Provider Press

Provider information

December 2017 / Vol. 22, No. 4

BlueCross BlueShield Minnesota

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 will be updated monthly as new high impact issues are identified and as existing issue statuses change.

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.

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 September to November 2017 that are available online at **providers.bluecrossmn.com**. As a reminder, Bulletins are mailed to all participating providers affected by the information. Quick Points are available only on our website unless noted otherwise in the bottom left corner of the publication.

QUICK POINTS	TITLE
QP24-17	Interpreter Services
QP25-17	Pharmacy Benefit Exclusion
QP26-17	Reporting Healthcare Common Procedure Coding System (HCPCS) on Hospital Outpatient Claims
QP27-17	Viewing Chiropractic Benefits
QP28-17	Notification of Provider Submitted Appeals
QP29-17	Pharmacy Benefit Exclusion for Kymriah
QP30-17	Disclosure of Ownership Form
QP31-17	New Pre-Authorization Form for Infliximab
QP32-17	Pharmacy Benefit Update – Dispense as Written (DAW 1) Clarification
QP33-17	ICD-10 Grouper Updates
QP34-17	New Pre-Authorization Form for Immunoglobulin Therapy
QP35-17	Implementation of New Utilization Management Platform
QP36-17	Pharmacy Benefit Exclusion for Yescarta
QP37-17	APR-DRG and EAPG Grouper Updates
QP38-17	Delay of Second Phase Transition with Magellan
BULLETINS	**TITLE**
P48-17	EquiClaim to Perform Focused and Limited Hospital Bill Validation Services
P49-17	Two New Medicare Advantage Prescription Drug Products in 2018
P50-17	Provider Data Accuracy and Identified Lack of Claim Submissions
P51-17	ACO Product and Network Name Changes
P51R1-17	Revised: ACO Product and Network Name Changes
P52-17	New Drug-Related Prior Authorization with Quantity Limit Criteria: Parathroid Hormone Analog for Osteoporosis
P53-17	New Drug-Related Prior Authorization Requirements for Radicava and Brineura
P54-17	Clarification to Commercial Prior Authorization Requirements for Early Intensive Behavioral Intervention
P55-17	Prior Authorization Requirement for Orthognathic Surgery
P56-17	Implementation of Medical Policy Drug Exclusions List
P57-17	Addition of Drugs to the Self-Administered Oncology Prior Authorization with Quantity Limit Program

(continued on next page)

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

PUBLICATIONS AVAILABLE ONLINE (continued from previous page)

BULLETINS	TITLE
P58-17	New Drug-Related Prior Authorization with Quantity Limit Criteria: Topical Doxepin
P59-17	Government Program Subscribers Prior Authorization Requirement for Spinal Fusion: Lumbar
P60-17	2018 Renewal Changes Summary for Institutional Providers
P61-17	FQHC/RHC Clinics Providing Interpreter Services for MHCP Subscribers
P62-17	Addition of Drug to the Parathyroid Hormone Analog for Osteoporosis PA with Quantity Limit Program
P63-17	New Drug-Related Prior Authorization with Quantity Limit Criteria: Otezla
P64-17	New Drug-Related Prior Authorization with Quantity Limit Criteria: Biologic Immunomodulators
P65-17	Clarification to the Commercial PA Requirements for Biologic Immunomodulators
P66-17	Clarification to Mid-Level Practitioners Definitions
P67-17	PA Requirements for New MAPD Products in 2018
P68-17	Reimbursement Rate Changes for Psychotherapy Codes 90837 and 90838
P69-17	New Reimbursement Policy for Facility IP Short Stay
P70-17	2018 Blue Plus PCC Provider Service Agreement

FYI

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

Over the past few months, Blue Cross 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.

2018 HOLIDAY SCHEDULE

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

Monday, January 1

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

PROVIDER MANUAL UPDATES

The following is a list of Blue Cross provider manuals that have been updated from September to November 2017. As a reminder, provider manuals are available online at **providers.bluecrossmn.com**. To view the manuals, select "Forms & publications," then "manuals." Updates to the manuals are documented in the "Summary of changes" section of the online manuals.

MANUAL NAME: CHAPTER NUMBER AND TITLE	CHANGE
Provider Policy and Procedure Manual: Chapter 2, Agreements	Content change to Required Notification
Provider Policy and Procedure Manual: Chapter 4, Medical Management	Updates to the following: • Introduction • Medical Management Medical and Behavioral Health Clinical Staff • Medical Policy and Behavioral Health Policy • Pre-Certification/Authorization /Notification Overview • Focused Utilization Review Overview • GA Modifiers • Referral to Commercial Case Management • Medical and Behavioral Health Policy Development • Pre-Authorization & Notification Request Forms
Provider Policy and Procedure Manual: Chapter 9, Reimbursement/ Reconciliation	Updates to the following: • Payment Methodology • Settlement for Hospitals
Provider Policy and Procedure Manual Chapter 11, Coding Policies and Guidelines, Introduction section	Content change to Preventive Care Services
Blue Plus Manual: Chapter 3, Government Programs	Updates to the following: • Provider Enrollment Requirements • Maternity Management Program • Minnesota Pregnancy Assessment Form
Blue Plus Manual: Chapter 4, Referrals	Updated Managed Care Referrals form

QUALITY IMPROVEMENT

HELPING ADOLESCENTS TRANSITION TO ADULT HEALTH CARE

Changing doctors is never easy especially for a teenager new to advocating for their own health care. If there is a chronic illness like diabetes or cystic fibrosis, it can be even more challenging to make the transition. Ideally, children should transition from pediatric to adult-oriented health care between the ages of 18 and 21 years.

For adolescents seeing a pediatrician, the transition will involve choosing a new physician, transferring medical records, and communicating treatment histories and insurance information. Although adolescents seeing a family physician may stay in the same practice, they may still need to transfer some aspects of their care.
It's important you have these conversations with your patients.

Blue Cross Customer Service can help find adult primary care practitioners who can best serve their medical needs. Customer Service can also assist pregnant adolescents in their transition from pediatrics to an adult primary care practitioner, OB/GYN, family practitioner or internist.

For assistance in medical care transitions, please direct your patients to contact Blue Cross Customer Service at the phone number on the back of their member ID card. The online "Find a Doctor" tool can also help them easily find a provider. Please direct your patients to visit **bluecrossmnonline.com** and sign in, then select "Find a Doctor."

BLUE PLUS MEDICAL RECORD DOCUMENTATION REVIEW ADVANCE DIRECTIVES

An advance directive provides an opportunity for adults of any age to make their health care wishes known if or when a potential life-threatening event occurs and they are unable to verbalize their wishes at the time of the event.

A representative sample review of our Blue Plus members' medical records for dates of service in 2016 has been completed and the results are below. We encourage providers to discuss the benefits of completing an advance directive with all our adult members.

	Total Members in Sample	Advanced Directive Present or Discussed	Change from 2016 Audit
Medicare/Medicaid Eligible (MSHO)	411	369 (90%)	Increase of 24% from 66%
Medicaid	543	17 (3%)	Decrease of 1% from 4%
Total	954	386 (40%)	Increase of 10% from 30%

These reviews were completed to encourage providers to open the door to meaningful discussions with their patients on important issues. If you have any questions concerning this article please send an email to the Quality and Medical Management Department via amy.johnson@bluecrossmn.com.

QUALITY IMPROVEMENT

HEDIS® SEASON IS HERE!

The Healthcare Effectiveness Data and Information Set (HEDIS®) medical record abstraction process is taking place from February 9 through May 4, 2018.

What is HEDIS®: Healthcare Effectiveness Data and Information Set?

HEDIS® is a government mandated set of measurements used to evaluate the health, and quality of service provided to our members.

Why is HEDIS® important?

- Results provide comparative data that consumers can use to make choices as to what health plan and which provider(s) they will access to meet their healthcare needs.
- Reporting HEDIS® results annually is a federal and state contractual requirement as well as a National Committee for Quality Assurance (NCQA) accreditation requirement.
- Many employer groups consider HEDIS® scores when choosing a Health Plan to offer to their employees.

Blue Cross and Blue Shield of Minnesota (Blue Cross) manages and staffs the Medical Record Review (MRR) project on an internal basis. The MRR project involves reviewing our members' medical records either at the clinic site or remotely from our office. If a site has less than 20 records that need to be reviewed, or if the site prefers, the requested medical records can be sent by secure electronic FTP transfer, faxed, or mailed to the plan.

During on-site visits, the abstractor is required to attach relevant copies of the medical record to the review software to validate their findings. In lieu of making paper copies, we encourage you to allow the abstractor to upload electronic copies to their encrypted USB device.

If you would like assistance setting up a secure electronic transfer account or EMR link access, please contact Heidi Nielsen by email at heidi.nielsen@bluecrossmn.com or by phone at **(651) 662-8909**.

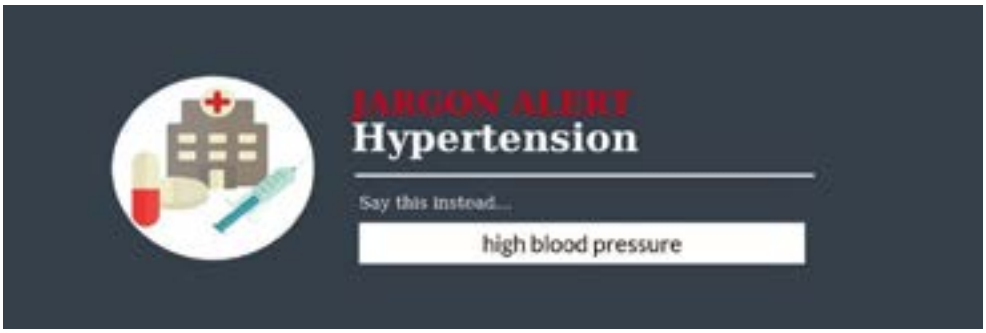
Thank you for accommodating our abstractors as we complete the review of over 20,000 medical records throughout the state of Minnesota. Blue Cross is committed to providing accurate HEDIS® results with the least amount of disruption to your clinic staff as possible. For questions or concerns please contact Heidi Nielsen, RN, BSN, MBA, Manager HEDIS and Health Measures Program by email at heidi.nielsen@bluecrossmn.com or by phone at **(651) 662-8909**.

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

CUT THE JARGON. USE PLAIN LANGUAGE!



Obtaining health care hinges on having the necessary skills to read, fill out and understand medical and health insurance forms. Patients also need to communicate with health care providers and follow basic instructions and medical advice. However, health systems, professionals and insurance plans often present information or resources in ways that are difficult for most people to understand. According to the National Assessment of Adult Literacy conducted by the U.S. Department of Education, nearly 9 out of 10 Americans have difficulty using the everyday health information that is routinely available. Resources provided on the internet or by health systems are dense, technical and use jargon-filled language. As a result, the health care system itself can pose a serious barrier to appropriate care.

Patients have the right to understand health care information that is necessary for them to safely care for themselves, and to choose among available alternatives. The U.S. Department of Health and Human Services states that health care professionals have a duty to provide information in simple, clear, and plain language, and to check that patients have understood the information before ending the conversation.

Plain language is a health literacy tool that allows people to find what they need, understand what they find, and act appropriately on that understanding after the first time they hear or read it. Using plain language means health care systems and staff eliminate jargon words and replace them with common words, speak in an active voice, use short sentences, and organize points logically to ensure better understanding.

"If you can't explain it simply, you don't understand it well enough."
- Albert Einstein

The Minnesota Health Literacy Partnership has developed a new campaign to help you and your organization promote plain language. Consider implementing the campaign in 2018.

Plain language campaign materials are available on the Partnership's website http://healthliteracymn.org/

QUALITY IMPROVEMENT

USING EHRs TO IMPROVE CARE COORDINATION

According to the Agency for Healthcare Research and Quality, care coordination involves "deliberately organizing patient care activities and sharing information among all of the participants concerned with a patient's care to achieve safer and more effective care. This means that the patient's needs and preferences are known ahead of time and communicated at the right time to the right people, and that this information is used to provide safe, appropriate, and effective care to the patient."

Electronic Health Records (EHRs) can help clinical staff share important information with the click of a button. Features like instant messaging, e-mail, and electronic tasking (electronic notification of tasks that need to be performed) help prevent patient care needs from "falling through the cracks" while improving efficiency. Tools such as these help to facilitate care coordination within a practice by making data available at a patient's visit.

Even so, barriers still exist as not all EHRs communicate with each other. The National Quality Forum (NQF) defined interoperability as "the ability of a system to exchange electronic health information with and use electronic health information from other systems without special effort on the part of the user." **Interoperability is more than EHR to EHR**. NQF noted, "Interoperability focuses equally on ensuring that patients, their families, and caregivers have full access to view, download, and exchange their health data, contribute patient-generated data to providers' EHRs, and arrange for the inclusion and exchange of data generated by multiple healthcare providers."

Research suggests that enhancing EHRs and clinical information exchanges can facilitate safer and efficient transitions of care. Transitions of care can be challenging even with the help of EHRs to exchange information between care teams. Focusing on improving sharing of information, especially during care transitions for high-risk patients can reduce readmission rates, enhance patient experience of care and improve overall health outcomes. A model that has been used to help identify these high-risk patients is the LACE model (length of stay, acuity of admission, comorbidities, and ED use). Higher-risk patients are more complex, more likely to be confused by medication and self-care regimens and often uncertain about timing for follow-up appointments.

EHR optimization is an integral part of leveraging the technology to improve clinical workflow. Simply because adopting and implementing an EHR does not mean the facility/practice will automatically function more effectively. Understanding how to improve is key. In improving clinical workflow through EHR best practices, healthcare organizations may be able to increase value, making them more viable in the changing healthcare landscape.

QUALITY IMPROVEMENT

REDUCING RACIAL AND ETHNIC DISPARITIES IN DEPRESSION MANAGEMENT AND IMPROVING DEPRESSION MANAGEMENT IN SENIORS

Blue Plus has been engaged in a performance improvement project aimed to reduce disparities and improve antidepressant medication management for our public assistance program members since 2015. In 2016, Blue Plus added a sister project aimed at improving depression management in our senior population. Despite efforts to improve medication adherence in the continuation phase of antidepressant management, there have been minimal changes for either of these populations.

Research suggests that basic health education about depression and antidepressants can improve treatment adherence. The collaborative of health plans (Blue Plus, HealthPartners, Medica, Hennepin Health and UCare) has and will continue to sponsor member, provider, and community educational events to raise awareness of the significance that major depression contributes to the health and quality of life for all members. Cultural beliefs and practices often play a large role in how patients approach both their depression diagnosis and their adherence to treatment.

A valuable toolkit and informative webinars are available for practitioners and specialists who treat people with major depression. These resources compile information on treatment that emphasizes racial and cultural perspectives as well as depression management in the senior population. Please follow this link to the Stratis Health website for easy access to the toolkit and recorded webinars at http://www.stratishealth.org/pip/antidepressant.html.

You can also download the Provider Toolkit on the Provider Tools and Resources page of the Blue Cross website at https://www.bluecrossmn.com/healthy/public/personal/home/providers/tools-resources/.

Thank you for your efforts supporting adherence to treatment, and helping to offer hope for a better quality of life and increase community awareness. If you have any questions concerning these projects please contact Sheila Dalen, RN, Sr. Project Manager, Healthcare Quality at Sheila.Dalen@bluecrossmn.com.

UTILIZATION MANAGEMENT STATEMENT

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

QUALITY IMPROVEMENT

CONDITION / DISEASE MANAGEMENT PROGRAMS

Medical Management includes a process for Condition/Disease Management (C/DM). This program is intended to increase advocacy, support and education for our members. C/DM is a multidisciplinary, continuum-based approach to health care delivery that proactively identifies populations who have or are at risk for chronic medical and behavioral health conditions. C/DM supports the practitioner-patient relationship and plan of care, emphasizes the prevention of exacerbation and complications using cost-effective, evidence-based practice guidelines and patient empowerment strategies such as education and self-management.

