of autologous cellular therapy (e.g., myoblasts, fibroblasts, muscle-derived stem cells, or adipose- derived stem cells), autologous fat, and autologous ear chondrocytes for the treatment of urinary incontinence is considered **EXPERIMENTAL/INVESTIGATIVE** due to the lack of clinical evidence demonstrating an impact on improved health outcomes.

IV. Use of any other periurethral bulking agents for urinary incontinence is considered **EXPERIMENTAL/INVESTIGATIVE** due to the lack of clinical evidence demonstrating an impact on improved health outcomes.

V. Use of perianal bulking agents to treat fecal incontinence is considered **EXPERIMENTAL/INVESTIGATIVE** due to the lack of clinical evidence demonstrating an impact on improved health outcomes.

Pelvic Floor Stimulation as a Treatment of Urinary Incontinence, IV-134

I. Pelvic Floor Electrical Stimulation

Use of pelvic floor electrical stimulation (i.e., pelvic TENS) may be considered **MEDICALLY NECESSARY AND APPROPRIATE** as treatment for stress and/or urge incontinence in patients who have undergone a documented trial of pelvic muscle exercises for a period of at least six (6) months with no significant improvement in incontinence.

II. Pelvic Floor Magnetic Stimulation

Use of magnetic stimulation (e.g., Extracorporeal Magnetic Innervation [ExMITM], NeoControl® Pelvic Floor system) of the pelvic floor muscles as treatment for urinary incontinence is considered **EXPERIMENTAL/INVESTIGATIVE** due to lack of clinical evidence demonstrating an impact on improved health outcomes.

Documentation Submission

Documentation supporting the medical necessity criteria for pelvic floor electrical stimulation described in the policy must be included in the prior authorization, when prior authorization is required. The following documentation must be submitted:
- Clinical notes describing:
  1. Diagnosis including type of urinary incontinence (e.g. stress, urge)
  2. Pelvic muscle exercise trial for a minimum of six months and response to exercise trial

Percutaneous Tibial Nerve Stimulation (PTNS), IV-135

I. Percutaneous tibial nerve stimulation may be considered **MEDICALLY NECESSARY AND APPROPRIATE** for treatment of urinary dysfunction (i.e., incontinence, urgency frequency, and non- obstructive urinary retention) in patients who meet **ALL** the following criteria:
- Absence of neurologic disease associated with detrusor hyperreflexia; AND
- Absence of outlet obstruction; AND
- Symptoms have resulted in significant disability (e.g., the frequency and/or severity of leakages are limiting the patient's ability to work or participate in activities outside the home); AND
- Conservative forms of treatment have been tried for at least one year and have failed.

II. The use of percutaneous tibial nerve stimulation for any other indication is considered **EXPERIMENTAL/INVESTIGATIVE** due to a lack of clinical evidence demonstrating an impact on improved health outcomes.

MEDICAL AND BEHAVIORAL HEALTH POLICY UPDATE

Transvaginal and Transurethral Radiofrequency Tissue Remodeling for Urinary Stress Incontinence, IV-136

I. Transvaginal Radiofrequency Bladder Neck Suspension

Use of transvaginal radiofrequency bladder neck suspension for treatment of stress urinary incontinence is considered **EXPERIMENTAL/INVESTIGATIVE** due to a lack of clinical evidence demonstrating an impact on improved health outcomes.

II. Transurethral Radiofrequency Micro-Remodeling

Use of transurethral radiofrequency micro-remodeling (e.g., Renessa®) for treatment of stress urinary incontinence is considered **EXPERIMENTAL/INVESTIGATIVE** due to a lack of clinical evidence demonstrating an impact on improved health outcomes.

Policies inactivated

Treatments for Urinary Dysfunction, II-50

Policies Effective: February 26, 2018 Notification Posted: January 5, 2018

Policies developed

Removal of Benign Skin Lesions, IV-138

I. Removal of a benign skin lesion (e.g., nevus [mole], sebaceous cyst, seborrheic keratosis, or pigmented lesion) may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when **ANY** of the following criteria are met:

- Prior biopsy suggests or is indicative of lesion malignancy; OR
- Clinical consideration of malignancy based on appearance of the lesion (eg, a change in the ABCDEs of skin cancer [Asymmetry, Border irregularity, Color, Diameter, Evolving or changing in size, shape or color]); OR
- Drainage, bleeding, burning, intense itching, or pain associated with the lesion; OR
- Clinical evidence of inflammation (eg, purulence, oozing, edema, erythema) refractory to medical management; OR
- Lesion obstructs a body orifice, or restricts vision; OR
- Due to its anatomical location, the lesion is prone to being recurrently traumatized.

II. Wart removal may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when **ANY** of the following criteria are met:

- Periocular warts associated with chronic recurrent conjunctivitis thought secondary to lesion virus shedding; OR
- Warts showing evidence of spread from one body area to another, particularly in immunosuppressed patients or warts of recent origin in immunocompromised patient; OR
- Lesions are condyloma acuminata or molluscum contagiosum; OR
- Cervical dysplasia or pregnancy is associated with genital warts.

III. Removal of skin tags that do not pose a threat to health or function are considered cosmetic as they are performed primarily to enhance or otherwise alter physical appearance without correcting or improving physiological function.

Composite Tissue Allotransplantation of the Face, II-186

Composite tissue allotransplantation of the hand is considered **EXPERIMENTAL/INVESTIGATIVE** for all indications due to the lack of evidence demonstrating an impact on improved health outcomes.

Axicabtagene Ciloleucel, II-187

I. Axicabtagene ciloleucel may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when **ALL** of the following criteria are met:

- Age 18 years or older; **AND**
- Diagnosis of ANY of the following large B-cell lymphomas:
  - Diffuse large B-cell lymphoma (DLBCL) not otherwise specified; OR
  - Primary mediastinal large B-cell lymphoma; OR
  - High-grade B-cell lymphoma; OR

MEDICAL AND BEHAVIORAL HEALTH POLICY UPDATE

- DLBCL arising from follicular lymphoma (FL) (i.e., transformed FL);

AND

- Disease is refractory or relapsed after TWO or more lines of systemic therapy. Examples include the following:
  - No response to last line of therapy, defined by progressive disease as best response to most recent therapy regimen; or
  - No response to last line of therapy, defined by stable disease as best response to most recent therapy with duration ≤6 months from last dose of therapy; or
  - Disease progression or relapsed ≤12 months post-autologous stem cell transplantation (ASCT); or
  - If salvage therapy is given post-ASCT, no response to or relapsed after the last line of therapy;

AND

- Patient must have received adequate prior therapy, including ALL of the following:
  - An anthracycline-containing chemotherapy regimen; AND
  - Anti-CD20 monoclonal antibody (e.g., rituximab) unless tumor is CD20-negative; AND
  - For patients with transformed FL, prior chemotherapy for FL with chemorefractory disease after transformation to DLBCL;

AND

- Not previously treated with axicabtagene ciloleucel; **AND**
- No FDA labeled contraindications to axicabtagene ciloleucel; **AND**
- Screened for hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV) infection;

AND

- Does not have ANY of the following:
  - Active infection;
  - Inflammatory disorders;
  - Primary central nervous system lymphoma.

II. All other uses of axicabtagene ciloleucel are considered **EXPERIMENTAL/INVESTIGATIVE** due to the lack of clinical evidence demonstrating an impact on improved health outcomes.

Documentation Submission

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

1. Clinical notes describing the diagnosis and clinical features of the diagnosis.
2. Laboratory results for HBV, HCV, and HIV screening.
3. Clinical notes describing current and past treatments for the diagnosis, including response to the treatments.
4. Clinical notes documenting absence of active infection, inflammatory disorders, and primary CNS lymphoma.

Baroreflex Stimulation Devices, IV-139

Use of baroreflex stimulation implanted devices is considered **EXPERIMENTAL/INVESTIGATIVE** for all indications, including but not limited to treatment of hypertension and heart failure due to the lack of clinical evidence demonstrating an impact on improved health outcomes.

Implantable Sinus Stents for Postoperative Use Following Endoscopic Sinus Surgery and for Recurrent Sinus Disease, IV-140

The use of implantable sinus stents is considered **EXPERIMENTAL/INVESTIGATIVE** for ALL indications including but not limited to the following, due to a lack of clinical evidence demonstrating an impact on improved health outcomes:

- Postoperative treatment following endoscopic sinus surgery;
- Treatment of recurrent sinonasal polyposis.

Endovascular Therapies for Extracranial Vertebral Artery Disease, IV-141

Endovascular therapy, including percutaneous transluminal angioplasty with or without stenting, is considered **EXPERIMENTAL/INVESTIGATIVE** for the management of extracranial vertebral artery disease due to the lack of clinical evidence demonstrating an impact on improved health outcomes.

MEDICAL AND BEHAVIORAL HEALTH POLICY UPDATE

Patient-Controlled End Range of Motion Stretching Devices, VII-62
Patient-controlled end range of motion stretching devices are considered **EXPERIMENTAL/INVESTIGATIVE** for all indications due to the lack of clinical evidence demonstrating an impact on improved health outcomes.

Policies revised

Advanced Pharmacologic Therapies for Pulmonary Arterial Hypertension, II-107
NOTE: **For criteria on oral or inhaled advanced therapies for pulmonary arterial hypertension, please refer to applicable pharmacy benefit plan.**

I. Initial Review

Epoprostenol (Flolan®, Veletri®), treprostinil (Remodulin®), or sildenafil injection (Revatio®) may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when **ALL** of the following criteria are met:

- The patient has a diagnosis of pulmonary arterial hypertension (PAH), WHO Group 1, as determined by right heart catheterization **AND** ALL of the following:
  - Mean pulmonary artery pressure > 25 mm Hg; AND
  - Pulmonary capillary wedge pressure, left atrial pressure, or left ventricular end-diastolic pressure ≤ 15 mm Hg; AND
  - Pulmonary vascular resistance > 3 Wood units;

  AND
- ONE of the following:
  - The patient had a negative response to acute pulmonary vasodilator testing; OR
  - The patient had an inadequate response to a calcium-channel antagonist; OR
  - The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to at least one calcium-channel antagonist;

  AND
- ONE of the following:
  - The requested agent will be used as monotherapy for PAH AND the patient is World Health Organization (WHO) functional class II or greater; OR
  - The requested agent will be used as add-on therapy to existing monotherapy for PAH AND ALL of the following:
    1. The patient is WHO functional class II or greater; AND
    2. The patient has unacceptable or deteriorating clinical status despite established PAH pharmacotherapy; AND
    3. Both advanced therapies for PAH are from different therapeutic classes.

    OR
  - The requested agent will be used as add-on therapy to existing combination therapy for PAH AND ALL of the following:
    1. The patient is WHO functional class III or IV; AND
    2. The patient has unacceptable or deteriorating clinical status despite established PAH pharmacotherapy; AND
    3. All advanced therapies for PAH are from different therapeutic classes.

  AND
- If the requested agent is sildenafil injection (Revatio®), the patient is currently prescribed oral sildenafil (Revatio®) and temporarily unable to take oral medication; **AND**
- The patient does not have any FDA labeled contraindications to therapy (see table below).