The process of C/DM evaluates clinical, social/humanistic and economic outcomes with the goal of improving overall health of the whole person. Members who receive C/DM services receive support from a dedicated clinician who assists in facilitating the health of the whole person, not just their individual condition. C/DM clinicians may call the provider when the subscriber triggers for C/DM and meets our provider call criteria. Provider call criteria may include:

- Concerns about member's compliance with the treatment plan
- Lack of clarity about member's treatment plan

Providers may also receive a letter including the member's goals and/or gap in care to inform the provider on what Blue Cross is working on with the member to advance their health care needs. Providers may make a referral by contacting the Nurse Guide Team at 1-866-489-6947 (for Commercial members) or 1-800-711-9868 (for Government Programs members). Please contact Government Programs Case Management when you have a patient who may need additional supportive services, such as a Restricted Recipient referral. Blue Cross looks forward to working with its member's Health Care Practitioners to make a healthy difference in the health of its members.

In addition to Condition/Disease Management, Wellness coaching is offered as part of Care Management. Wellness coaching helps members make lifestyle changes that can enhance their quality of life and reduce the risk of a serious health crisis in the future. Wellness topics include weight management, nutrition, stress management, physical activity, tobacco cessation, and sleep. Coaches work with members to set attainable goals and overcome barriers to achieving them. The process of wellness coaching evaluates the individual holistically with the goal of improving overall health and well-being. Members who receive wellness coaching services receive support from a dedicated coach, however may work with a wellness coach while also addressing chronic or acute issues through C/DM. Coaches encourage members to share their health goals with providers and seek additional information on resources such as nicotine replacement therapy as needed.

Additional information regarding our Condition/Disease Management program can be found in Chapter 4 of the Provider Policy and Procedure Manual. To access the manual, go to providers.bluecrossmn.com and select "Forms and Publications" then "Manuals."

For questions about Condition/Disease Management, Wellness Coaching or if you would like to determine program eligibility for one of your patients, please contact provider services at **(651) 662-5200 or 1-800-262-0820.**

Please note: services are offered to members; however, participation is optional. Member eligibility for condition/disease management is determined by their Benefit Plan.

PHARMACY SECTION

PHARMACY UPDATES FOR QUARTER 4, 2017

Pharmacy Drug Formulary Changes

As part of our continued efforts to evaluate and update our formularies, Blue Cross and Blue Shield of Minnesota and Blue Plus (Blue Cross) evaluate drugs on a regular basis. This evaluation includes a thorough review of clinical information, including safety information and utilization. Based on our most recent review, the following BRAND name drugs have been added to or removed from drug formularies **effective October 1, 2017.**

ADDITIONS TO FlexRx FORMULARY	ADDITIONS TO GenRx FORMULARY
ALUNBRIG	ALUNBRIG
CIALIS	FLUTICASONE PROPIONATE/SALMETEROL AER POWDER
FLUTICASONE PROPIONATE/SALMETEROL AER POWDER	IMFINZI
IMFINZI	ISENTRESS HD
ISENTRESS HD	KISQALI FEMARA PACK
KISQALI FEMARA PACK	RYDAPT
RYDAPT	SELZENTRY ORAL SOLN
SELZENTRY ORAL SOLN	SULFADIAZINE
SULFADIAZINE	TEPADINA
TEPADINA	TYMLOS
TYMLOS	XATMEP
WELCHOL	ZEJULA
XATMEP	ZENPEP
ZEJULA	ZERIT ORAL SOLN
ZENPEP	
ZERIT ORAL SOLN	

REMOVALS FROM FlexRx FORMULARY	REMOVALS FROM GenRx FORMULARY
AGGRENOX	BUSULFEX
BUSULFEX	KALETRA SOLN 400-100 MG/5ML (80-20 MG/ML)
FML OPHTH OINT	SEROQUEL XR 50 MG, 150 MG, 200 MG, 300 MG
KALETRA SOLN 400-100 MG/5ML (80-20 MG/ML)	STELARA IV SOLN 130 MG/26ML (5 MG/ML)
SEROQUEL XR 50 MG, 150 MG, 200 MG, 400 MG	
STELARA IV SOLN 130 MG/26ML (5 MG/ML)	
TOBREX OPHTH OINT	
TENCON	
VAGIFEM	
ZETIA	

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PHARMACY SECTION

PHARMACY UPDATES FOR QUARTER 4, 2017 (cont. from previous page)

The complete list of formulary changes for the following formularies can be found at:
FlexRx Formulary –
https://www.myprime.com/content/dam/prime/memberportal/forms/2017/FullyQualified/Other/ALL/BCBSMN/COMMERCIAL/MNFLEXRX/MN_FlexRx_Alpha_Drug_List.pdf

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

Information on additional formularies can be found at:

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

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

PHARMACY BENEFIT EXCLUSION

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

DRUG NAME	Medical Prior Authorization Required	Pharmacy Benefit Exclusion Effective Date
KYMRIAH SUSPENSION for IV INFUSION	To be determined	09/22/2017
ACTEMRA IV INJ 80 MG/4ML	YES	10/01/2017
ACTEMRA IV INJ 200 MG/10ML	YES	
ACTEMRA IV INJ 400 MG/20ML	YES	
ORENCIA IV SOLN 250 MG	YES	
STELARA IV SOLN 130 MG/26ML (5 MG/ML)	YES	

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PHARMACY SECTION

UDPATE FOR DIABETES TESTING SUPPLIES FOR THE COMMERCIAL LINES OF BUSINESS

Starting **January 1, 2018**, the preferred glucose test strips for the Commercial lines of business will be the Ascensia Diabetes Care portfolio products. Other glucose testing supplies will be excluded from the pharmacy benefit for the Commercial lines of business. Subscribers must use the covered alternative test strips that are covered under the pharmacy benefit plan or pay full price for continued use of their current use of their test strips.

Affected subscribers who recently received a non-preferred test strip brand will be notified and directed to contact their providers to discuss the preferred glucose test stripe choices. At no charge, affected subscribers are being offered a choice of a covered blood glucose monitoring system for a limited time.
A summary of the excluded test strips and preferred covered alternative test strips can be found below.

Excluded Test Strips	Covered Alternative Test Strips
All other glucose test strip manufacturers (except Ascensia/Bayer)* e.g. ACCU-CHEK, ADVOCATE, ASSURE, CLEVER-CHEK, EASYTALK, EASY TOUCH, EMBRACE, FREESTYLE, GLUCOCARD, INFINITY, ONETOUCH. PRECISION, PRODIGY, RELION, TRUE METRIX, TRUETEST, UNISTRIP, WAVESENSE	Ascensia (formerly known as Bayer) CONTOUR®NEXT CONTOUR®NEXT EZ CONTOUR®NEXT ONE

**Not a comprehensive list of all available excluded glucose strips*

PHARMACY UTILIZATION MANAGEMENT (UM) UPDATE

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

Changes to Existing UM Programs Effective 7/1/17

BRAND NAME (generic name - if available)	Requirement		
KEVZARA		QL	ST

Changes to Existing Utilization Management Program, Effective 8/15/17

BRAND NAME (generic name - if available)	Requirement		
VOSEVI	PA		

Changes to Existing Utilization Management Programs, Effective 8/29/17

BRAND NAME (generic name - if available)	Requirement		
MAVYRET	PA		

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PHARMACY SECTION

PHARMACY UTILIZATION MANAGEMENT (UM) UPDATE (continued)

New Utilization Management Program Effective 9/01/17

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

Changes to Existing Utilization Management Programs, Effective 10/1/17

BRAND NAME (generic name - if available)	Requirement		
ACETAMINOPHEN/CAFFEINE/DIHYDROCODEINE tabs		QL	
AFREZZA 12 units/cartridge	PA	QL	
AFREZZA 8 units/cartridge	PA	QL	
AIRDUO RESPICLIC		QL	
ALUNBRIG	PA	QL	
ARISTADA		QL	ST
ESBRIET 267 mg caps	PA	QL	
ESBRIET 267 mg tabs	PA	QL	
ESBRIET 801 mg	PA	QL	
FLUTICASONE PROPIONATE/SALMETEROL		QL	
ISENTRESS HD		QL	
KISQALI FEMARA PACK	PA	QL	
MORPHABOND ER		QL	
MYDAYIS		QL	
NERLYNX	PA	QL	
ORENCIA 50 mg/0.4 mL, 87.5 mg/0.7 mL		QL	ST
RUBRACA 250 mg	PA	QL	
RYDAPT	PA	QL	
SELZENTRY solution		QL	
SILIQ		QL	ST
VIIBRYD starter kit		QL	ST
ZEJULA	PA	QL	
ZYTIGA 500 mg	PA	QL	

New Utilization Management Program Effective 10/01/17

Targeted Drugs - targeted only when there is a concurrent claim for a buprenorphine or buprenorphine/naloxone containing product	Requirement		
Opioids, Opioid combinations, tramadol, tramadol ER, Conzip, Nucynta ER, Ryzolt, Ultram ER	PA	QL**	

PA=Prior Authorization; QL=Quantity Limit; ST=Step Therapy
**QL currently in place

Effective October 1, 2017

- The Inhaled Corticosteroid (ICS) and Long-Acting Beta Agonist (LABA) Combinations Prior Authorization with Quantity Limit Program was implemented for the Medicaid lines of business.

(continued on next page)

PHARMACY SECTION

PHARMACY UTILIZATION MANAGEMENT (UM) UPDATE (continued)

Effective December 1, 2017

- The Forteo (teriparatide) Prior Authorization with Quantity Limit Program will be renamed to Parathyroid Hormone Analog for Osteoporosis Prior Authorization with Quantity Limit Program and will include the addition of Tymlos (abaloparatide) as a target for the Medicaid lines of business.

Effective January 1, 2018

- The Doxepin Prior Authorization with Quantity Limit Program will be implemented for the Commercial and Medicaid lines of business.
- The Oral NSAID (Non-Steroidal Anti-Inflammatory Drugs) Step Therapy Program will be implemented for the Commercial lines of business.
- The Forteo (teriparatide) Prior Authorization Program will be renamed to Parathyroid Hormone Analog for Osteoporosis Prior Authorization with Quantity Limit Program and will include the addition of Tymlos (abaloparatide) as a preferred target for the Commercial lines of business.
- The Glucose Test Strips/Disks/Meters Step Therapy Program will be discontinued for the Commercial lines of business, but the Glucose Test Strips/Disks/Meters Quantity Limit Program will remain in place.
- The Biologic Immunomodulators Step Therapy Program will transition to a Prior Authorization Program for the Commercial and Medicaid lines of business. Subscribers who are currently on a biologic immunomodulator agent as of January 1, 2018 will be allowed continuation of therapy for the same agent. Quantity limits will continue to apply.
- The Otezla (apremilast) Step Therapy Program will transition to a Prior Authorization Program for the Commercial and Medicaid lines of business. Subscribers who are currently on Otezla as of January 1, 2018 will be allowed continuation of therapy with Otezla. Quantity limits will continue to apply.

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

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

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

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

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PHARMACY SECTION

PHARMACY UTILIZATION MANAGEMENT (UM) UPDATE (continued)

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

ALLIANCERX WALGREENS PRIME UPDATE

Recently Prime Therapeutics LLC and Walgreens formed a collaboration to deliver central specialty pharmacy and mail order services. Subscribers will begin to see the AllianceRx Walgreens Prime name and logo on prescriptions and documentation based on the following timelines.

- Specialty – AllianceRx Walgreens Prime brand will be effective **January 1, 2018**
- Mail – AllianceRx Walgreens Prime brand will be effective **March 31, 2018**

MEDICAL DRUG EXCLUSIONS LIST

As stewards of healthcare expenditures for our subscribers, Blue Cross is charged with ensuring the highest quality, evidence based care for our members, while driving quality, safety, and affordability. To accomplish this, when multiple versions of the same drug exist, Blue Cross may decide to cover only certain versions of a drug when they are a safe, effective alternative to other brands that may be more expensive. In December, Blue Cross will introduce a new Medical Drug Exclusion List that identifies preferred drug brands for members that meet medical necessity guidelines for Infliximab and Hyaluronan Injections. For more information on the preferred drug brands and which health plan products will be impacted, see the Provider Bulletin P56-17. You can find this bulletin at the following location:
https://intranet.bcbsmn.com/cs/partition3/groups/bcbsmn/@mybc_documents/documents/mybc_documents/p11ga_16244386.pdf

ADDITIONAL RESOURCES

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

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

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

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

MEDICAL AND BEHAVIORAL HEALTH POLICY UPDATE

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

For out-of-area Blue Plan patients:
Under "Medical Policy and Pre-Certification/Authorization Router," click Go. You will be taken to the page where you select either medical policy or pre-certification/prior authorization and enter the patient's three-letter alpha prefix as found on their member identification card, and click Go. Once you accept the requirements, you will be routed to the patient's home plan where you can access medical policy or pre-certification/pre-authorization information.

For local Blue Cross and Blue Shield of Minnesota plan patients:
Select "Medical policy" (under Tools & Resources), and then read and accept the Blue Cross Medical Policy Statement. You have now navigated to the Blue Cross and Blue Shield of Minnesota Medical Policy web page.

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

- The "Upcoming Medical Policy Notifications" section lists new or revised policies approved by the Blue Cross Medical and Behavioral Health Policy Committee and are effective **50** days from the date they were posted.
- The "Medical and Behavioral Health Policies" section lists all policies effective at the time of your inquiry.
    - Note: On November 1, 2015, Blue Cross and Blue Shield of Minnesota began migrating subscribers from our legacy operating system to our new operating system. Subscriber migration will continue over the next few years with the goal of having all subscribers migrated to the new operating system by the end of 2018. During the migration, there will be two sets of medical policies: one for migrated subscribers (new operating system) and one for non-migrated subscribers (legacy operating system). Please follow the instructions on the web page to select the applicable medical policy based upon the member's migration status. This change was previously communicated in the Provider Bulletin entitled "Medical Policies on the New Operating System Effective November 1, 2015" (P-32-15), which published September 9, 2015.

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

- The Pre-Certification/Pre-Authorization lists identify various services, procedures, prescription drugs, and medical devices that require pre-certification/pre-authorization. These lists are not exclusive to medical policy services only; they encompass other services that are subject to pre-certification/pre-authorization requirements.

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

MEDICAL AND BEHAVIORAL HEALTH POLICY UPDATE

MEDICAL AND BEHAVIORAL HEALTH POLICY ACTIVITY

Policies Effective: October 16, 2017 Notification Posted: August 25, 2017

Policies developed

Trigger Point Injections, II-175

I. Initial Treatment

Trigger point injections with anesthetic and/or corticosteroid may be considered **MEDICALLY NECESSARY AND APPROPRIATE** for the treatment of myofascial pain syndrome when **ALL** of the following criteria are met:

- There is a regional pain complaint in the expected distribution of referral pain from a trigger point; AND
- Spot tenderness in a palpable taut band in a muscle; AND
- Restricted range of motion; AND
- Trial of conservative therapy (e.g., physical therapy, active exercises, ultrasound, heating or cooling, massage, activity modification, or pharmacotherapy) or is not feasible, AND
- As a component of a multi-modal pain management plan (e.g. pharmacologic treatment, behavioral therapy, physical therapy).

II. Repeated Treatment

Repeated trigger point injections with anesthetic and/or corticosteroid may be considered **MEDICALLY NECESSARY AND APPROPRIATE** for the treatment of myofascial pain syndrome when ALL of the following criteria are met:

- All of the criteria for trigger point injections listed above are met; AND
- Injections are given in the same muscle band as the previous course of treatment; AND
- Beneficial clinical response (e.g., improvement in pain, increased mobilization and function) was achieved with the previous course of treatment; AND
- No more than 6 injections are given in a single muscle band in a 12-month period.

III. Trigger point injections are considered **EXPERIMENTAL/INVESTIGATIVE** for all other indications, including but not limited to the following, due to a lack of clinical evidence demonstrating an impact on improved health outcomes:

- Myofascial pain syndrome when the above criteria are not met;
- If the **sole indication** is ANY of the following conditions:
  - Complex regional pain syndrome; OR
  - Abdominal wall pain; OR
  - Fibromyalgia.

IV. Ultrasound and other imaging guidance of trigger point injections is considered **EXPERIMENTAL/INVESTIGATIVE** due to lack of evidence of improved clinical outcomes.