II. Renewal Review

Epoprostenol (Flolan®, Veletri®), treprostinil (Remodulin®), or sildenafil injection (Revatio®) may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when **ALL** of the following criteria are met:

- 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**
- The patient does not have any FDA labeled contraindications to therapy (see table below).

III. Experimental/Investigative Indications

All other uses of epoprostenol (Flolan®, Veletri®), treprostinil (Remodulin®), or sildenafil injection (Revatio®) are

MEDICAL AND BEHAVIORAL HEALTH POLICY UPDATE

considered **EXPERIMENTAL/INVESTIGATIVE**, including but not limited to the following, due to the lack of clinical evidence demonstrating an impact on improved health outcomes:

- As part of combination therapy (i.e., two or more advanced therapies) for first-line treatment of PAH;
- Treatment of pulmonary hypertension conditions other than PAH, including but not limited to:
  - Pulmonary hypertension associated with left heart diseases (WHO Group 2);
  - Pulmonary hypertension associated with lung diseases and/or hypoxemia (including chronic obstructive pulmonary disease) (WHO Group 3);
  - Pulmonary hypertension due to chronic thrombotic and/or embolic disease (WHO Group 4);
  - Miscellaneous conditions (i.e., sarcoidosis, histocytosis X and lymphangiomatosis) (WHO Group 5).

• Table. FDA-Labeled Contraindications

AGENT	FDA LABELED CONTRAINDICATIONS
Epoprostenol (Flolan®)	Heart failure with reduced ejection fraction; Hypersensitivity
Epoprostenol (Veletri®)	Congestive heart failure due to severe left ventricular systolic dysfunction; Pulmonary edema; Hypersensitivity
Treprostinil (Remodulin®)	None
Sildenafil injection (Revatio®)	Use with organic nitrates or riociguat; Hypersensitivity

Documentation Submission

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

Initial Review

1. Clinical notes describing confirmation of PAH by right heart catheterization and WHO functional class.
2. Clinical notes describing current and past medications for the diagnosis, including response to the medications.

Renewal Review

1. Documentation of prior approval for the requested PAH agent 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.

Policies inactivated

None

Policies Effective: March 12, 2018 Notification Posted: January 26, 2018

Policies developed

Wearable Cardioverter Defibrillators, II-91

I. Use of a wearable cardioverter defibrillator (WCD) for the prevention of sudden cardiac death is considered **MEDICALLY NECESSARY AND APPROPRIATE** as interim treatment for patients who:

- Meet the criteria for an implantable cardioverter defibrillator (ICD). (Refer to Medical Policy IV-84 Implantable

MEDICAL AND BEHAVIORAL HEALTH POLICY UPDATE

Cardioverter Defibrillator); **AND**

- Meet one or more of the following:
  - A temporary contraindication to receiving an ICD (e.g., systemic infection, recovery from surgery, lack of vascular access) that prevents immediate implantation of an ICD; OR
  - Previously implanted ICD that requires explantation due to infection (e.g., device pocket or lead infection, endocarditis) as a bridge to ICD reimplantation; OR
  - As a bridge to heart transplantation in carefully selected patients with end-stage heart failure who meet patient selection criteria established by the Organ Procurement and Transplantation Network (OPTN) and the United Network of Organ Sharing (UNOS). (For more information refer to policy IV-128 Organ Transplantation.)

OR

- On or after hospital discharge in patients with a left ventricular ejection fraction (LVEF) less than or equal to 35% who may be candidates for an ICD **AND** who meet one of the following:
  - Within 40 days following myocardial Infarction; OR
  - Ischemic heart disease within 90 days post-revascularization (e.g. coronary artery bypass graft or percutaneous transluminal coronary angioplasty); OR
  - Within 30 days of newly diagnosed nonischemic dilated cardiomyopathy in patients starting medical therapy; OR
  - Within 30 days of newly diagnosed secondary cardiomyopathy (e.g. tachycardia mediated, thyroid mediated or peripartum) in which the underlying cause is potentially treatable, and the patient exhibits high-risk features.

II. Use of a WCD is considered **EXPERIMENTAL/INVESTIGATIVE** for all other indications due to a lack of clinical evidence demonstrating an effect on health outcomes.

Voretigene Neparvovec, II-188

I. Voretigene neparvovec may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when **ALL** of the following criteria are met:

- Diagnosis of inherited retinal dystrophy (e.g., Leber congenital amaurosis, retinitis pigmentosa); **AND**
- Genetic testing has confirmed biallelic RPE65 gene mutations (NOTE: laboratory documentation must be provided); **AND**
- Age 12 months or older; **AND**
- Optical coherence tomography (OCT) has confirmed sufficient viable retinal cells (i.e., an area of retina within the posterior pole of >100 µm thickness); **AND**
- Not previously treated with voretigene neparvovec or any other gene therapy; **AND**
- No FDA labeled contraindications to voretigene neparvovec; **AND**
- None of the following:
  - Use of high-dose (>7500 retinol equivalent units [or >3300 IU] per day of vitamin A) retinoid compounds within the previous 18 months;
  - Intraocular surgery within the previous 6 months;

AND

- Voretigene neparvovec will be administered by a retinal surgeon experienced in performing intraocular surgery; **AND**
- Voretigene neparvovec will be administered to each eye on separate days, no fewer than 6 days apart, when applicable (both eyes treated).

II. All other uses of voretigene neparvovec are considered **EXPERIMENTAL/INVESTIGATIVE** due to the lack of clinical evidence demonstrating an impact on improved health outcomes.

• Table. FDA-Labeled Contraindications

AGENT	FDA-LABELED CONTRAINDICATIONS
Voretigene neparvovec	None

Documentation Submission

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

MEDICAL AND BEHAVIORAL HEALTH POLICY UPDATE

1. Clinical notes describing the diagnosis and clinical features of the diagnosis.
2. Laboratory documentation confirming biallelic RPE65 gene mutations.
3. Written report describing results of ophthalmic optical coherence tomography (OCT) testing.

Saturation Biopsy of the Prostate, IV-142

I. Saturation biopsy of the prostate may be considered **MEDICALLY NECESSARY AND APPROPRIATE** in men with the following:
- At least **TWO** prior extended (12 – 14 core) transrectal prostate biopsies that are negative for invasive cancer; AND
- **ONE** or more of the following:
  - An elevated prostate specific antigen (PSA) that is persistently rising; OR
  - Histologic evidence of atypia on prior prostate biopsy; OR
  - Histologic findings of high-grade prostatic intraepithelial neoplasia (PIN) on prior biopsy.

II. Saturation biopsy of the prostate is considered **EXPERIMENTAL/INVESTIGATIVE** for all other indications, including but not limited to surveillance of men with prostate cancer, due to lack of clinical evidence demonstrating an impact on improved health outcomes.

Transcatheter Arterial Chemoembolization to Treat Primary or Metastatic Liver Malignancies, II-190

I. Transcatheter arterial chemoembolization may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when **ANY** of the following criteria are met:
- To treat hepatocellular cancer that is unresectable but confined to the liver and not associated with portal vein thrombosis and liver function not characterized as Child-Pugh class C; **OR**
- As a bridge to transplant in patients with hepatocellular cancer where the intent is to prevent further tumor growth and to maintain a patient's candidacy for liver transplant*; **OR**
- To treat liver metastasis in symptomatic patients with metastatic neuroendocrine tumor whose symptoms persist despite systemic therapy and who are not candidates for surgical resection: **OR**
- To treat liver metastasis in patients with liver-dominant metastatic uveal melanoma.

*When using transcatheter arterial chemoembolization of the liver as a bridge to transplantation to prevent further tumor growth, the patient candidate should have the following characteristics: a single tumor less than 5 cm or no more than 3 tumors each less than 3 cm in size, absence of extrahepatic disease or vascular invasion, and Child-Pugh class A or B.

II. Transcatheter arterial chemoembolization is considered **EXPERIMENTAL/INVESTIGATIVE** for all other indications, including but not limited to the following:
- As neoadjuvant or adjuvant therapy in hepatocellular cancer that is considered resectable
- To treat unresectable cholangiocarcinoma
- To treat liver metastasis from any other tumors or to treat hepatocellular cancer that does not meet the criteria noted above, including recurrent hepatocellular carcinoma
- To treat hepatocellular tumors prior to liver transplantation except as noted above.

Intravitreal Corticosteroid Implants, II-100

I. A dexamethasone intravitreal implant 0.7 mg (Ozurdex®) may be considered **MEDICALLY NECESSARY AND APPROPRIATE** for the treatment of:
- Noninfectious ocular inflammation, or uveitis, affecting the intermediate or posterior segment of the eye; OR
- Macular edema following branch or central retinal vein occlusion; OR
- Diabetic macular edema.

II. A fluocinolone acetonide intravitreal implant 0.59 mg (Retisert®) may be considered **MEDICALLY NECESSARY AND APPROPRIATE** for the treatment of chronic noninfectious intermediate, posterior, or panuveitis.

III. A fluocinolone acetonide intravitreal implant 0.19 mg (Iluvien®) may be considered **MEDICALLY NECESSARY AND APPROPRIATE** for the treatment of diabetic macular edema in patients who have been previously treated with a course of standard corticosteroid injection and did not have a clinically significant rise in intraocular pressure.

IV. A fluocinolone acetonide intravitreal implant 0.59 mg (Retisert®) or 0.19 mg (Iluvien®) or dexamethasone intravitreal

MEDICAL AND BEHAVIORAL HEALTH POLICY UPDATE

implant 0.7 mg (Ozurdex®) is considered **EXPERIMENTAL/INVESTIGATIVE** for all other indications including but not limited to the following due to the lack of clinical evidence demonstrating an impact on improved health outcomes:

- Birdshot retinochoroidopathy
- Cystoid macular edema related to retinitis pigmentosa
- Idiopathic macular telangiectasia type 1
- Postoperative macular edema
- Circumscribed choroidal hemangiomas
- Proliferative vitreoretinopathy
- Radiation retinopathy

Confocal Laser Endomicroscopy, II-191

Confocal laser endomicroscopy is considered **EXPERIMENTAL/INVESTIGATIVE** for all indications due to lack of clinical evidence demonstrating an impact on improved health outcomes, including but not limited to:

- Analysis of colorectal polyps;
- Detecting dysplasia in Barrett's esophagus;
- Evaluation of suspicious lesions.

Chronic Intermittent Intravenous Insulin Therapy, II-189

Chronic intermittent intravenous insulin therapy is considered **EXPERIMENTAL/INVESTIGATIVE** for all indications due to the lack of clinical evidence demonstrating an impact on improved health outcomes.

Policies Revised

Sacroiliac Joint Fusion, IV-126

I. Sacroiliac joint fusion, performed by an open procedure, may be considered **MEDICALLY NECESSARY AND APPROPRIATE** for **ANY** of the following indications:

- Adjunct to sacrectomy or partial sacrectomy for treatment of sacral tumors;
- Adjunct to the medical treatment of sacroiliac joint infection (e.g., osteomyelitis, pyogenic sacroiliitis);
- Treatment of severe traumatic injuries associated with pelvic ring fracture.