Cerliponase Alfa, II-176

I. Initial Review

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

- The patient has a diagnosis of late infantile neuronal ceroid lipofuscinosis type 2 (CLN2), including **ONE or more** of the following:

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- Laboratory testing confirms deficiency in TPP1 enzyme activity (NOTE: laboratory documentation must be provided); OR
- Genetic testing confirms mutation in the TPP1 gene (NOTE: laboratory documentation must be provided).

AND

- The patient is 3 years of age or older; **AND**
- The patient is symptomatic (e.g., unprovoked seizures, ataxia, language/development delay); **AND**
- The patient is ambulatory; **AND**
- Cerliponase alfa is prescribed by or in consultation with a neurologist; **AND**
- Cerliponase alfa will be administered by, or under the direction of a physician knowledgeable in intraventricular administration; **AND**
- The patient does not have any FDA labeled contraindications to therapy (see table 1 below); **AND**
- The dose is within the FDA labeled dose (see table 2 below).

II. Renewal Review

Cerliponase alfa may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when **ALL** 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., improvement in motor function or stabilization of motor function loss); **AND**
- The patient is ambulatory; **AND**
- Cerliponase alfa is prescribed by or in consultation with a neurologist; **AND**
- Cerliponase alfa will be administered by, or under the direction of a physician knowledgeable in intraventricular administration; **AND**
- The patient does not have any FDA labeled contraindications to therapy (see table 1 below); **AND**
- The dose is within the FDA labeled dose (see table 2 below).

III. All other uses of cerliponase alfa are considered **EXPERIMENTAL/INVESTIGATIVE**, including but not limited to treatment of other (non-CLN2) subtypes of neuronal ceroid lipofuscinoses/Batten disease, due to the lack of clinical evidence demonstrating an impact on improved health outcomes.

- **Table 1. FDA Labeled Contraindications**

AGENT	FDA LABELED CONTRAINDICATIONS
Cerliponase alfa	Acute intraventricular access device-related complications (e.g., leakage, device failure, or device-related infection) Patients with ventriculoperitoneal shunts

- **Table 2. Dosing**

FDA LABELED INDICATIONS	DOSING
Late infantile neuronal ceroid lipofuscinosis type 2 (CLN2)	300 mg administered once every other week as an intraventricular infusion followed by infusion of intraventricular electrolytes over approximately 4.5 hours

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Documentation Submission

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

Initial Review

1. Clinical notes describing the diagnosis and clinical features of the diagnosis.
2. Laboratory documentation confirming diagnosis of CLN2, including one or more of the following:
   - Deficiency in TPP1 enzyme activity; or
   - Mutation in the *TPP1 gene*.
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 cerliponase alfa through the initial review process.
2. Documentation supporting positive clinical response (e.g., improvement in motor function or stabilization of motor function loss).
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.

Policies revised

Bariatric Surgery, IV-19

I. Patient Selection Criteria for Adults and Adolescents

The surgical treatment of morbid obesity may be considered **MEDICALLY NECESSARY AND APPROPRIATE** for patients who meet **ALL** the following criteria:

- Body mass index (BMI) of ONE of the following:
  - BMI of ≥ 40 kg/m^2 OR
  - BMI of 35 kg/m^2 to < 40 kg/m^2 with **AT LEAST ONE** of the following comorbid conditions:
    - Hypertension refractory to standard treatment; OR
    - Cardiovascular disease; OR
    - Type 2 diabetes mellitus (HbA1C of 7 or greater, or requiring medication); OR
    - Obstructive sleep apnea requiring continuous positive airway pressure (CPAP) or other related treatment; OR
    - Obesity-hypoventilation syndrome (OHS); OR
    - Pickwickian syndrome (a combination of OSA and OHS); OR
    - Nonalcoholic fatty liver disease (NAFLD); OR
    - Nonalcoholic steatohepatitis (NASH); OR
    - Pseudotumor cerebri; OR
    - Polycystic ovarian syndrome (PCOS)

II. Preoperative Preparation

- **Adults**

  The surgical treatment of morbid obesity may be considered **MEDICALLY NECESSARY AND APPROPRIATE** for patients 18 years of age or older who meet patient selection criteria in section I and **ALL** the following criteria:
  - Patient meets one of the following to improve surgical outcomes, reduce the potential for surgical complications, and establish the patient's ability to comply with post-operative medical care and dietary restrictions:

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- Over the past year prior to surgery, the patient has completed one of the following:
  1. Actively participated in an organized multi- disciplinary surgical preparatory regimen with a substantial face-to-face component of at least 6 visits within a 6-month time-frame meeting **all** of the following criteria:
     - Behavior modification program supervised by a qualified professional; AND
     - Consultation with a dietician or nutritionist; AND
     - Exercise regimen (unless contraindicated) to improve pulmonary reserve prior to surgery, supervised by exercise therapist or other qualified professional; AND
     - Reduced-calorie diet program supervised by dietician or nutritionist

     OR
  2. Actively participated in a nutrition and exercise program with a substantial face-to-face component that meets **all** of the following criteria:
     - Program is supervised by a physician, physician's assistant, nurse practitioner/advanced practice nurse or registered dietician; **AND**
     - Participation takes place for a cumulative total of 6 months or longer; **AND**
     - Components of the program include visits with dieticians and/or nutritionists.

     Note: Community-based weight loss programs are acceptable alternatives if participation is in conjunction with the supervision of a physician, physician's assistant, nurse practitioner/advanced practice nurse or registered dietician.

AND

- The patient is evaluated preoperatively by an eligible licensed Mental Health Professional to ensure the absence of significant psychopathology that would hinder the ability of an individual to understand the procedure and comply with medical/surgical recommendations. The Mental Health Professional must meet the Minnesota Department of Human Services qualifications, as set forth in Minn.Stat. §245.462, subd. 18 (2016). Providers outside Minnesota must be appropriately licensed according to applicable state law.

AND

- The physician requesting authorization for the surgery confirms that the patient's treatment plan includes a surgical preparatory program addressing all the following components to improve outcomes related to the surgery and to establish the patient's ability to comply with post-operative medical care and dietary restrictions:
  - Pre-operative and post-operative dietary plan; AND
  - Behavior modification strategies; AND
  - Counseling and instruction on exercise and increased physical activity; AND
  - Ongoing support for lifestyle changes necessary to make and maintain appropriate choices that will reduce health risk factors and improve overall health.

- **Adolescents:**

  The surgical treatment of morbid obesity may be considered **MEDICALLY NECESSARY AND APPROPRIATE** for patients younger than 18 years of age who meet patient selection criteria in section I and **ALL** the following criteria:
  - Absence of a previous history of genetic or syndromic obesity, such as Prader-Willi syndrome; **AND**
  - Patient has attained Tanner IV or V pubertal development **AND ONE** of the following:
    - Bone age of ≥ 13 years in girls or ≥ 15 years in boys; OR
    - Attainment of 95% of adult height based on estimates of bone age;

  AND
  - Patient meets one of the following in order to improve surgical outcomes, reduce the potential for surgical complications, and establish the patient's ability to comply with post-operative medical care and dietary restrictions:
    - Over the past year prior to surgery, the patient has completed one of the following:
      1. Actively participated in an organized multi- disciplinary surgical preparatory regimen with a substantial face-to-face component of at least 6 visits within a 6-month time-frame meeting **all** of the following criteria:
         - Behavior modification program supervised by a qualified professional; AND
         - Consultation with a dietician or nutritionist; AND
         - Exercise regimen (unless contraindicated) to improve pulmonary reserve prior to surgery, supervised by exercise therapist or other qualified professional; AND

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- Reduced-calorie diet program supervised by dietician or nutritionist.

OR

2. Actively participated in a nutrition and exercise program with a substantial face-to-face component that meets all of the following criteria:
   - Program is supervised by a physician, physician's assistant, nurse practitioner/advanced practice nurse or registered dietician; **AND**
   - Participation takes place for a cumulative total of 6 months or longer; **AND**
   - Components of the program include visits with dieticians and/or nutritionists

   Note: Community-based weight loss programs are acceptable alternatives if participation is in conjunction with the supervision of a physician, physician's assistant, nurse practitioner/advanced practice nurse or registered dietician.

AND

- A preoperative evaluation by an eligible licensed Mental Health Professional must be conducted that includes **ALL** of the following:
  - Ensures the absence of significant psychopathology that would hinder the ability of an individual to understand the procedure and comply with medical/surgical recommendations; AND
    - Addresses the patient's ability to provide informed assent without coercion; AND
    - Assesses family and social support; AND
    - Assesses the use of any pharmacologic agents (e.g., anti-psychotic medications) that may contribute to obesity;

  The Mental Health Professional must meet the Minnesota Department of Human Services qualifications, as set forth in Minn.Stat. §245.4871, subd. 27 (2016). Providers outside Minnesota must be appropriately licensed according to applicable state law.

AND

- The physician requesting authorization for the surgery must confirm that the patient's treatment plan includes an adolescent-specific surgical preparatory program addressing all the following components to improve outcomes related to the surgery and to establish the patient's ability to comply with postoperative medical care and dietary restrictions:
  - Pre-operative and post-operative dietary plan; AND
  - Behavior modification strategies; AND
  - Counseling and instruction on exercise and increased physical activity; AND
  - Ongoing support for lifestyle changes necessary to make and maintain appropriate choices that will reduce health risk factors and improve overall health.

III. Bariatric surgery is considered **EXPERIMENTAL/INVESTIGATIVE** for the treatment of morbid obesity in preadolescent children due to a lack of evidence demonstrating an impact on improved health outcomes.

IV. Surgical Procedures

- The following surgical procedures may be considered **MEDICALLY NECESSARY AND APPROPRIATE** in the treatment of morbid obesity when the previous patient selection criteria for adults or adolescents have been met:
  - Open gastric bypass using a Roux-en-Y anastomosis with an alimentary or Roux limb of ≤ 150 cm
  - Laparoscopic gastric bypass using a Roux-en-Y anastomosis
  - Adjustable gastric banding, consisting of an adjustable external band placed around the stomach (i.e., Lap-Band® and REALIZE Band)
  - Open or laparoscopic biliopancreatic diversion (i.e., Scopinaro procedure) with duodenal switch
  - Open or laparoscopic sleeve gastrectomy

- Any other surgical or minimally invasive procedure is considered **EXPERIMENTAL/INVESTIGATIVE** as a treatment of morbid obesity including but not limited to the following due to the lack of evidence demonstrating an impact on improved health outcomes:
  - Open or laparoscopic vertical banded gastroplasty

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- Gastric bypass using a Billroth II type of anastomosis, known as the mini-gastric bypass
- Biliopancreatic diversion (i.e., the Scopinaro procedure) without duodenal switch
- Long limb gastric bypass procedure (i.e., > 150 cm)
- Single anastomosis duodenoileal bypass with sleeve gastrectomy
- Bariatric surgery (any procedure) for patients with a BMI < 35 kg/m^2 including but not limited to solely as a cure for type 2 diabetes mellitus
- Endoluminal (also called endosurgical, endoscopic, sclerosing endotherapy or natural orifice transluminal endoscopic) procedure as a primary bariatric procedure or as a revision procedure by any method including but not limited to:
  - Aspiration therapy device (e.g., AspireAssist® Weight Loss Therapy System)
  - Duodenal-jejunal sleeve
  - Intragastric balloon therapy
  - Primary Obesity Surgery, Endoluminal (POSE) StomaphyX™

V. Reoperation Criteria

- Revision bariatric surgery **OR** conversion of one type of bariatric surgery to a different procedure may be considered **MEDICALLY NECESSARY AND APPROPRIATE** using one of the procedures identified in section III as medically necessary, for **EITHER** of the following indications:
  - Treatment of surgical complications following the original bariatric surgery. Complications may include, but are not limited to: staple line failure, obstruction, stricture, malnutrition, erosion or band slippage, pouch dilation, or stoma ulcer;

  OR
  - Inadequate weight loss following the original surgery when **ALL** the following criteria are met:
    - Patient was compliant with the postoperative dietary and exercise program described in section I (for adults) or section II (for adolescents);
    - Patient currently has a BMI ≥ 40 kg/m^2 OR a BMI of 35 kg/m^2 to < 40 kg/m^2 with an obesity related comorbid condition as described in section I; **AND**
    - At least two (2) years have elapsed since the original bariatric surgery.

Positron Emission Tomography (PET), V-27

I. Cardiac Applications

- Positron emission tomography (PET) or positron emission tomography/computed tomography (PET/CT) may be considered **MEDICALLY NECESSARY AND APPROPRIATE** for the following indications:
  - **Myocardial perfusion** assessment and diagnosis of coronary artery disease in patients with either of the following indications:
    - Indeterminate SPECT; OR
    - The patient's body type or physique is expected to lead to an indeterminate SPECT (e.g., BMI ≥ 35 kg/m^2, chest wall deformity, breast implant)
  - **Myocardial viability** assessment in patients with severe left ventricular dysfunction, as a technique to determine candidacy for cardiac surgery
  - **Suspected cardiac sarcoidosis** assessment in patients with a medical contraindication to magnetic resonance imaging (MRI) (e.g., patients with pacemakers, automatic implanted cardioverter- defibrillators, or other metal implants).
- PET or PET/CT is considered **EXPERIMENTAL/INVESTIGATIVE** for all other cardiac applications, including but not limited to quantification of myocardial blood flow in patients diagnosed with coronary artery disease, due to a lack of evidence demonstrating an impact on improved health outcomes.

MEDICAL AND BEHAVIORAL HEALTH POLICY UPDATE

II. Oncologic Applications

- **Initial Treatment Strategy**
  - PET or PET/CT may be considered **MEDICALLY NECESSARY AND APPROPRIATE** as an **Initial Treatment Strategy (Diagnosis and Staging)** for known or suspected malignancy when the following criteria are met:
    - One (1) PET or PET/CT for solitary pulmonary nodule, myeloma, and all solid malignant tumors (except those listed below as experimental/investigative) when the test is needed to determine the location and/or extent of the suspected or proven malignancy in order to make at least one of the following determinations:
      1. Whether or not the patient is an appropriate candidate for an invasive diagnostic or therapeutic procedure; OR
      2. The optimal anatomic location for an invasive procedure; OR
      3. The anatomic extent of malignancy, when recommended therapy reasonably depends on the extent of malignancy; **AND**
    - Other standard imaging modalities (e.g., CT, MRI or ultrasound) are either not indicated or are unable to conclusively provide the required information.
  - PET or PET/CT is considered **EXPERIMENTAL/INVESTIGATIVE** as an I**nitial Treatment Strategy (Diagnosis and Staging)** for all other non-solid primary tumors and the following solid primary malignant tumors:
    - Basal and squamous cell skin cancers
    - Bladder, urinary
    - Early-stage melanoma (0, I, or II)
    - Kidney
    - Penile cancers
    - Prostate
- **Subsequent Treatment Strategy**
  - PET or PET/CT may be considered **MEDICALLY NECESSARY AND APPROPRIATE** as a **Subsequent Treatment Strategy (Restaging and Monitoring)** for known or suspected malignancies when the following criteria are met:
    - PET or PET/CT for myeloma and all solid primary malignant tumors (except those listed below as experimental/investigative) when the test is performed after completion of initial therapy for malignancy and the imaging results are required to assess therapeutic success, in order to establish the need for any subsequent therapy, by determining at least one of the following:
      1. Presence or extent of residual disease; or
      2. Presence or extent of recurrent disease; or
      3. Presence or extent of metastasis; or
      4. Other assessment of tumor response; **AND**
    - Other standard imaging modalities (e.g., CT, MRI, or ultrasound) are either not indicated or unable to conclusively provide the required information.
  - PET or PET/CT is considered **EXPERIMENTAL/INVESTIGATIVE** when used as a **Subsequent Treatment Strategy (Restaging and Monitoring)** for all other non-solid primary tumors and the following solid primary malignant tumors:
    - Basal and squamous cell skin cancers
    - Early-stage melanoma (0, I, or II)
    - Kidney
    - Pancreas
    - Penile cancers
    - Prostate

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    - Small cell lung
    - Solitary pulmonary nodule
- **Early Treatment Response Assessment**
  - PET or PET/CT for **early treatment response assessment**, also referred to as interim PET (i.e., involving comparison of PET images before treatment and at some interval during the initial course of treatment), may be considered **MEDICALLY NECESSARY AND APPROPRIATE** for patients with Hodgkin lymphoma after completion of at least 2 cycles of chemotherapy, when the result of interim PET is needed to guide treatment decisions.
  - PET or PET/CT for **early treatment response assessment**, also referred to as interim PET (i.e., involving comparison of PET images before treatment and at some interval during the initial course of treatment), is considered **EXPERIMENTAL/INVESTIGATIVE** for all other oncologic applications due to a lack of evidence demonstrating an impact on improved health outcomes.
- **Surveillance**
  - PET or PET/CT as a **surveillance** tool for patients with cancer or with a history of cancer when there are no new or worsening symptoms, physical findings, lab tests, or other imaging tests suggesting recurrence or progression of malignancy is considered **EXPERIMENTAL/INVESTIGATIVE** due to a lack of evidence demonstrating an impact on improved health outcomes.

III. Miscellaneous Applications

- PET or PET/CT may be considered **MEDICALLY NECESSARY AND APPROPRIATE** for the following indications:
  - Localization of epileptic seizure focus in patients with complex partial epileptic seizures who are candidates for resections of a suspected epileptogenic focus and who:
    - Have not responded to standard medical treatment; **AND**
    - Have undergone conventional techniques for seizure localization which suggested, but did not conclusively determine, seizure focus.
  - Diagnosis of chronic osteomyelitis.
- PET or PET/CT is considered **EXPERIMENTAL/INVESTIGATIVE** for the diagnosis or evaluation of all other non-cardiac and non-oncologic conditions or disorders not identified in the medical necessity criteria directly above due to the lack of evidence demonstrating an impact on improved health outcomes including but not limited to:
  - Detection of plaque density in adults who are being evaluated for Alzheimer's disease and/or other causes of cognitive decline.

IV. Integrated PET/Magnetic Resonance Imaging (PET/MRI)

- PET/MRI is considered **EXPERIMENTAL/INVESTIGATIVE** for all indications due to the lack of evidence demonstrating an impact on improved health outcomes.

Reduction Mammoplasty, IV-32

I. Reduction mammoplasty may be considered **MEDICALLY NECESSARY AND APPROPRIATE** for patients 18 years of age and older who meet **ALL** of the following criteria:

- At least a six (6) month history of two (2) or more of the following clinical symptoms:
  - Shoulder, neck, or back pain that is not responsive to at least six (6) weeks of conservative therapy (e.g., appropriate support bra, exercises, heat/cold treatment, and appropriate non-steroidal anti-inflammatory agents [NSAIDS]/muscle relaxants);
  - Recurrent or chronic intertrigo between the pendulous breast and the chest wall;
  - Persistent shoulder grooving;
  - Neurologic symptoms associated with brachial plexus pressure (e.g., numbness or tingling of the shoulder, arm, or hand); **AND**

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- The weight of breast tissue planned to be removed from at least one breast, meets one of the following:
  - Greater than or equal to the amount referenced on the Schnur Sliding Scale based on the Mosteller formula for body surface area:
    - BSA (m^2) = SQR RT ([Height(in) x Weight(lb)] / 3131)
    - Online calculators are available; for example, at https://www.easycalculation.com/medical/bsa-Mostellers.php
    - https://qxmd.com/calculate/calculator_28/bmi-and-bsa-mosteller

    OR
  - Greater than 600 grams of breast tissue is planned to be removed from each breast.

  AND
- A preoperative mammogram that was negative for cancer during the year prior to surgery for women 40 years of age or older.

II. Liposuction is considered **EXPERIMENTAL/INVESTIGATIVE** as a primary (i.e., stand alone) surgical procedure for breast reduction.

III. Reduction mammoplasty performed solely to remove fat and/or skin, but not the minimum specimen weight of breast tissue outlined above, is considered cosmetic as it is performed primarily to enhance or otherwise alter physical appearance.

Cellular Immunotherapy for Prostate Cancer, II-144

I. Sipuleucel-T therapy may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when **ALL** the following criteria are met:
- Diagnosis of metastatic, castrate-resistant (also known as castration-recurrent, hormone-refractory, or androgen-independent) prostate cancer, as defined by:
  - Disease progression despite hormonal therapy (e.g., luteinizing hormone-releasing hormone [LHRH] analogs or anti-androgens); **AND**
  - Evidence of extrahepatic metastases on advanced imaging.

  AND
- Asymptomatic or minimally symptomatic disease; **AND**
- Eastern Cooperative Oncology Group (ECOG) performance status 0 - 1; **AND**
- No liver metastases.

II. Sipuleucel-T therapy is considered **EXPERIMENTAL/INVESTIGATIVE** for all other indications, including but not limited to treatment of the following conditions, due to the lack of evidence demonstrating an impact on improved health outcomes:
- Hormone-responsive prostate cancer;
- Moderate to severe symptomatic metastatic prostate cancer.

Autologous Chondrocyte Implantation of Focal Articular Cartilage Lesions, IV-113

I. Autologous chondrocyte implantation (ACI) may be considered **MEDICALLY NECESSARY AND APPROPRIATE** for the treatment of disabling full-thickness articular cartilage defects of the knee, caused by acute or repetitive trauma, in patients who have had an inadequate response to a prior surgical procedure (e.g., debridement, subchondral drilling, abrasion arthroscopy, microfracture) or who are not candidates for such procedures when **ALL** of the following criteria are met:
- Patient is an adult **OR** a skeletally mature adolescent with documented closure of growth plates (e.g., 15 years or older): AND
- Total area of the cartilage lesion (i.e., length x width, in centimeters or cm) is greater than 1.5 cm^2 (centimeters

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squared); AND
- Focal, full-thickness (Modified Outerbridge grade III or IV) unipolar lesions of the patella or the weight bearing surface of the femoral condyles or trochlea; AND
- Documented minimal to absent degenerative changes in the surrounding articular cartilage (Modified Outerbridge grade II or less), and normal-appearing hyaline cartilage surrounding the border of the defect; AND
- Presence of persistent symptoms (e.g., pain, swelling and catching/locking) that significantly limit activities of daily living; AND
- Normal knee biomechanics or alignment and stability achieved concurrently with ACI.

II. ACI for treatment of all other articular cartilage defects of the knee (i.e., defects that do not meet the criteria outlined in section I) are considered **EXPERIMENTAL/INVESTIGATIVE** due to a lack of evidence demonstrating an impact on improved health outcomes.

III. ACI for all other indications, including but not limited to lesions in joints other than knee (e.g., talus), is considered **EXPERIMENTAL/INVESTIGATIVE** due to a lack of evidence demonstrating an impact on improved health outcomes.

Policies inactivated

None

Policies Effective: November 20, 2017 Notification Posted: September 29, 2017

Policies developed

Edaravone, II-178

IV. Initial Review

Edaravone may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when **ALL** the following criteria are met:
- The patient is 18 years of age or older; **AND**
- The patient has a diagnosis of clinically definite or probable amyotrophic lateral sclerosis (ALS) based on El Escorial/ revised Airlie House criteria or Awaji-Shima criteria; **AND**
- The patient has a disease duration of 2 years or less; **AND**
- The patient has normal respiratory function (i.e., percent-predicted forced vital capacity [%FVC] ≥80%); **AND**
- The patient has retained functionality of most activities of daily living (i.e., score of 2 points or more on each individual item of the ALS Functional Rating Scale–Revised); **AND**
- ONE of the following:
  - Edaravone will be used in combination with riluzole; OR
  - The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to riluzole.

  AND
- Edaravone is prescribed by or in consultation with a neurologist; **AND**
- The patient does not have any FDA labeled contraindications to therapy (see table 1 below); **AND**
- The dose is within the FDA labeled dose (see table 2 below).

V. Renewal Review

Edaravone may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when **ALL** 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., improvement in function or stabilization of functional decline); **AND**

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- ONE of the following:
  - Edaravone will be used in combination with riluzole; OR
  - The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to riluzole.

  AND
- Edaravone is prescribed by or in consultation with a neurologist; **AND**
- The patient does not have any FDA labeled contraindications to therapy (see table 1 below); **AND**
- The dose is within the FDA labeled dose (see table 2 below).

VI. All other uses of edaravone are considered **EXPERIMENTAL/INVESTIGATIVE**, including but not limited to treatment of acute ischemic stroke, due to the lack of clinical evidence demonstrating an impact on improved health outcomes.

- **Table 1. FDA Labeled Contraindications**

AGENT	FDA LABELED CONTRAINDICATIONS
Edaravone	Hypersensitivity

- **Table 2. Dosing**

FDA LABELED INDICATIONS	DOSING
Amyotrophic lateral sclerosis (ALS)	60 mg administered as an intravenous infusion over 60 minutes as follows: • Initial treatment cycle: daily dosing for 14 days, followed by a 14-day drug-free period. • Subsequent treatment cycles: daily dosing for 10 days out of 14-day periods, followed by 14-day drug-free periods.

<u>Documentation Submission</u>

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

Initial Review

1. Clinical notes describing the diagnosis and clinical features of the diagnosis, including El Escorial/revised Airlie House criteria or Awaji-Shima criteria.
2. %FVC from pulmonary function testing.
3. Scores on the ALS Functional Rating Scale–Revised.
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 edaravone through the initial review process.
2. Documentation supporting positive clinical response (e.g., improvement in function or stabilization of functional decline).
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

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dosing (strength and frequency) associated with inadequate response.

Nerve Fiber Density Measurement, II-177

I. Epidermal/Intraepidermal Nerve Fiber (IENF) Density Measurement

Skin biopsy with epidermal nerve fiber density measurement for the diagnosis of small fiber neuropathy may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when ALL of the following criteria are met:

- Individual presents with symptoms of painful sensory neuropathy; AND
- No history of a disorder known to predispose to painful neuropathy (e.g., diabetic neuropathy, toxic neuropathy, HIV neuropathy, celiac neuropathy, inherited neuropathy); AND
- Physical examination shows no evidence of findings consistent with large-fiber neuropathy, such as reduced or absent muscle-stretch reflexes or reduced proprioception and vibration sensation; AND
- Electromyography and nerve-conduction studies are normal and show no evidence of large-fiber neuropathy; AND
- The test is ordered by a neurologist.

II. Skin biopsy with epidermal nerve fiber density measurement is considered **EXPERIMENTAL/INVESTIGATIVE** for the monitoring of disease progression or response to treatment due to the lack of clinical evidence demonstrating an impact on improved health outcomes.

III. Skin biopsy with epidermal nerve fiber density measurement is considered **EXPERIMENTAL/INVESTIGATIVE** for ALL other indications including but not limited to the following, due to a lack of clinical evidence demonstrating an impact on improved health outcomes:

- Fibromyalgia
- Sarcoidosis

IV. Sweat Gland/Sudomotor Nerve Fiber (SGNF) Density Measurement

Measurement of sweat gland nerve fiber density is considered **EXPERIMENTAL/INVESTIGATIVE** due to lack of evidence demonstrating an impact on improved clinical outcomes.

Policies revised

Wheelchairs and Options/Accessories, VII-04

I. Criteria for All Wheelchairs and Power Mobility Devices

- **All** of the following criteria must be met for any wheelchair or power mobility device to be considered **MEDICALLY NECESSARY AND APPROPRIATE**:
  - The patient has a mobility limitation that significantly impairs his or her ability to participate in mobility related activities of daily living (MRADLs) appropriate to the patient's needs and abilities. These activities include toileting, dressing, personal hygiene and eating, education, working or job training. A mobility limitation is one that:
    - Prevents the patient from accomplishing the MRADLs entirely; OR
    - Places the patient at reasonably determined heightened risk of morbidity or mortality secondary to the attempts to participate in MRADLs. Weakness and fatigue alone are not considered significant impairments in the ability to participate in MRADLs; AND
  - The patient has a home mobility limitation that cannot be sufficiently resolved by use of an appropriately fitted cane or walker; AND
  - Features of the wheelchair are based upon the patient's physical and functional capabilities and body size as assessed by a qualified professional or professionals and appropriate to the type of device requested; AND
  - An assessment of the patient's home demonstrated that the home provides adequate access between rooms, maneuvering space and surfaces for use of the wheelchair provided.

II. Manual (Non-Motorized) Wheelchair

- A standard manual (non-motorized) wheelchair may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when:

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- The patient has **met the criteria in section I**; AND
- The patient meets one of the following:
  - Has sufficient upper extremity function and other physical and mental capabilities needed to safely self-propel the manual wheelchair that is provided; OR
  - Patient is willing and able to self-propel a standard manual wheelchair or a caregiver has been trained and is willing and able to assist with or operate the manual wheelchair when the patient's condition precludes self-operation of the manual wheelchair.

- A specific manual wheelchair may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when the criteria for a standard wheelchair above are met AND the following criteria for the specific wheelchair being requested are met:
  - Standard hemi wheelchair when the patient requires lower seat height (17" - 18") due to short stature or to enable the patient to place his/her feet on the ground.
  - Light weight wheelchair when the patient cannot self-propel in a standard wheelchair but can, and does, self-propel in a light-weight wheelchair.
  - High strength lightweight wheelchair when the patient meets the following criteria:
    - Self-propels in the wheelchair while engaging in frequent activities in the home that cannot be performed in a standard or lightweight wheelchair; OR
    - Requires a seat width, depth, or height that cannot be accommodated in a standard lightweight or hemi-wheelchair; AND spends at least 2 hours per day in the wheelchair
  - Ultra-lightweight manual wheelchair when the patient:
    - Uses the manual wheelchair full-time; AND
    - Requires individualized fitting and adjustments for one or more features such as, but not limited to, axle configuration, wheel camber, or seat and back angles, and which cannot be accommodated by a standard, lightweight, or high strength lightweight wheelchair; AND
    - Has had a specialty evaluation that was performed by a licensed/certified medical professional such as a physical therapist (PT) or occupational therapist (OT), or physician who has specific training and experience in rehabilitation, and experience in wheelchair evaluations and its special features and who has no financial relationship with the supplier.
  - Heavy duty manual wheelchair when the patient:
    - Weighs more than 250 pounds; OR
    - Has severe spasticity
  - Extra heavy duty wheelchair when the patient weighs more than 300 pounds
  - Wide heavy duty wheelchair when the patient has a hip width greater than 18".
  - Manual wheelchair with tilt in space when patient has had a specialty evaluation that was performed by a licensed/certified medical professional such as a physical therapist (PT) or occupational therapist (OT), or physician who has specific training and experience in rehabilitation, and experience in wheelchair evaluations and its special features and who has no financial relationship with the supplier.
  - Manual wheelchair with push-rim activated power assist device when the patient:
    - Has been self-propelling in a manual wheelchair for at least one-year; AND
    - Does not have sufficient upper extremity function to self-propel an optimally-configured manual wheelchair in the home to perform MRADLs during a typical day including (e.g., limitations of strength, endurance, range of motion, or coordination, presence of pain, or deformity or absence of one or both upper extremities). An optimally-configured manual wheelchair is one with an appropriate wheelbase, device weight, seating options, and other appropriate nonpowered accessories; AND
    - Has had a specialty evaluation that was performed by a licensed/certified medical professional such as a physical therapist (PT) or occupational therapist (OT), or practitioner who has specific training and experience in rehabilitation, and experience in wheelchair evaluations and its special features and who has no financial relationship with the supplier; AND
    - The wheelchair is provided by a supplier that employs a RESNA-certified Assistive Technology Professional (ATP) who specializes in wheelchairs and who has direct, in-person involvement in the wheelchair selection for the patient.

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- A customized basic or adaptive pediatric stroller may be considered **MEDICALLY NECESSARY AND APPROPRIATE** for a child who:
  - Meets the criteria for a standard wheelchair; AND
  - Is non-ambulatory; AND
  - Either of the following conditions apply:
    - The child requires more support than is available in a standard pediatric wheelchair; OR
    - The child is too small to safely use a standard pediatric wheelchair.

- A standard commercial stroller is not considered durable medical equipment since it does not serve a medical purpose.

- Use of a manual wheelchair only outside the home is considered **NOT MEDICALLY NECESSARY AND APPROPRIATE**.