II. Minimally invasive or percutaneous sacroiliac joint fusion/stabilization using a titanium triangular implant may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when **ALL** of the following are met:

- Moderate to severe pain that limits activities of daily living and/or results in functional disability;

AND

- Pain is suggestive of sacroiliac joint origin as determined by **ALL** of the following:
  - Pain is caudal to the lumbar spine (L5 vertebra), localized over the posterior sacroiliac joint; AND
  - Physical examination demonstrates localized tenderness with palpation over the sacral sulcus (Fortin's point) in the absence of tenderness of similar severity elsewhere; AND
  - There is a positive response to at least 3 provocative tests (e.g. thigh thrust test, compression test, Gaenslen's test, distraction test, Patrick's sign);

AND

- Absence of **BOTH** of the following:
  - Generalized pain behavior (e.g. somatoform disorder); AND
  - Generalized pain disorder (e.g. fibromyalgia);

AND

- Diagnostic imaging (plain radiographs and a CT [computed tomography] or MRI [magnetic resonance imaging]) obtained within the previous 12 months, including **ALL** of the following:
  - Exclusion of other conditions of the SI joint that would not be properly addressed by percutaneous SI joint fusion (e.g. tumor, infection, inflammatory arthropathy)
  - Exclusion of all other conditions that are the primary cause of low back or buttock pain (e.g. concomitant hip pathology, lumbar spine conditions) AND

MEDICAL AND BEHAVIORAL HEALTH POLICY UPDATE

- Indication of injury and/or degeneration of the sacroiliac joint;

AND

- Image-guided, contrast-enhanced intra-articular sacroiliac joint anesthetic injection on 2 separate occasions demonstrating at least 75% reduction of pain for the duration of the anesthetic used;

AND

- Trial of therapeutic sacroiliac joint injection (i.e. corticosteroid injection) on at least one occasion is associated with temporary pain relief;

AND

- Documented unremitting pain and functional impairment despite at least 6 months of intensive conservative therapy during the previous 12 months, including ALL of the following;
  - Medical management with nonsteroidal anti-inflammatory drugs (NSAIDS) or other analgesic medications; AND
  - Activity modification; AND
  - Active physical therapy program including exercise targeted at the lumbar spine, pelvis, sacroiliac joint, and hip including a home exercise program. NOTE: if a patient is unable to complete physical therapy due to progressively worsening pain and disability, the case may be reviewed on an individual basis.

III. Fusion/stabilization of the sacroiliac joint for the treatment of back pain presumed to originate from the sacroiliac joint is considered **EXPERIMENTAL/INVESTIGATIVE** under all other conditions and with any other devices not listed above due to a lack of clinical evidence demonstrating an impact on improved health outcomes.

Documentation Submission

Documentation supporting the medical necessity criteria described in the policy must be included in the prior authorization, when prior authorization is required. The following must be submitted:

For ALL sacroiliac fusions approaches:

- Clinical notes describing the patient's diagnosis including clinical features requiring sacroiliac joint fusion * (e.g., sacral tumor, sacroiliac infection, trauma injury associated pelvic ring fracture); AND
- Surgical approach planned (e.g. open or minimally invasive).

For minimally invasive sacroiliac fusions ONLY:

- Clinical notes indicating ALL of the following:

1. History of moderate to severe pain of at least 6 months duration including date of onset: AND
2. Location and description of pain, and at least 3 provocative tests and results indicating pain arising from the sacroiliac joint; AND
3. Documentation of the absence of generalized pain behavior or generalized pain disorders; AND
4. Procedure report describing at least TWO SI joint anesthetic injections and follow-up reports on the percent change in the level of pain, for the duration of the specific local anesthetic used; AND
5. Trial of therapeutic injection (e.g. corticosteroid) including response; AND
6. Conservative non-surgical therapy:
   - Medical management with NSAIDs or other analgesics; AND
   - Physical therapy. If the patient is unable to complete PT due to progressively worsening symptoms of pain and disability, the case will be reviewed on an individual basis by an internal physician reviewer. Documentation must include clinical notes from the physical therapist describing the patient's inability to complete PT.

- Radiology reports (plain radiographs and a CT OR MRI) of ALL of the following:

1. Hip/pelvis
2. Lumbar spine
3. Sacroiliac joint

Botulinum Toxin, II-16

I. Abobotulinum Toxin A (Dysport®) Initial Review

MEDICAL AND BEHAVIORAL HEALTH POLICY UPDATE

Abobotulinum toxin A (Dysport®) may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when **ALL** of the following criteria are met:

- Diagnosis of ONE of the following:
  - Blepharospasm associated with dystonia, including benign essential blepharospasm or VII (facial) nerve disorders, in a patient 12 years of age or older; OR
  - Cervical dystonia (spasmodic torticollis; applicable whether congenital, due to child birth injury, or traumatic injury) **AND** BOTH of the following:
    1. Cervical dystonia must be associated with sustained head tilt or abnormal posturing with limited range of motion in the neck; AND
    2. History of recurrent involuntary contraction(s) of one or more of the muscles of the neck (e.g., sternocleidomastoid, splenius, trapezius, or posterior cervical muscles).

    OR
  - Hemifacial spasm; OR
  - Spasticity associated with ONE of the following conditions:
    1. Cerebral palsy; OR
    2. Stroke;

    OR
  - Spasticity of the lower limb; OR
  - Spasticity of the upper limb;

  AND
- No FDA labeled contraindications to therapy (see table 1 below); **AND**
- Dose is within the FDA labeled dose for labeled indications or supported in literature for additional indications (see table 2 below).

II. <u>Abobotulinum Toxin A (Dysport®) Renewal Review</u>

Abobotulinum toxin A (Dysport®) may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when **ALL** of the following criteria are met:

- Previously approved for therapy through the initial review process; **AND**
- Abobotulinum toxin A treatment has resulted in a reduction of symptom severity and/or frequency from baseline (prior to therapy); **AND**
- No FDA labeled contraindications to therapy (see table 1 below); **AND**
- Dose is within the FDA labeled dose for labeled indications or supported in literature for additional indications (see table 2 below).