III. Power-Operated Vehicle (POV) (i.e., Scooter or motorized 3-4 wheeled vehicles)

- A Group 1 POV may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when the patient meets the criteria in section I and **ALL** of the following criteria are met:
  - Patient is unable to self-propel a manual wheelchair; AND
  - Patient is able to safely transfer in and out of the POV; AND
  - Patient is cognitively and physically able to safely maintain stability and position for adequate operation; AND
  - The patient's condition is non-progressive; AND
  - The patient's weight does not exceed the weight capacity of the POV being requested and greater than or equal to 95% of the weight capacity of the next lower weight class POV (i.e., a Heavy Duty POV generally indicated for patient weighing 285-450 pounds; a Very Heavy Duty POV generally indicated for a patient weighing 428-600 pounds); AND
  - Use of a POV will significantly improve the patient's ability to participate in MRADLs, and the patient will use it in the home; AND
  - The patient is agreeable to the use of a POV in the home; AND
  - The POV meets the needs of the patient in lieu of a power wheelchair.

AND

- A Group 2 POV is considered is considered **NOT MEDICALLY NECESSARY AND APPROPRIATE** as these wheelchairs have additional capabilities that are not necessary for use within the home.

- Use of a POV only outside the home is considered **NOT MEDICALLY NECESSARY AND APPROPRIATE**.

IV. Motorized/Power Wheelchair (PWC)

- A PWC may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when the **ALL** of the following have been met:
  - Patient has **met the criteria in section I**; AND
  - An optimally-configured manual wheelchair (i.e., appropriate wheelbase, device weight, seating options, and other appropriate nonpowered accessories) is determined to be inadequate to address the patient's need for mobility inside and outside the patient's home:
    - The patient does not have sufficient upper extremity function to self-propel an optimally-configured manual wheelchair in the home to perform MRADLs during a typical day.
    - Limitations of strength, endurance, range of motion, or coordination, presence of pain, or deformity or absence of one or both upper extremities are relevant to the assessment of upper extremity function

  AND
  - Patient's condition is such that he/she is unable to operate a manual wheelchair due to lack of upper body strength; AND
  - The patient's home mobility limitations cannot be sufficiently resolved by the use of POV (i.e., Patient is not able

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to safely operate a POV or maintain postural stability and position while operating a POV); AND
- The patient is capable of safely operating the controls of a PWC or has a caregiver who cannot push a manual chair but can propel the power chair using an attendant control; AND
- The patient must be able to safely transfer, or be transferred, in and out of the PWC and have adequate trunk stability to be able to safely ride in the wheelchair; AND
- The patient's weight is less than or equal to the weight capacity of the PWC that is provided and greater than or equal to 95% of the weight capacity of the next lower weight class PWC (i.e., a Heavy Duty PWC is generally indicated for patient weighing 285-450 pounds; a Very Heavy Duty PWC is generally indicated for a patient weighing 428-600 pounds); AND
- Use of a PWC will significantly improve the patient's ability to participate in MRADLs, and the patient will use it in the home; AND
- The patient is willing to use a PWC in the home; AND
- A patient under age 4 has been evaluated and found to be developmentally ready to begin to operate a power chair equipped with appropriate attendant control and safeguards.

- A customized motorized/power wheelchair base is considered **MEDICALLY NECESSARY AND APPROPRIATE** when the following are met:
  - The patient meets the criteria for a power wheelchair; AND
  - The specific configurational needs of the patient is not able to be met using wheelchair cushions, or options or accessories (prefabricated or custom fabricated), which may be added to another power wheelchair base.

- **PWC Groups 1, 2, 3 or 5** may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when the criteria for a PWC above are met AND the following group-related criteria for the PWC being requested are met:
  - Group 1 standard PWC or Group 2 standard PWC when the wheelchair is appropriate for the patient's weight;
  - Group 2 single power option PWC when the patient:
    - Has had a specialty evaluation that was performed by a licensed/certified medical professional such as a physical therapist (PT) or occupational therapist (OT), or practitioner who has specific training and experience in rehabilitation, and experience in wheelchair evaluations and its special features and who has no financial relationship with the supplier; AND
    - The wheelchair is provided by a supplier that employs a RESNA-certified Assistive Technology Professional (ATP) who specializes in wheelchairs and who has direct, in-person involvement in the wheelchair selection for the patient; .AND
    - Meets one of the following:
      1. requires a drive control interface other than a hand- or chin-operated standard proportional joystick (e.g., head control, sip and puff, switch control) OR
      2. meets criteria for a power tilt, power recline, or combination power tilt/power recline seating system (see criteria below) and the system is to be used on the PWC
  - Group 2 multiple power option PWC when the patient:
    - Has had a specialty evaluation that was performed by a licensed/certified medical professional such as a physical therapist (PT) or occupational therapist (OT), or practitioner who has specific training and experience in rehabilitation, and experience in wheelchair evaluations and its special features and who has no financial relationship with the supplier; AND
    - The wheelchair is provided by a supplier that employs a RESNA-certified Assistive Technology Professional (ATP) who specializes in wheelchairs and who has direct, in-person involvement in the wheelchair selection for the patient; AND
    - Meets one of the following:
      1. criteria for a power tilt and recline seating system (see criteria below) and the system is to be used on the wheelchair; OR
      2. uses a ventilator which is mounted on the wheelchair.
  - Group 3 PWC with no power options when the patient:

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    - Has had a specialty evaluation that was performed by a licensed/certified medical professional such as a physical therapist (PT) or occupational therapist (OT), or practitioner who has specific training and experience in rehabilitation, and experience in wheelchair evaluations and its special features and who has no financial relationship with the supplier; AND
    - The wheelchair is provided by a supplier that employs a RESNA-certified Assistive Technology Professional (ATP) who specializes in wheelchairs and who has direct, in-person involvement in the wheelchair selection for the patient; AND
    - Has a mobility limitation due to a neurological condition, myopathy, or congenital skeletal deformity
  - Group 3 PWC with single power option when:
    - The patient's mobility limitation is due to a neurological condition, myopathy, or congenital skeletal deformity; AND
    - The Group 2 single power option criteria are met;
  - Group 3 PWC with multiple power options when:
    - The patient's mobility limitation is due to a neurological condition, myopathy, or congenital skeletal deformity; AND
    - Has had a specialty evaluation that was performed by a licensed/certified medical professional such as a physical therapist (PT) or occupational therapist (OT), or practitioner who has specific training and experience in rehabilitation, and experience in wheelchair evaluations and its special features and who has no financial relationship with the supplier; AND
    - The wheelchair is provided by a supplier that employs a RESNA-certified Assistive Technology Professional (ATP) who specializes in wheelchairs and who has direct, in-person involvement in the wheelchair selection for the beneficiary; .AND
    - Meets one of the following:
      1. criteria for a power tilt and recline seating system (see criteria below) and the system is to be used on the wheelchair; OR
      2. uses a ventilator which is mounted on the wheelchair.
  - Group 5 pediatric PWC with single power option when:
    - The patient is expected to grow in height; AND
    - The Group 2 single power option criteria are met.
  - Group 5 pediatric PWC with multiple power options when:
    - The patient is expected to grow in height AND
    - The Group 2 multiple power option criteria are met.
- Power tilt and/or recline seating systems – tilt only, recline only, or a combination tilt and recline – with or without power elevating leg rests may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when ALL of the following criteria are met:
  - The patient meets medical necessity criteria for a power wheelchair; AND
  - A specialty evaluation was performed by a licensed/certified medical professional, such as a physical therapist (PT) or occupational therapist (OT) or physician who has specific training and experience in rehabilitation wheelchair evaluations documents the patient's seating and positioning needs; and
  - One of the following criteria are met:
    - Patient is at high risk for development of a pressure ulcer and is unable to perform a functional weight shift; or
    - The patient uses intermittent catheterization for bladder management and is unable to independently transfer from the wheelchair to bed; or
    - The power seating system is needed to manage increased tone or spasticity.

- Up to 2 batteries at one time may be considered **MEDICALLY NECESSARY AND APPROPRIATE** if required for the power wheelchair.

- Non-sealed lead acid batteries are considered **NOT MEDICALLY NECESSARY AND APPROPRIATE**.

- A Group 4 PWC is considered **NOT MEDICALLY NECESSARY AND APPROPRIATE** as these wheelchairs have

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additional capabilities that are not necessary for use within the home.

- Use of any PWC only outside the home is considered **NOT MEDICALLY NECESSARY AND APPROPRIATE**.
- A PWC for a child under 18 months of age is considered **NOT MEDICALLY NECESSARY AND APPROPRIATE**.

V. The base of a wheelchair with stair-climbing ability (e.g., IBOT® 4000) may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when a patient meets coverage criteria for a wheelchair. The stair climbing features (the 4-wheel, balance, stair and remote functions) are considered an **UPGRADE** and are **NOT COVERED**.

VI. Wheelchairs designed for sports or recreational purposes are considered **NOT MEDICALLY NECESSARY AND APPROPRIATE** as these wheelchairs have additional capabilities that are not necessary for use within the home.

VII. Specialized Seating

- Specialized wheelchair seating is considered **MEDICALLY NECESSARY AND APPROPRIATE** when the patient meets all criteria for the specific type of wheelchair being requested AND the following criteria for the specific seating option:
  - Solid seat insert when the patient spends at least two hours per day in a wheelchair or roll-about chair that meets coverage criteria.
  - Adjustable or non-adjustable prefabricated skin protection seat when the patient meets one or more of the following:
    - Current pressure ulcer or history of a pressure ulcer on the area of contact with the seating surface;
    - Absent or impaired sensation in the area of contact with the seating surface;
    - Inability to carry out a functional weight shift due to spinal cord injury resulting in quadriplegia or paraplegia, other spinal cord disease, multiple sclerosis, other demyelinating disease, cerebral palsy, anterior horn cell diseases including amyotrophic lateral sclerosis, post-polio paralysis, traumatic brain injury resulting in quadriplegia, spina bifida and childhood cerebral degeneration.
  - Positioning seat cushion, positioning back cushion, and positioning accessories when the patient has any significant postural asymmetries that are due to spinal cord injury resulting in quadriplegia or paraplegia, other spinal cord disease, multiple sclerosis, other demyelinating disease, cerebral palsy, anterior horn cell diseases including amyotrophic lateral sclerosis, post-polio paralysis, traumatic brain injury resulting in quadriplegia, spina bifida childhood cerebral degeneration, Alzheimer's disease, Parkinson's disease, monoplegia of the lower limb, hemiplegia due to stroke, traumatic brain injury, or other etiology, muscular dystrophy, torsion dystonias, or spinocerebellar disease.
  - Adjustable or non-adjustable combination skin protection or positioning seat cushions may be considered meets the criteria for both a skin protection seat cushion and a positioning seat cushion.
  - Custom fabricated seat cushion when:
    - The patient meets ALL of the coverage criteria for a prefabricated skin protection seat cushion or positioning seat cushion; AND
    - There is a comprehensive written evaluation by a licensed/certified medical professional, such as a physical therapist (PT) or occupational therapist (OT), which clearly explains why a prefabricated seating system is not sufficient to meet the patient's seating and positioning needs.
  - Custom fabricated back cushion when:
    - The patient meets ALL of the coverage criteria for a prefabricated skin protection back cushion or positioning seat cushion; AND
    - There is a comprehensive written evaluation by a licensed/certified medical professional, such as a physical therapist (PT) or occupational therapist (OT), which clearly explains why a prefabricated seating system is not sufficient to meet the patient's seating and positioning needs.
  - Seat elevation or a seat lift when:
    - The patient must routinely transfer between uneven surfaces that cannot be adjusted and the seat elevation feature allows them to independently transfer; OR

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    - The patient cannot be safely transferred using a patient lift or standing transfer but can safely be transferred with that seat elevation feature; OR
    - The seat elevation has been demonstrated to allow the patient to independently access areas in the home necessary for completion of ADLs (cupboards, closets, etc.).
  - Reinforced back upholstery or reinforced seat upholstery when the patient weighs more than 200 lbs.
    Note: When used in conjunction with heavy duty or extra heavy-duty wheelchair base, the allowance for reinforced upholstery is included in the allowance for the wheelchair base. Reinforced back and seat upholstery if used in conjunction with other manual wheelchair bases is **INELIGIBLE FOR COVERAGE**.
- A captain's chair is not considered **NOT MEDICALLY NECESSARY AND APPROPRIATE** for a patient who needs a separate wheelchair seat and/or back cushion.
- A skin protection and/or positioning seat or back cushion is considered **NOT MEDICALLY NECESSARY AND APPROPRIATE** when provided with a POV or PWC with captain's chair,
- A battery powered, prefabricated cushion is considered **NOT MEDICALLY NECESSARY AND APPROPRIATE**.

VIII. Options/Accessories (This list is not all-inclusive)

- Back Support: A back support may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when the patient:
  - Meets the criteria above for a wheelchair; AND
  - Requires trunk or body support due to neurological impairments, flexible asymmetrical/symmetrical deformities or fixed asymmetrical/symmetrical deformities.
- Adjustable Arm Height Option: An adjustable arm height option may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when the patient:
  - Meets the criteria above for a wheelchair; AND
  - Requires arm height that is different than that available using non-adjustable arms; AND
  - Spends at least two hours per day in the wheelchair.
- Arm Trough: An arm trough may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when the patient:
  - Meets the criteria above for a wheelchair; AND
  - Has quadriplegia, hemiplegia, or uncontrolled arm movements.
- Detachable Arms: Detachable arms may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when the patient:
  - Meets the criteria above for a wheelchair; AND
  - Must transfer from wheelchair to bed/chair by "sliding over" and cannot walk or stand and pivot to transfer.
- Hook-On Head Rest Extension: A hook-on head rest extension may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when the patient:
  - Meets the criteria above for a wheelchair; AND
  - Has weak neck muscles and needs a head rest for support OR patient meets the criteria for and has reclining back on the wheelchair.
- Elevating Leg Rests: Elevating leg rests may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when the patient:
  - Meets the criteria above for a wheelchair; AND
  - Meets one or more of the following:
    - Has a musculoskeletal condition, cast or brace that prevents 90 degrees of knee flexion; OR
    - Has a below knee amputation and is in an early rehabilitation phase; OR
    - Meets the criteria and has a reclining wheelchair; OR
    - Has significant edema of the lower extremities that requires having an elevated leg rest.
- Safety Belt/Pelvic Strap: A safety belt/pelvic strap may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when the patient:
  - Meets the criteria above for a wheelchair; AND
  - Has weak upper body muscles, upper body instability or muscle spasticity requiring belt/strap to maintain proper positioning.
- Tray: A tray may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when:

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  - The patient meets the criteria above for wheelchair base; AND
  - The tray is primarily required for support or positioning.
- The following are **INELIGIBLE FOR COVERAGE**:
  - Baskets
  - Cane holders
  - Canopies
  - Crutch holders
  - Color upgrades
  - Cup holders
  - Flags
  - High-low chassis or frames
  - Lights
  - Modifications to the home environment to accommodate the device (e.g., widening doors, lowering counters)
  - Motorized lifts used to place the wheelchair in a vehicle
  - Standing features
  - Stand and drive features
  - Storage devices (e.g., backpacks, seat pouches)
  - Tie-downs for vehicles
  - Transit accessories (e.g., headrest, headrest cover, harness and position belt)
  - Trays that are not required primarily for support or positioning.

<u>Documentation Submission</u>

- The patient's practitioner must submit documentation of a face-to-face examination by a licensed/certified medical professional to support medical necessity for the wheelchair options or accessories (within 6 months of written order). This documentation must include ALL of the following:
  - The patient's diagnosis, prognosis, and severity of the condition; AND
  - Narrative description including functional impairments that necessitate use of the requested wheelchair and any requested non-standard features; AND
  - Relevant medical records including pertinent laboratory tests, radiology reports or other diagnostic tests.
- For POVs and PWC a detailed narrative chart note by the treating physician The report should provide pertinent information about the following elements, but may include other details. Each element would not have to be addressed in every evaluation.
  - History of the present condition(s) and past medical history that is relevant to mobility needs
  - Symptoms that limit ambulation
  - Diagnoses that are responsible for these symptoms
  - Medications or other treatment for these symptoms
  - Progression of ambulation difficulty over time
  - Other diagnoses that may relate to ambulatory problems
  - How far the beneficiary can walk without stopping
  - Pace of ambulation
  - What ambulatory assistance (cane, walker, wheelchair, caregiver) is currently used
  - What has changed to now require use of a power mobility device
  - Ability to stand up from a seated position without assistance
  - Description of the home setting and the ability to perform activities of daily living in the home
  - Physical examination that is relevant to mobility needs
    - Weight and height
    - Cardiopulmonary examination
    - Musculoskeletal examination
    - Arm and leg strength and range of motion
  - Neurological examination
    - Gait

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    - Balance and coordination
- The following written reports may be required and must be available on request:
  - On-site evaluation of the patient's home by the supplier or practitioner verifying that the patient can adequately maneuver the device provided considering physical layout, doorway width, doorway thresholds, and surfaces.
  - Specialty evaluation required for patients who receive a Group 2 Single Power Option or Multiple Power Options PWC and any Group 3 PWC or a push-rim activated power assist device.
  - Supplier verification of a supplier that a RESNA-certified ATP is employed who specializes in wheelchairs and has direct, in-person involvement in the wheelchair selection for the patient.