III. <u>Incobotulinum Toxin A (Xeomin®) Initial Review</u>

Incobotulinum toxin A (Xeomin®) may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when **ALL** of the following criteria are met:

- Diagnosis of ONE of the following:
  - Blepharospasm associated with dystonia, including benign essential blepharospasm or VII (facial) nerve disorders, in a patient 18 years of age or older who was previously treated with onabotulinum toxin A (Botox®); OR
  - Cervical dystonia (spasmodic torticollis; applicable whether congenital, due to child birth injury, or traumatic injury) **AND** BOTH of the following:
    1. Cervical dystonia must be associated with sustained head tilt or abnormal posturing with limited range of motion in the neck; AND
    2. History of recurrent involuntary contraction(s) of one or more of the muscles of the neck (e.g., sternocleidomastoid, splenius, trapezius, or posterior cervical muscles);

    OR
  - Spasticity of the upper limb;

  AND
- No FDA labeled contraindications to therapy (see table 1 below); **AND**
- Dose is within the FDA labeled dose for labeled indications (see table 2 below).

IV. <u>Incobotulinum Toxin A (Xeomin®) Renewal Review</u>

Incobotulinum toxin A (Xeomin®) may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when **ALL** of the following criteria are met:

MEDICAL AND BEHAVIORAL HEALTH POLICY UPDATE

- Previously approved for therapy through the initial review process; **AND**
- Incobotulinum toxin A treatment has resulted in a reduction of symptom severity and/or frequency from baseline (prior to therapy); **AND**
- No FDA labeled contraindications to therapy (see table 1 below); **AND**
- Dose is within the FDA labeled dose for labeled indications (see table 2 below).

V. <u>Onabotulinum Toxin A (Botox®) Initial Review</u>

Onabotulinum toxin A (Botox®) may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when **ALL** of the following criteria are met:

- Diagnosis of ONE of the following:
  - Blepharospasm associated with dystonia, including benign essential blepharospasm or VII (facial) nerve disorders, in a patient 12 years of age or older; OR
  - Cervical dystonia (spasmodic torticollis; applicable whether congenital, due to child birth injury, or traumatic injury) **AND** BOTH of the following:
    1. Cervical dystonia must be associated with sustained head tilt or abnormal posturing with limited range of motion in the neck; AND
    2. History of recurrent involuntary contraction(s) of one or more of the muscles of the neck (e.g., sternocleidomastoid, splenius, trapezius, or posterior cervical muscles);

    OR
  - Chronic anal fissures **AND** the following:
    1. Failed one conventional therapy (e.g., bulking agents, sitz baths, laxatives, dietary changes, or 0.4% intra-anal nitroglycerin).

    OR
  - Chronic migraine headache in a patient 18 years of age or older **AND** ALL of the following:
    1. 15 or more headache days (headaches last 4 hours or more per day) per month for at least 3 months, with ≥50% of headaches being migraine/probable migraine; AND
    2. Evaluated for and does not have medication overuse headache; AND
    3. ONE of the following:
       - Failed at least two conventional agent prerequisites from two of the following classes: antidepressants (e.g., amitriptyline, venlafaxine), antihypertensives (e.g., propranolol, metoprolol, bisoprolol), and antiepileptics (e.g., topiramate, valproic acid); OR
       - Documented intolerance, FDA labeled contraindication, or hypersensitivity to at least two conventional agents from two of the following classes: antidepressants (e.g., amitriptyline, venlafaxine), antihypertensives (e.g., propranolol, metoprolol, bisoprolol), and antiepileptics (e.g., topiramate, valproic acid).

    OR
  - Dystonia associated with ONE of the following conditions:
    1. Focal upper limb dystonia (e.g., organic writer's cramp); OR
    2. Oromandibular dystonia (e.g., orofacial dyskinesia, jaw-closing dystonia, Meige syndrome); OR
    3. Laryngeal dystonia (adductor spasmodic dysphonia); OR
    4. Idiopathic (primary or genetic) torsion dystonia; OR
    5. Symptomatic (acquired) torsion dystonia;

    OR
  - Esophageal achalasia **AND** ONE of the following:
    1. Failed to respond to pneumatic dilation or myotomy; OR
    2. Not a good candidate for pneumatic dilation or myotomy;

    OR
  - Facial synkinesis; OR
  - Hemifacial spasm; OR
  - Overactive bladder **AND** ALL of the following:
    1. Symptoms of urge urinary incontinence, urgency, and frequency; AND
    2. Conservative therapies including bladder training, pelvic floor muscle exerecises, and fluid management have been inadequate; AND

MEDICAL AND BEHAVIORAL HEALTH POLICY UPDATE

3. ONE of the following:
   - Failed two conventional agent prerequisites, including one anticholinergic agent (e.g., oxybutynin, tolterodine, trospium, darifenacin, solifenacin, or fesoterodine) AND mirabegron; OR
   - Documented intolerance, FDA labeled contraindication, or hypersensitivity to at least one anticholinergic agent AND mirabegron.

OR

- Palmar or axillary hyperhidrosis **AND** ONE of the following:
  1. Failed aluminum chloride 20% solution; OR
  2. Documented intolerance, FDA labeled contraindication, or hypersensitivity to aluminum chloride 20% solution;

  OR
- Sialorrhea **AND** ONE of the following:
  1. Failed one conventional agent prerequisite (e.g., oral hyoscine, atropine drops, glycoprrolate, or amitriptyline); OR
  2. Documented intolerance, FDA labeled contraindication, or hypersensitivity to at least one conventional agent;

  OR
- Spasticity associated with ONE of the following conditions:
  1. Cerebral palsy; OR
  2. Stroke; OR
  3. Acquired spinal cord or traumatic brain injury; OR
  4. Hereditary spastic paraplegia; OR
  5. Spastic hemiplegia; OR
  6. Neuromyelitis optica; OR
  7. Multiple sclerosis; OR
  8. Schilder's disease;

  OR
- Spasticity of the lower limb; OR
- Spasticity of the upper limb; OR
- Strabismus, including persistent cranial VI nerve palsy of one month or longer, in a patient 12 years of age or older **AND** ALL of the following:
  1. Inadequate response to corrective lenses; AND
  2. Inadequate response to any other additional, patient appropriate, conservative corrective therapies (e.g., exercises); AND
  3. Good vision in both eyes; AND
  4. Eye movements are not restricted; AND
  5. Small to moderate angle of esotropia; AND
  6. Potential for the patient to experience binocular vision;

  OR
- Urinary incontinence due to detrusor overactivity associated with a neurologic condition (e.g., spinal cord injury, multiple sclerosis) **AND** ONE of the following:
  1. Failed two conventional agent prerequisites, including one anticholinergic agent (e.g., oxybutynin, tolterodine, trospium, darifenacin, solifenacin, or fesoterodine) AND mirabegron; OR
  2. Documented intolerance, FDA labeled contraindication, or hypersensitivity to at least one anticholinergic agent AND mirabegron;

AND

- No FDA labeled contraindications to therapy (see table 1 below); **AND**
- Dose is within the FDA labeled dose for labeled indications or supported in literature for additional indications (see table 2 below).

VI. <u>Onabotulinum Toxin A (Botox®) Renewal Review</u>

Onabotulinum toxin A (Botox®) may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when **ALL** of the following criteria are met:

- Previously approved for therapy through the initial review process; **AND**

MEDICAL AND BEHAVIORAL HEALTH POLICY UPDATE

- ONE of the following:
  - Diagnosis of chronic migraine headache **AND** ONE of the following:
    1. Onabotulinum toxin A treatment has resulted in a reduction of 7 or more headache days per month from baseline (prior to therapy); OR
    2. Onabotulinum toxin A treatment has resulted in a reduction of 100 or more headache hours per month from baseline (prior to therapy);

  OR
  - Another diagnosis AND onabotulinum toxin A treatment has resulted in a reduction of symptom severity and/or frequency from baseline (prior to therapy).

AND

- No FDA labeled contraindications to therapy (see table 1 below); **AND**
- Dose is within the FDA labeled dose for labeled indications or supported in literature for additional indication (see table 2 below).

VII. <u>Rimabotulinum Toxin B (Myobloc®) Initial Review</u>

Rimabotulinum toxin B (Myobloc®) may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when **ALL** of the following criteria are met:

- Diagnosis of ONE of the following:
  - Cervical dystonia (spasmodic torticollis; applicable whether congenital, due to child birth injury, or traumatic injury) **AND** BOTH of the following:
    1. Cervical dystonia must be associated with sustained head tilt or abnormal posturing with limited range of motion in the neck; AND
    2. History of recurrent involuntary contraction(s) of one or more of the muscles of the neck (e.g., sternocleidomastoid, splenius, trapezius, or posterior cervical muscles);

    OR
  - Sialorrhea **AND** ONE of the following:
    1. Failed one conventional agent prerequisite (e.g., oral hyoscine, atropine drops, glycoprrolate, or amitriptyline);

    OR
    2. Documented intolerance, FDA labeled contraindication, or hypersensitivity to at least one conventional agent;

AND

- No FDA labeled contraindications to therapy (see table 1 below); **AND**
- Dose is within the FDA labeled dose for labeled indications or supported in literature for additional indications (see table 2 below).

VIII. <u>Rimabotulinum Toxin B (Myobloc®) Renewal Review</u>

Rimabotulinum toxin B (Myobloc®) may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when **ALL** of the following criteria are met:

- Previously approved for therapy through the initial review process; **AND**
- Rimabotulinum toxin B treatment has resulted in a reduction of symptom severity and/or frequency from baseline (prior to therapy); AND
- No FDA labeled contraindications to therapy (see table 1 below); **AND**
- Dose is within the FDA labeled dose for labeled indications or supported in literature for additional indications (see table 2 below).

IX. <u>Cosmetic Indications</u>

The use of abobotulinum toxin A, incobotulinum toxin A, onabotulinum toxin A, or rimabotulinum toxin B is considered **COSMETIC** for the treatment of glabellar lines or wrinkles and other indications solely to improve appearance.

X. <u>Experimental/Investigative Indications</u>

All other uses of abobotulinum toxin A, incobotulinum toxin A, onabotulinum toxin A, or rimabotulinum toxin B are considered **EXPERIMENTAL/INVESTIGATIVE**, including but not limited to the following conditions, due to the lack of clinical evidence demonstrating an impact on improved health outcomes:

- Bell's palsy
- Benign prostatic hyperplasia

MEDICAL AND BEHAVIORAL HEALTH POLICY UPDATE

- Chronic low back pain
- Chronic motor tic disorder, and tics associated with Tourette syndrome (motor tics)
- Depressive disorders
- Detrusor sphincteric dyssynergia
- Essential tremor
- Facial wound healing
- Gastroparesis
- Headaches, except as noted above for chronic migraine headache
- Hirschsprung's disease
- Internal anal sphincter (IAS) achalasia
- Interstitial cystitis
- Joint pain
- Lateral epicondylitis
- Mechanical neck disorders
- Myofascial pain syndrome
- Neuropathic pain after neck dissection
- Pain after hemorrhoidectomy or lumpectomy
- Prevention of pain associated with breast reconstruction after mastectomy
- Raynaud's disease/Raynaud's phenomenon
- Tinnitus
- Trigeminal neuralgia

- **Table 1. FDA Labeled Contraindications**

AGENT	FDA LABELED CONTRAINDICATIONS
Abobotulinum toxin A (Dysport®)	Hypersensitivity; Allergy to cow's milk protein; Infection at the proposed injection site(s)
Incobotulinum toxin A (Xeomin®)	Hypersensitivity; Infection at the proposed injection sites
Onabotulinum toxin A (Botox®)	Hypersensitivity; Infection at the proposed injection site; For intradetrusor injections, urinary tract infection or urinary retention
Rimabotulinum toxin B (Myobloc®)	Hypersensitivity; Infection at the proposed injection site(s)

- **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.