Note: Forms created from suppliers that have not been approved by CMS are not considered part of the medical record. Even if the practitioner completes this type of form and puts it in his/her chart, this supplier-generated form is not a substitute for the comprehensive medical record as noted above.

Link to Commercial Pre-Authorization Form: https://www.bluecrossmn.com/healthy/public/portalcomponents/PublicContentServlet?contentId=P11GA_13331080

Coverage
Standard wheelchairs in a skilled nursing facility are included in the per diem charge. Required modifications to a wheelchair or a customized wheelchair that is used exclusively and continuously by the member will be reviewed for medical necessity. Wheelchairs approved outside the facility per diem become the property of the resident, not the facility.

Duplication

Requests for a second chair of the same type as a covered chair (e.g., a second manual chair, stroller or a second power chair) are considered duplicates and are **NOT COVERED**.

A manual wheelchair may be authorized for a patient who has a power wheelchair AND documentation is provided that the patient requires a manual wheelchair for transportation where a power wheelchair cannot be used.

Repairs / Maintenance
Coverage includes batteries and repairs required to keep the device operational. Routine maintenance, however, is not covered.

Replacement
Average useable life of a wheelchair is considered to be approximately five (5) years. Coverage for replacement will be considered when:

- The cost of the repair is in excess of the replacement cost;
- Other extenuating medical circumstances occur which require special consideration; OR
- The current wheelchair no longer meets the patient's needs

If an upgrade in equipment is requested, the patient's functional status (diagnosis, prognosis and severity of condition) must be reviewed for special consideration, in accordance with the justification for medical necessity described above.

In the absence of a medical policy addressing a specific DME item, the medical criteria of the regional DME Medicare Administrative Contractor (MAC) Centers will be used in determining the medical necessity of the item. Those policies are available by accessing the List of LCDs on the CMS Coverage Database.

Infliximab, II-97
I. Initial Review

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

- **ONE** of the following:
  - The patient has a diagnosis of perianal fissuring/chronic fistulizing Crohn's disease and is 6 years of age or older; OR
  - BOTH of the following:
    - The patient has a diagnosis of ONE of the following:
      1. Moderately to severely active rheumatoid arthritis in a patient 18 years of age or older; OR
      2. Moderately to severely active Crohn's disease in a patient 6 years of age or older; OR
      3. Moderately to severely active ulcerative colitis in a patient 6 years of age or older; OR
      4. Active ankylosing spondylitis in a patient 18 years of age or older; OR
      5. Chronic, severe (i.e., extensive and/or disabling) plaque psoriasis in a patient 18 years of age or older; OR
      6. Active psoriatic arthritis in a patient 18 years of age or older; OR
      7. Moderately to severely active juvenile idiopathic arthritis in a patient 2 years of age or older.

      AND
    - ONE of the following:
      1. The patient is currently being treated with infliximab; OR
      2. The patient has previously failed another biologic immunomodulator with FDA approval for the same indication; OR
      3. The patient has used one conventional agent prerequisite for the indication (see table 2 below); OR
      4. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to at least one conventional agent.

    OR
  - BOTH of the following:
    - The patient has a diagnosis of chronic, recurrent, treatment-refractory, or vision- threatening non-infectious uveitis; AND
    - ONE of the following:
      1. The patient is currently being treated with infliximab; OR
      2. The patient has previously failed another biologic immunomodulator with FDA approval for the same indication; OR
      3. The patient has used at least 2 conventional agent prerequisites for the indication (see table 2 below); OR
      4. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to at least 2 conventional agents.

  AND
- The patient does not have any FDA labeled contraindications to therapy (see table 1 below); **AND**
- The patient is not currently being treated with another biologic therapy; **AND**
- For patients not currently receiving infliximab, the patient has been screened for hepatitis B infection and has begun therapy if appropriate; **AND**
- For patients not currently receiving infliximab, the patient has been screened for latent tuberculosis (TB) and started on TB therapy if the patient tests positive; **AND**
- The dose is within the FDA labeled dose for the labeled indications or is supported in literature for additional indications (see table 3 below).

II. Renewal Review

Infliximab 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 with infliximab (see table 1 below); **AND**
- The patient is not currently being treated with another biologic therapy; **AND**

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- The dose is within the FDA labeled dose for the labeled indications or is supported in literature for additional indications (see table 3 below).

III. All other uses of infliximab are considered **EXPERIMENTAL/INVESTIGATIVE**, including but not limited to intra-articular injections and treatment of the following conditions, due to the lack of clinical evidence demonstrating an impact on improved health outcomes.

- Age-related macular degeneration
- Alcoholic hepatitis
- Arthritis (other than rheumatoid arthritis, psoriatic arthritis, and juvenile idiopathic arthritis)
- Behcet syndrome
- Cancer cachexia
- Depression
- Diabetic macular edema
- Endometriosis
- Erythrodermic or exfoliative psoriasis
- Giant cell arteritis
- Graft-versus-host disease
- Hidradenitis suppurativa
- Kawasaki syndrome
- Polyarteritis nodosa
- Polymyalgia rheumatica
- Renal cell carcinoma
- Sacroiliitis
- Sarcoidosis
- Sclerosing cholangitis
- Sjogren syndrome
- Systemic lupus erythematosus
- Systemic necrotizing vasculitides
- Systemic sclerosis
- Takayasu's arteritis

- Wegener's Granulomatosis

• Table 1. FDA Labeled Contraindications

AGENT	FDA LABELED CONTRAINDICATIONS
Infliximab	Doses >5 mg/kg in moderate to severe heart failure Hypersensitivity

• Table 2. Conventional Agent Prerequisites

FDA LABELED INDICATIONS	CONVENTIONAL AGENT PREREQUISITES
Rheumatoid arthritis (RA) Psoriatic arthritis (PsA)	methotrexate leflunomide minocycline sulfasalazine hydroxychloroquine

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• **Table 2. Conventional Agent Prerequisites - continued**

FDA LABELED INDICATIONS	CONVENTIONAL AGENT PREREQUISITES
Psoriasis (Ps)	methotrexate topical corticosteroids coal tar products anthralin calcipotriene calcitriol acitretin tazarotene cyclosporine methoxsalen tacrolimus pimecrolimus PUVA (phototherapy)
Crohn's disease (CD) Ulcerative colitis (UC)	methotrexate aminosalicylates corticosteroids (including budesonide EC capsule) cyclosporine azathioprine 6-mercaptopurine metronidazole ciprofloxacin
Ankylosing spondylitis (AS)	NSAIDs (ibuprofen, ketoprofen, celecoxib)
Off Label Indications	**Conventional Agent Prerequisites**
Juvenile idiopathic arthritis (JIA)	methotrexate leflunomide minocycline sulfasalazine hydroxychloroquine
Non-infectious uveitis	ophthalmic corticosteroids (prednisolone, rimexolone) ophthalmic cycloplegic agents (atropine, homatropine, scopolamine, cyclopentolate) methotrexate azathioprine cyclosporine NSAIDs (ibuprofen, ketoprofen, celecoxib)

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- **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
Rheumatoid arthritis, moderately to severely active in adults with inadequate response to one or more DMARDs	3 mg/kg at weeks 0, 2, and 6 followed by 3 mg/kg every 8 weeks. May go up to 10 mg/kg every 4 weeks.
Crohn's disease - adult	5 mg/kg at weeks 0, 2, and 6 followed by 5 mg/kg every 8 weeks. May go up to 10 mg/kg. If no response by 14 weeks, discontinue.
Crohn's disease – pediatric (≥6 years)	5 mg/kg at weeks 0, 2, and 6 followed by 5 mg/kg every 8 weeks.
Ulcerative colitis – adult and pediatric (≥6 years)	5 mg/kg at weeks 0, 2, and 6 followed by 5 mg/kg every 8 weeks.
Ankylosing spondylitis	5 mg/kg at weeks 0, 2, and 6 followed by 5 mg/kg every 6 weeks.
Psoriatic arthritis and plaque psoriasis	5 mg/kg at weeks 0, 2, and 6 followed by 5 mg/kg every 8 weeks.
Off Label Indications	**Dosing**
Juvenile idiopathic arthritis	3 to 6 mg/kg at weeks 0, 2, and 6 followed by 3 to 6 mg/kg every 8 weeks.
Non-infectious uveitis	5 mg/kg at weeks 0, 2, and 6 followed by 5 mg/kg every 6 to 8 weeks.

Documentation Submission

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

Initial Review

1. Clinical notes describing the diagnosis and clinical features of the diagnosis.
2. For patients not currently receiving infliximab, laboratory results for hepatitis B and latent tuberculosis (TB) screening. If either test was positive, describe follow-up therapy.
3. Clinical notes describing current and past medications for the diagnosis, including response to the medications.
4. The dose being requested, including the patient's weight. If the requested dose is higher or more frequent than the dosing guidelines provided in the table above, a clear explanation for the medical necessity of the requested dose MUST be submitted, including prior dosing (strength and frequency) associated with inadequate response.

Renewal Review

1. Documentation of prior approval for infliximab through the initial review process.
2. Documentation supporting positive clinical response (e.g., slowing of disease progression or decrease in symptom

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severity and/or frequency).

3. Clinical notes describing current and past medications for the diagnosis, including response to the medications.
4. The dose being requested, including the patient's weight. If the requested dose is higher or more frequent than the dosing guidelines provided in the table above, a clear explanation for the medical necessity of the requested dose MUST be submitted, including prior dosing (strength and frequency) associated with inadequate response.

Expanded Molecular Panel Testing of Cancers to Identify Targeted Therapies, VI-49

- The use of expanded molecular panel testing using multiplex or next generation sequencing (NGS) testing of tumor tissue is considered **MEDICALLY NECESSARY AND APPROPRIATE** for selection of targeted therapy in patients with metastatic non-small cell lung cancer.
- The use of expanded molecular panel testing of cancers to identify targeted therapies is considered **EXPERIMENTAL/INVESTIGATIVE** for all other indications due to a lack of evidence demonstrating an impact on improved health outcomes.

Selected Treatments for Hyperhidrosis, II-55

NOTE: Use of Botulinum Toxin for Treatment of Hyperhidrosis is addressed in policy II-16, Botulinum Toxin.

I. Endoscopic Transthoracic Sympathectomy (ETS) or Thoracic Sympathectomy

Endoscopic transthoracic sympathectomy (ETS) or thoracic sympathectomy may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when ALL criteria are met:

- Primary hyperhidrosis occurs in ONE OR MORE of the following specific foci:
  - Axillary; OR
  - Palmar; OR
  - Craniofacial;

AND

- ONE of the following criteria are met:
  - Chronic dermatological complications secondary to hyperhidrosis (e.g. skin maceration with secondary infection, dermatitis/fungal infection); OR
  - Significant disruption of professional/personal life or significant functional impairment as a result of hyperhidrosis, as documented in the medical record;

AND

- BOTH of the following criteria are met:
  - Topical prescription aluminum chloride 20% administered for a minimum of one month is contraindicated, poorly tolerated, or ineffective; AND
  - Failure, contraindication, or intolerance to botulinum toxin therapy.

All other uses of endoscopic transthoracic sympathectomy or thoracic sympathectomy for the treatment of hyperhidrosis including but not limited to treatment of plantar hyperhidrosis are considered **EXPERIMENTAL/INVESTIGATIVE** due to a lack of clinical evidence demonstrating an impact on improved health outcomes.

II. Tympanic Neurectomy

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

- As a treatment for secondary gustatory hyperhidrosis;

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AND

- One of the following criteria are met:
  - Chronic dermatological complications secondary to hyperhidrosis (e.g. skin maceration with secondary infection, dermatitis/fungal infection); OR
  - Significant disruption of professional/personal life or significant functional impairment as a result of hyperhidrosis, as documented in the medical record;

AND

- Topical prescription aluminum chloride 20% administered for a minimum of one month is contraindicated, poorly tolerated, or ineffective.

All other uses of tympanic neurectomy for the treatment of hyperhidrosis are considered **EXPERIMENTAL/INVESTIGATIVE** due to a lack of clinical evidence demonstrating an impact on improved health outcomes.

III. EXPERIMENTAL/INVESTIGATIVE Procedures

The following procedures for hyperhidrosis are considered **EXPERIMENTAL/INVESTIGATIVE** due to a lack clinical evidence indicating an impact in improved outcomes, including but not limited to:

- Liposuction (e.g. axillary);
- Coagulation of lymph glands (e.g. axillary);
- Microwave treatment;
- Radiofrequency ablation;
- Subdermal laser treatment

Hematopoietic Stem-Cell Transplantation for Solid Tumors of Childhood, II-131

I. Autologous Hematopoietic Stem-Cell Transplantation

- Autologous hematopoietic stem-cell transplantation may be considered **MEDICALLY NECESSARY AND APPROPRIATE** for:
  - Initial treatment of high-risk neuroblastoma;
  - Recurrent or refractory neuroblastoma;
  - Initial treatment of high-risk Ewing's sarcoma;
  - Recurrent or refractory Ewing's sarcoma;
  - Metastatic retinoblastoma
- Tandem autologous hematopoietic stem-cell transplantation may be considered **MEDICALLY NECESSARY AND APPROPRIATE** for treatment of high-risk neuroblastoma.
- Autologous hematopoietic stem-cell transplantation (single or tandem) is considered **EXPERIMENTAL/INVESTIGATIVE** for treatment of all other solid tumors of childhood, including but not limited to:
  - Initial treatment of low- or intermediate-risk neuroblastoma,
  - Initial treatment of low- or intermediate-risk Ewing's sarcoma,
  - Rhabdomyosarcoma;
  - Wilms tumor;
  - Osteosarcoma;
  - Retinoblastoma without metastasis

II. Allogeneic Hematopoietic Stem-Cell Transplantation

- Allogeneic (myeloablative or nonmyeloablative) hematopoietic stem-cell transplantation for treatment of pediatric solid tumors is considered **EXPERIMENTAL/INVESTIGATIVE** due to a lack of evidence demonstrating an impact on improved health outcomes.

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- Salvage allogeneic hematopoietic stem-cell transplantation for neuroblastoma or other pediatric solid tumor that relapse after autologous transplantation or fail to respond is considered **EXPERIMENTAL/INVESTIGATIVE** due to a lack of evidence demonstrating an impact on improved health outcomes.

Policies inactivated

None

Policies Effective: December 1, 2017 Notification Posted: October 17, 2017

Policies developed

None

Policies revised

NOTE: Effective December 1, 2017, Blue Cross and Blue Shield of Minnesota and Blue Plus will implement a new Medical Drug Exclusions List (See Provider Bulletin P56-17 "Implementation of a Medical Drug Exclusions List" for more information). Coverage statements will be added to the following two policies to reflect these medical drug exclusions.

Infliximab, II-97

- There are no changes to the policy criteria; these criteria remain the same.
- A coverage statement will be added to the policy:
  - The following coverage statement applies to commercial health plan members:
    If infliximab is deemed medically necessary per this policy and a benefit under the member's Summary Plan Description, the following infliximab product is covered by Blue Cross and Blue Shield of Minnesota (BCBSMN): Remicade®. Other infliximab products (Inflectra®, Renflexis®) are not covered. For additional information, please refer to the BCBSMN Medical Drug Exclusion List.

Intra-Articular Hyaluronan Injections for Osteoarthritis, II-29

- There are no changes to the policy criteria; these criteria remain the same.
- A coverage statement will be added to the policy:
  - The following coverage statement applies to commercial health plan members and Minnesota Health Care Programs subscribers to Blue Advantage Prepaid Medical Assistance Program (PMAP), MinnesotaCare (MNCare), Minnesota Senior Care Plus (MSC+), or SecureBlue (MSHO):
    If intra-articular hyaluronan injection (viscosupplementation) is deemed medically necessary per this policy and a benefit under the member's Summary Plan Description, the following hyaluronan products are covered by Blue Cross and Blue Shield of Minnesota (BCBSMN): Synvisc® and Synvisc-One®. Other hyaluronan products are not covered. For additional information, please refer to the BCBSMN Medical Drug Exclusion List.

Policies inactivated

None

Policies Effective: December 18, 2017 Notification Posted: October 27, 2017

MEDICAL AND BEHAVIORAL HEALTH POLICY UPDATE

Policies developed

None

Policies revised

Orthognathic Surgery, IV-16

I. Orthognathic surgery may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when the following criteria are met:

- Abnormalities in the mandibular and/or maxillary facial skeletal structure;

AND

- Discrepancies or asymmetries in at least one of the three standard spatial reference planes (horizontal, vertical, and/or transverse) meeting **one or more** of criteria 1-4 below:
  1. Anteroposterior discrepancies greater than 2 standard deviations from the norm; defined as either of the following:
     - Maxillary/mandibular incisor relationship: overjet of 5 millimeters (mm) or more, or a 0 to a negative value (norm 2 mm); **OR**
     - Maxillary/mandibular anteroposterior molar relationship discrepancy of 4 mm or more (norm 0 to 1 mm)
  2. Vertical discrepancies that meet **one or more** of the following:
     - Presence of a vertical facial skeletal deformity which is two or more standard deviations from the published norms for accepted skeletal landmarks; **OR**
     - Open bite
       - No vertical overlap of anterior teeth
       - Unilateral or bilateral posterior open bite greater than 2 mm; **OR**
     - Deep overbite with impingement or irritation of buccal or lingual soft tissues of the opposing arch; OR
     - Supraeruption of a dentoalveolar segment due to lack of occlusion creating a dysfunction not amenable to conventional prosthetics
  3. Transverse discrepancies meeting **either** of the following:
     - Presence of a transverse skeletal discrepancy which is two or more standard deviations from published norms; **OR**
     - Total bilateral maxillary palatal cusp to mandibular fossa discrepancy of 4 mm or greater, or a unilateral discrepancy of 3 mm or greater, given normal axial inclination of the posterior teeth;
  4. Anteroposterior, transverse or lateral asymmetries greater than 3 mm with concomitant occlusal asymmetry;

AND

- Functional deficits including ONE or MORE of the following:
  1. Difficulty with swallowing or chewing
     - Symptoms must be documented in the medical record and must persist for at least four (4) months; **AND**
     - Other causes of swallowing, choking or chewing problems have been ruled out through physical exam and/or appropriate diagnostic study including but not limited to allergies, neurologic or metabolic disease, or hypothyroidism; **OR**
  2. Speech abnormalities determined by a multidisciplinary team (e.g, speech pathologist or therapist along with a cleft palate or craniofacial specialist) to be due to the facial skeletal deformity and not alleviated by speech therapy or orthodontia; **OR**
  3. Obstructive sleep apnea that has been evaluated and documented and is not treatable or is unresponsive after appropriate medical management has been attempted. (**Refer to the medical policy on Treatment for Obstructive Sleep Apnea and Snoring in Adults, IV-07, for treatments that may be considered medically**

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necessary in the management of OSA); **OR**

4. Temporomandibular disorder (TMD) not responsive to nonsurgical treatments including those that mimic the effects of occlusal alteration such as removable intra-oral devices, orthotics, or splints. (**Refer to the medical policy on Treatment for Temporomandibular Disorder (TMD), II-07, for treatments that may be considered medically necessary in the management of TMD**).

II. Certain procedures performed in conjunction with orthognathic surgery are considered cosmetic as they are performed primarily to enhance or otherwise alter physical appearance without correcting or improving physiological function. Those procedures include, but are not limited to:

- Rhinoplasty
- Genioplasty/mentoplasty
- Rhytidectomy

Osteochondral Allografts and Autografts in the Treatment of Focal Articular Cartilage Lesions, IV-115

I. Osteochondral Allografting

- Osteochondral allografting may be considered **MEDICALLY NECESSARY AND APPROPRIATE** for the treatment of symptomatic full-thickness articular cartilage defects of the knee caused by acute or repetitive trauma, in patients who have had an inadequate response to a prior surgical procedure (e.g., debridement, subchondral drilling, abrasion arthroscopy, microfracture) or are not candidates for such procedures, when **ALL** the following criteria are met:
  - Patient is an adult **OR** a skeletally mature adolescent with documented closure of growth plates (e.g., 15 years or older);
  - Total area of the cartilage lesion (i.e., length x width, in centimeters or cm) is greater than 1.5 cm2 (centimeters squared);
  - Focal full-thickness (modified Outerbridge grade III or IV) cartilage lesions on the weight-bearing surface of the femoral condyles (medial or lateral) or trochlea;
  - Documented minimal to absent degenerative changes in the surrounding articular cartilage (modified Outerbridge grade II or less) and normal appearing hyaline cartilage surrounding the border of the defect;
  - Presence of persistent symptoms (e.g., pain, swelling and catching/locking) that significantly limit activities of daily living;
  - Presence of stable ligaments (if ligaments are unstable, documentation should be provided as to how this condition will be addressed);
  - No malalignment present (if malalignment is present, documentation should indicate planned concurrent correction of alignment).
- The following are considered **EXPERIMENTAL/INVESTIGATIVE** due to a lack of evidence demonstrating an impact on improved health outcomes:
  - Osteochondral allografting for articular cartilage defects of the knee that do not meet medical necessity criteria above
  - Osteochondral allografting for all other indications and in all other joints including but not limited to the talus, patella or tibia
  - Allograft minced cartilage for all indications and in all joints
  - Decellularized osteochondral graft plugs (eg., Chondrofix) for all indications and in all joints
  - Allograft discs (e.g., ProChondrix, Cartiform) for all indications and in all joints

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II. Osteochondral Autografting

- Osteochondral autografting (OATS or autologous mosaicplasty), using one or more cores of osteochondral tissue, may be considered **MEDICALLY NECESSARY AND APPROPRIATE** for the treatment of symptomatic, full-thickness cartilage defects of the knee caused by acute or repetitive trauma in patients who have had an inadequate response to a prior surgical procedure (e.g., debridement, subchondral drilling, abrasion arthroscopy, microfracture) or are not candidates for such procedures, when **ALL** the following criteria are met:
  - Patient is an adult OR a skeletally mature adolescent with documented closure of growth plates (e.g., 15 years or older);
  - Total area of the cartilage lesion (i.e., length x width, in centimeters or cm) is ≥ 1.0 cm2 (centimeters squared) and ≤ 4.0 cm2;
  - Focal full-thickness (modified Outerbridge grade III or IV) cartilage lesions on the weight-bearing surface of the femoral condyles (medial or lateral) or trochlea;
  - Documented minimal to absent degenerative changes in the surrounding articular cartilage (modified Outerbridge grade II or less) and normal appearing hyaline cartilage surrounding the border of the defect;
  - Presence of persistent symptoms (e.g., pain, swelling and catching/locking) that significantly limit activities of daily living;
  - Presence of stable ligaments (if ligaments are unstable, documentation should be provided as to how this condition will be addressed);
  - No malalignment present (if malalignment is present, documentation should indicate planned concurrent correction of alignment).
- The following are considered **EXPERIMENTAL/INVESTIGATIVE** due to a lack of evidence demonstrating an impact on improved health outcomes:
  - Osteochondral autografting for articular cartilage defects of the knee that do not meet medical necessity criteria above
  - Osteochondral autografting for all other indications and in all other joints including but not limited to the talus, patella or tibia
  - Autograft minced cartilage procedures for all indications and in all joints

Rituximab, II-47

I. Initial and Renewal Review for Oncologic Indications

Intravenous rituximab may be considered **MEDICALLY NECESSARY AND APPROPRIATE** for oncologic indications when **ALL** of the following criteria are met:

- The patient has a diagnosis of ONE of the following:
  - Acute lymphoblastic/lymphocytic leukemia (ALL); OR
  - Central nervous system (CNS) lymphoma, including but not limited to:
    - Primary CNS lymphoma; or
    - Leptomeningeal metastases from lymphomas. OR
  - Hodgkin lymphoma, including but not limited to:
    - Nodular lymphocyte-predominant Hodgkin lymphoma. OR
  - Non-Hodgkin lymphoma (NHL), including but not limited to:
    - AIDS-related B-cell lymphoma; or
    - B-cell lymphoma; or
    - Burkitt lymphoma; or
    - Castleman's disease (angiofollicular lymph node hyperplasia); or

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  - Chronic lymphocytic leukemia (CLL); or
  - Chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL); or
  - Diffuse large B-cell lymphoma (DLBCL); or
  - Follicular lymphoma; or
  - Gastric mucosa-associated lymphoid tissue (MALT) lymphoma; or
  - Hairy cell leukemia; or
  - Lymphoblastic lymphoma; or
  - Mantle cell lymphoma; or
  - Nodal marginal zone lymphoma; or
  - Non-gastric MALT lymphoma; or
  - Post-transplant lymphoproliferative disorder (PTLD); or
  - Primary cutaneous B-cell lymphoma; or
  - Splenic marginal zone lymphoma. OR
- Waldenstrom's macroglobulinemia (lymphoplasmacytic lymphoma).;

AND

- The patient does not have any FDA labeled contraindications to therapy (see table 1 below);

AND

- The dose is within the FDA labeled dose for the labeled indications or is supported in literature for additional indications.

Subcutaneous rituximab may be considered **MEDICALLY NECESSARY AND APPROPRIATE** for **oncologic indications** when **ALL** of the following criteria are met:

- The patient has a diagnosis of ONE of the following:
  - Chronic lymphocytic leukemia (CLL); or
  - Chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL); or
  - Diffuse large B-cell lymphoma (DLBCL); or
  - Follicular lymphoma (FL);

  AND
- The patient does not have any FDA labeled contraindications to therapy (see table 1 below); **AND**
- For initial review, the patient has received one full dose of intravenous rituximab; **AND**
- The dose is within the FDA labeled dose for the labeled indications.

II. Initial Review for Non-Oncologic Indications

Intravenous rituximab may be considered **MEDICALLY NECESSARY AND APPROPRIATE** for non-oncologic indications when **ALL** of the following criteria are met:

- The patient has a diagnosis of ONE of the following:
  - Autoimmune hemolytic anemia (AIHA); OR
  - Autoimmune mucocutaneous blistering disease (pemphigus vulgaris, pemphigus foliaceus, paraneoplastic pemphigus, bullous pemphigoid, mucous membrane pemphigoid, or epidermolysis bullosa acquisita) **AND** ONE of the following:

    The patient is currently receiving rituximab; OR
    - The patient has failed glucocorticoid therapy OR has a documented intolerance, FDA labeled contraindication, or hypersensitivity to at least one glucocorticoid. OR
  - Chronic graft versus host disease **AND** ONE of the following:

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  - The patient is currently receiving rituximab; OR
  - BOTH of the following:
    1. The patient has failed an immunosuppressant OR has a documented intolerance, FDA labeled contraindication, or hypersensitivity to at least one immunosuppressant; AND
    2. The patient has failed glucocorticoid therapy OR has a documented intolerance, FDA labeled contraindication, or hypersensitivity to at least one glucocorticoid. OR
- Chronic idiopathic/immune thrombocytopenic purpura (ITP) **AND** ONE of the following:
  - The patient is currently receiving rituximab; OR
  - The patient has had an inadequate response to splenectomy, glucocorticoid therapy, or immune globulin therapy; OR
  - The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to immune globulin therapy AND at least one glucocorticoid. OR
- Dermatomyositis **AND** ONE of the following:
  - The patient is currently receiving rituximab; OR
  - BOTH of the following:
    1. The patient has failed an immunosuppressant OR has a documented intolerance, FDA labeled contraindication, or hypersensitivity to at least one immunosuppressant; AND
    2. The patient has failed glucocorticoid therapy OR has a documented intolerance, FDA labeled contraindication, or hypersensitivity to at least one glucocorticoid. OR
- Granulomatosis with polyangiitis (GPA or Wegener's granulomatosis) and microscopic polyangiitis (MPA) **AND** ONE of the following:
  - The patient will receive glucocorticoid therapy in combination with rituximab; OR
  - The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to at least one glucocorticoid. OR
- Moderately to severely active rheumatoid arthritis in a patient 18 years of age or older **AND** ONE of the following:
  - The patient is currently receiving rituximab; OR
  - The patient has failed at least one tumor necrosis factor (TNF) antagonist OR has a documented intolerance, FDA labeled contraindication, or hypersensitivity to at least one TNF antagonist. OR
- Neuromyelitis optica; OR
- Polymyositis **AND** ONE of the following:
  - The patient is currently receiving rituximab; OR
  - BOTH of the following:
    1. The patient has failed an immunosuppressant OR has a documented intolerance, FDA labeled contraindication, or hypersensitivity to at least one immunosuppressant; AND
    2. The patient has failed glucocorticoid therapy OR has a documented intolerance, FDA labeled contraindication, or hypersensitivity to at least one glucocorticoid. OR
- Prior to renal transplantation, for patients at high risk of antibody-mediated rejection, including highly sensitized patients and those receiving an ABO incompatible organ; OR
- Thrombotic thrombocytopenic purpura (TTP) **AND** ONE of the following:
  - The patient will receive plasma exchange and glucocorticoid therapy in combination with rituximab; OR
  - The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to plasma exchange AND at least one glucocorticoid;

AND

- The patient does not have any FDA labeled contraindications to therapy (see table 1 below); **AND**

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- The patient is not currently being treated with another biologic immunomodulator; AND
- For patients not currently receiving rituximab, the patient has been screened for hepatitis B infection and has begun therapy if appropriate; **AND**
- The dose is within the FDA labeled dose for the labeled indications or is supported in literature for additional indications (see table 2 below).

III. Renewal Review for Non-Oncologic Indications

Intravenous rituximab may be considered **MEDICALLY NECESSARY AND APPROPRIATE** for **non-oncologic indications** 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 with rituximab (see table 1 below); **AND**
- The patient is not currently being treated with another biologic immunomodulator; **AND**
- The dose is within the FDA labeled dose for the labeled indications or is supported in literature for additional indications (see table 2 below).

IV. The use of intravenous or subcutaneous rituximab is considered **EXPERIMENTAL/INVESTIGATIVE** for all other indications due to the lack of clinical evidence demonstrating an impact on improved health outcomes.

- **Table 1. FDA Labeled Contraindications**

AGENT	FDA CONTRAINDICATIONS
Rituximab (Rituxan ®)	None
Rituximab and hyaluronidase (Rituxan HycelaTM)	None

- **Table 2. 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
Rheumatoid arthritis (RA)	Two 1000 mg infusions separated by 2 weeks. Subsequent courses every 24 weeks or based on clinical response, not less than every 16 weeks.
Granulomatosis with polyangiitis (GPA or Wegener's granulomatosis)	375 mg/m^2 once weekly for 4 weeks. Subsequent courses have not been evaluated.
Microscopic polyangiitis (MPA)	375 mg/m^2 once weekly for 4 weeks. Subsequent courses have not been evaluated.
Off Label Indications	**Dosing**

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Autoimmune hemolytic anemia (AIHA)	375 mg/m^2 once weekly for 4 weeks.
Chronic graft-versus-host disease (cGVHD)	375 mg/m^2 once weekly for 4 weeks.
Idiopathic/immune thrombocytopenic purpura (ITP)	375 mg/m^2 once weekly for 4 weeks.
Autoimmune mucocutaneous blistering diseases	375 mg/m^2 once weekly for 4 weeks OR two 1000 mg infusions separated by 2 weeks
Neuromyelitis optica (NMO)	375 mg/m^2 once weekly for 4 weeks OR two 1000 mg infusions separated by 2 weeks
Thrombotic thrombocytopenic purpura (TTP)	375 mg/m^2 once weekly for 4 weeks
Dermatomyositis	375 mg/m^2 once weekly for 4 weeks OR two 1000 mg infusions separated by 2 weeks
Polymyositis	375 mg/m^2 once weekly for 4 weeks OR two 1000 mg infusions separated by 2 weeks
Prior to renal transplantation, for patients at high risk of antibody- mediated rejection	375 mg/m^2 or 1000 mg prior to transplantation

Documentation Submission

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

Initial Review for Non-Oncologic Indications

1. Clinical notes describing the diagnosis and clinical features of the diagnosis.
2. For patients not currently receiving rituximab, laboratory results for hepatitis B screening. If the test was positive, describe follow-up therapy.
3. Clinical notes describing current and past medications for the diagnosis, including response to the medications.
4. The dose being requested, including the patient's weight if the diagnosis requires weight-based dosing. 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 for Non-Oncologic Indications

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

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for the medical necessity of the requested dose MUST be submitted, including prior dosing (strength and frequency) associated with inadequate response.