MEDICAL AND BEHAVIORAL HEALTH POLICY UPDATE

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
Spasticity	400 units 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 months
Chronic anal fissure	25 units	100 billable units	Every 12 weeks
Facial synkinesis	100 units divided among affected muscles	100 billable units	Every 12 weeks
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

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 1,500 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
Spasticity in adults	1,500 units divided among affected muscles	300 billable units	Every 12 weeks
Spasticity in pediatric patients	30 units/kg or 1,000 units, whichever is lower, divided among affected muscles	200 billable units	Every 12 weeks
OFF-LABEL INDICATIONS			
Blepharospasm	240 units (120 units per eye)	60 billable units	Every 12 weeks
Hemifacial spasm	220 units divided among affected muscles	60 billable units	Every 12 weeks

MEDICAL AND BEHAVIORAL HEALTH POLICY UPDATE

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: 5,000 units divided among affected muscles Retreatment: 10,000 units divided among affected muscles	100 billable units	Every 12 weeks
OFF-LABEL INDICATIONS			
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

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

Initial Review
1. Clinical notes describing the diagnosis and clinical features of the diagnosis.
2. Clinical notes describing current and past treatments for the diagnosis, including response to the treatments. For onabotulinum toxin A (Botox®) requests to treat chronic migraine headache, clinical notes should include evaluation for potential medication overuse headache.
3. The dose being requested, including the patient's weight if the requested botulinum toxin agent and diagnosis require weight-based dosing. If the requested dose is higher or more frequent than the dosing guidelines provided 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 the requested botulinum toxin agent through the initial review process.
2. Documentation supporting reduction of symptom severity and/or frequency from baseline. For onabotulinum toxin A (Botox®) requests to treat chronic migraine headache, include information from the medical record and/or headache diary/log entries quantifying a reduction in migraine frequency or duration compared to baseline.
3. Clinical notes describing current and past treatments for the diagnosis, including response to the treatments.
4. The dose being requested, including the patient's weight if the requested botulinum toxin agent and diagnosis require weight-based dosing. If the requested dose is higher or more frequent than the dosing guidelines provided 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.

MEDICAL AND BEHAVIORAL HEALTH POLICY UPDATE

Policies inactivated

None

Policies reviewed

Policies reviewed with no changes in November or December 2017, or January 2018:

Actigraphy, II-127

Allogeneic Hematopoietic Stem-Cell Transplantation for Genetic Diseases and Acquired Anemias, II-129

Biofeedback, X-25

Bioimpedance Spectroscopy Devices for Detection and Management of Lymphedema, II-148

Bone Morphogenetic Protein (BMP), IV-85

Breast Implant, Removal or Replacement, IV-14

Durable Medical Equipment (DME), VII-07

Electromagnetic Navigational Bronchoscopy, II-132

Extended Hours Skilled Nursing in the Home for Patients with Medically Complex Conditions, IX-01

Functional Neuromuscular Electrical Stimulation Devices in the Home Setting, VII-11

General Anesthesia Services for Dental Procedures, II-166

Genetic Testing for Familial Alzheimer's Disease, VI-04

Genetic Testing for Statin-Induced Myopathy, VI-52

Hematopoietic Stem-Cell Transplantation for Autoimmune Disease, II-121

Hematopoietic Stem-Cell Transplantation for Hodgkin Lymphoma, II-135

Intradiscal Electrothermal Annuloplasty (IDET), Percutaneous Radiofrequency Annuloplasty (PIRFT), and Intradiscal Biacuplasty, IV-10

Intravenous Anesthetics for the Treatment of Chronic Pain, II-141

Intravitreal Angiogenesis Inhibitors for Treatment of Retinal and Choroidal Vascular Conditions, II-71

Laboratory and Genetic Testing for Use of 5-Fluorouracil (5-FU) in Patients with Cancer, VI-41

Left Atrial Appendage Occluder Devices, II-73

Magnetic Esophageal Ring for Treatment of Gastroesophageal Reflux Disease (GERD), IV-124

MRI-Guided High-Intensity Focused Ultrasound Ablation of Uterine Fibroids and Other Tumors, IV-119

Nonpharmacologic Treatment of Acne, II-33

Nonpharmacologic Treatment of Rosacea, II-08

Optical Coherence Tomography of the Anterior Eye Segment, II-79

Ovarian and Internal Iliac Vein Embolization as a Treatment for Pelvic Congestion Syndrome, V-26

PathFinderTG Molecular Testing, VI-15

Percutaneous Electrical Nerve Stimulation (PENS) or Percutaneous Neuromodulation Therapy (PNT), II-81

MEDICAL AND BEHAVIORAL HEALTH POLICY UPDATE

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

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

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

03/18

BlueCross BlueShield Minnesota

Blue Cross® and Blue Shield® of Minnesota and Blue Plus® are nonprofit independent licensees of the Blue Cross and Blue Shield Association

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