Abatacept, Il-161

NOTE: When abatacept (Orencia®) will be self-administered by subcutaneous injection, please refer to applicable pharmacy benefit plan.

I. Initial Review

Abatacept 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:
  - Moderately to severely active rheumatoid arthritis in a patient 18 years of age or older; OR
  - Moderately to severely active polyarticular juvenile idiopathic arthritis in a patient 2 years of age or older; OR
  - Active psoriatic arthritis in a patient 18 years of age or older.

  AND
- **ONE** of the following:
  - The patient is currently receiving the requested biologic immunomodulator; OR
  - The patient has previously failed another biologic immunomodulator with FDA approval for the same indication; OR
  - The patient has used one conventional agent prerequisite for the indication (see table 2 below); OR
  - The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to at least one conventional agent.

  AND
- The patient does not have any FDA labeled contraindications to therapy (see table 1 below); **AND**
- The patient is not currently being treated with another biologic immunomodulator; **AND**
- For patients not currently receiving the requested biologic immunomodulator, the patient has been screened for latent tuberculosis (TB) and started on TB therapy if the patient tests positive; **AND**
- The dose is within the FDA labeled dose for the labeled indications (see table 3 below).

II. Renewal Review

Abatacept 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 the requested agent (see table 1 below); **AND**
- The patient is not currently being treated with another biologic immunomodulator; **AND**
- The dose is within the FDA labeled dose for the labeled indications (see table 3 below).

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

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- **Table 1. FDA Labeled Contraindications**

AGENT	FDA LABELED CONTRAINDICATIONS
Abatacept	None

- **Table 2. Conventional Agent Prerequisites**

FDA LABELED INDICATIONS	CONVENTIONAL AGENT PREREQUISITES
Rheumatoid arthritis (RA) Psoriatic arthritis (PsA) Polyarticular juvenile idiopathic arthritis (PJIA)	methotrexate leflunomide minocycline sulfasalazine hydroxychloroquine

- **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
Rheumatoid arthritis – monotherapy or in combination with non-TNF DMARD	IV: 500 mg for those <60 kg, 750 mg for those 60-100 kg, 1000 mg for those >100 kg at weeks 0, 2, and 4, then every 4 weeks. SC: 125 mg once weekly with or without initial IV loading dose
Polyarticular juvenile idiopathic arthritis – 2 years or older as monotherapy or in combination with methotrexate	IV: 10 mg/kg for those <75 kg, adult dose up to 1000 mg for those ≥75 kg at weeks 0, 2, and 4, then every 4 weeks. SC: 50 mg for those 10 to <25 kg, 87.5 mg for those 25 to <50 kg, 125 mg for those ≥50 kg once weekly.
Psoriatic arthritis	IV: 500 mg for those <60 kg, 750 mg for those 60-100 kg, 1000 mg for those >100 kg at weeks 0, 2, and 4, then every 4 weeks. SC: 125 mg once weekly.

IV (intravenous); SC (subcutaneous)

Documentation Submission

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

Initial Review

1. Clinical notes describing the diagnosis and clinical features of the diagnosis.
2. For patients not currently receiving the requested biologic immunomodulator, laboratory results for latent tuberculosis (TB) screening. If the test was positive, describe follow-up therapy.

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3. Clinical notes describing current and past medications for the diagnosis, including response to the medications.
4. The dose being requested, including the patient's weight if the requested biologic immunomodulator and diagnosis require weight-based dosing. 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 the requested biologic immunomodulator through the initial review process.
2. Documentation supporting positive clinical response (e.g., slowing of disease progression or decrease in symptom severity and/or frequency).
3. Clinical notes describing current and past medications for the diagnosis, including response to the medications.
4. The dose being requested, including the patient's weight if the requested biologic immunomodulator and diagnosis require weight-based dosing. 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.

Certolizumab Pegol, Il-179

NOTE: When certolizumab pegol (Cimzia®) will be self-administered by subcutaneous injection, please refer to applicable pharmacy benefit plan.

I. Initial Review

Certolizumab pegol 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 **ONE** of the following:
  - Moderately to severely active rheumatoid arthritis; OR
  - Moderately to severely active Crohn's disease; OR
  - Active psoriatic arthritis; OR
  - Active ankylosing spondylitis.

  AND
- **ONE** of the following:
  - The patient is currently receiving the requested biologic immunomodulator; OR
  - The patient has previously failed another biologic immunomodulator with FDA approval for the same indication; OR
  - The patient has used one conventional agent prerequisite for the indication (see table 2 below); OR
  - The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to at least one conventional agent.

  AND
- The patient does not have any FDA labeled contraindications to therapy (see table 1 below); **AND**
- The patient is not currently being treated with another biologic immunomodulator; **AND**

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- For patients not currently receiving the requested biologic immunomodulator, the patient has been screened for latent tuberculosis (TB) and started on TB therapy if the patient tests positive; **AND**
- The dose is within the FDA labeled dose for the labeled indications (see table 3 below).

II. Renewal Review

Certolizumab pegol 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 the requested agent (see table 1 below); **AND**
- The patient is not currently being treated with another biologic immunomodulator; **AND**
- The dose is within the FDA labeled dose for the labeled indications (see table 3 below).

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

- **Table 1. FDA Labeled Contraindications**

AGENT	FDA LABELED CONTRAINDICATIONS
Certolizumab pegol	None

- **Table 2. Conventional Agent Prerequisites**

FDA LABELED INDICATIONS	CONVENTIONAL AGENT PREREQUISITES
Rheumatoid arthritis (RA) Psoriatic arthritis (PsA)	methotrexate leflunomide minocycline sulfasalazine hydroxychloroquine
Crohn's disease (CD)	methotrexate aminosalicylates corticosteroids (including budesonide EC capsule) cyclosporine azathioprine 6-mercaptopurine metronidazole ciprofloxacin
Ankylosing spondylitis (AS)	NSAIDs (ibuprofen, ketoprofen, celecoxib)

- **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

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Crohn's disease – after inadequate response to conventional therapy	400 mg at weeks 0, 2, and 4, then 400 mg every 4 weeks
Rheumatoid arthritis	400 mg at weeks 0, 2, and 4, then 200 mg every other week or 400 mg every 4 weeks
Psoriatic arthritis	400 mg at weeks 0, 2, and 4, then 200 mg every other week or 400 mg every 4 weeks
Ankylosing spondylitis (AS)	400 mg at weeks 0, 2, and 4, then 200 mg every other week or 400 mg every 4 weeks

Documentation Submission:

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

Initial Review

1. Clinical notes describing the diagnosis and clinical features of the diagnosis.
2. For patients not currently receiving the requested biologic immunomodulator, laboratory results for latent tuberculosis (TB) screening. If the test was positive, describe follow-up therapy.
3. Clinical notes describing current and past medications for the diagnosis, including response to the medications.
4. The dose being requested, including the patient's weight if the requested biologic immunomodulator and diagnosis require weight-based dosing. 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 the requested biologic immunomodulator through the initial review process.
2. Documentation supporting positive clinical response (e.g., slowing of disease progression or decrease in symptom severity and/or frequency).
3. Clinical notes describing current and past medications for the diagnosis, including response to the medications.
4. The dose being requested, including the patient's weight if the requested biologic immunomodulator and diagnosis require weight-based dosing. 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.

Golimumab (Simponi Aria), II-180

NOTE: This policy addresses intravenous golimumab (Simponi Aria®) only. When golimumab will be administered by subcutaneous injection, please refer to applicable pharmacy benefit plan.

I. Initial Review

Intravenous golimumab 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 rheumatoid arthritis; **AND**
- **ONE** of the following:

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- The patient is currently receiving the requested biologic immunomodulator; OR
- The patient has previously failed another biologic immunomodulator with FDA approval for the same indication; OR
- The patient has used one conventional agent prerequisite for the indication (see table 2 below); OR
- The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to at least one conventional agent.

AND

- The patient does not have any FDA labeled contraindications to therapy (see table 1 below); **AND**
- The patient is not currently being treated with another biologic immunomodulator; **AND**
- For patients not currently receiving the requested biologic immunomodulator, the patient has been screened for latent tuberculosis (TB) and started on TB therapy if the patient tests positive; **AND**
- The dose is within the FDA labeled dose for the labeled indications (see table 3 below).

II. Renewal Review

Intravenous golimumab 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 the requested agent (see table 1 below); **AND**
- The patient is not currently being treated with another biologic immunomodulator; **AND**
- The dose is within the FDA labeled dose for the labeled indications (see table 3 below).

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

- **Table 1. FDA Labeled Contraindications**

AGENT	FDA LABELED CONTRAINDICATIONS
Intravenous golimumab	None

- **Table 2. Conventional Agent Prerequisites**

FDA LABELED INDICATIONS	CONVENTIONAL AGENT PREREQUISITES
Rheumatoid arthritis (RA)	methotrexate leflunomide minocycline sulfasalazine hydroxychloroquine

- **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

(continued on next page)

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Rheumatoid arthritis – in combination with methotrexate	2 mg/kg at weeks 0 and 4, then every 8 weekss

Documentation Submission:

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

Initial Review

1. Clinical notes describing the diagnosis and clinical features of the diagnosis.
2. For patients not currently receiving the requested biologic immunomodulator, laboratory results for latent tuberculosis (TB) screening. If the test was positive, describe follow-up therapy.
3. Clinical notes describing current and past medications for the diagnosis, including response to the medications.
4. The dose being requested, including the patient's weight if the requested biologic immunomodulator and diagnosis require weight-based dosing. 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 the requested biologic immunomodulator through the initial review process.
2. Documentation supporting positive clinical response (e.g., slowing of disease progression or decrease in symptom severity and/or frequency).
3. Clinical notes describing current and past medications for the diagnosis, including response to the medications.
4. The dose being requested, including the patient's weight if the requested biologic immunomodulator and diagnosis require weight-based dosing. 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.

Tocilizumab, Il-181

NOTE: When tocilizumab (Actemra®) will be self-administered by subcutaneous injection, please refer to applicable pharmacy benefit plan.

I. Initial and Renewal Review for Oncologic Indications

Tocilizumab may be considered **MEDICALLY NECESSARY AND APPROPRIATE** for **oncologic indications** when **ALL** of the following criteria are met:

- The patient has a diagnosis of **ONE** of the following:
  - Chimeric antigen receptor (CAR) T cell-induced severe or life-threatening cytokine release syndrome associated with treatment of oncologic indications; OR
  - Castleman's disease (angiofollicular lymph node hyperplasia) **AND ONE** of the following:
    - Tocilizumab will be used as second-line therapy as a single agent for relapsed or refractory unicentric Castleman's disease for patients who are human immunodeficiency virus-negative and human herpesvirus-8-negative; OR
    - Tocilizumab will be used as subsequent therapy as a single agent for multicentric Castleman's disease that has progressed following treatment of relapsed/refractory or progressive disease.

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AND

- The patient does not have any FDA labeled contraindications to therapy (see table 1 below);

AND

- The dose is within the FDA labeled dose for the labeled indications or is supported in the literature for additional indications.

II. Initial Review for Non-Oncologic Indications

Tocilizumab may be considered **MEDICALLY NECESSARY AND APPROPRIATE** for **non- oncologic indications** when **ALL** of the following criteria are met:

- The patient has a diagnosis of **ONE** of the following:
  - Moderately to severely active rheumatoid arthritis in a patient 18 years of age or older; OR
  - Active polyarticular juvenile idiopathic arthritis in a patient 2 years of age or older; OR
  - Active systemic juvenile idiopathic arthritis in a patient 2 years of age or older; OR
  - Giant cell arteritis in a patient 18 years of age or older.
  - **NOTE:** See policy section I for chimeric antigen receptor (CAR) T cell-induced severe or life-threatening cytokine release syndrome.

  AND
- **ONE** of the following:
  - The patient is currently receiving the requested biologic immunomodulator; OR
  - The patient has previously failed another biologic immunomodulator with FDA approval for the same indication; OR
  - The patient has used one conventional agent prerequisite for the indication (see table 2 below); OR
  - The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to at least one conventional agent.

  AND
- The patient does not have any FDA labeled contraindications to therapy (see table 1 below); **AND**
- The patient is not currently being treated with another biologic immunomodulator; **AND**
- For patients not currently receiving the requested biologic immunomodulator, the patient has been screened for latent tuberculosis (TB) and started on TB therapy if the patient tests positive; **AND**
- The dose is within the FDA labeled dose for the labeled indications (see table 3 below).

III. Renewal Review for Non-Oncologic Indications

Tocilizumab may be considered **MEDICALLY NECESSARY AND APPROPRIATE** for **non- oncologic indications** 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 the requested agent (see table 1 below); **AND**
- The patient is not currently being treated with another biologic immunomodulator; **AND**

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

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

- **Table 1. FDA Labeled Contraindications**

AGENT	FDA LABELED CONTRAINDICATIONS
Tocilizumab	Hypersensitivity

- **Table 2. Conventional Agent Prerequisites**

FDA LABELED INDICATIONS	CONVENTIONAL AGENT PREREQUISITES
Rheumatoid arthritis (RA) Polyarticular juvenile idiopathic arthritis (PJIA) Systemic juvenile idiopathic arthritis (SJIA)	methotrexate leflunomide minocycline sulfasalazine hydroxychloroquine
Giant cell arteritis (GCA)	systemic corticosteroids (e.g., prednisone, methylprednisolone)

- **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
Rheumatoid arthritis – inadequate response to 1 or more DMARDs	IV: 4-8 mg/kg every 4 weeks. Not to exceed 800 mg per infusion. SC: 162 mg weekly.
PJIA – in patients 2 years or older	IV: 10 mg/kg for those <30 kg, 8 mg/kg for those ≥30 kg every 4 weeks
SJIA – in patients 2 years or older	IV: 12 mg/kg for those <30 kg, 8 mg/kg for those ≥30 kg every 2 weeks
Giant cell arteritis	SC: 162 mg once every week. Once every other week may be prescribed based on clinical considerations.

IV (intravenous); SC (subcutaneous)

General Dosing Information: It is recommended that tocilizumab not be initiated in patients with an absolute neutrophil count (ANC) below 2000 per mm^3, platelet count below 100,000 per mm^3, or who have ALT or AST above 1.5 times the upper limit of normal (ULN).

Documentation Submission:

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

Initial Review for Non-Oncologic Indications

1. Clinical notes describing the diagnosis and clinical features of the diagnosis.

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2. For patients not currently receiving the requested biologic immunomodulator, laboratory results for latent tuberculosis (TB) screening. If the test was positive, describe follow-up therapy.
3. Clinical notes describing current and past medications for the diagnosis, including response to the medications.
4. The dose being requested, including the patient's weight if the requested biologic immunomodulator and diagnosis require weight-based dosing. 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 for Non-Oncologic Indications

1. Documentation of prior approval for the requested biologic immunomodulator through the initial review process.
2. Documentation supporting positive clinical response (e.g., slowing of disease progression or decrease in symptom severity and/or frequency).
3. Clinical notes describing current and past medications for the diagnosis, including response to the medications.
4. The dose being requested, including the patient's weight if the requested biologic immunomodulator and diagnosis require weight-based dosing. 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.

Ustekinumab, Il-168

NOTE: When ustekinumab (Stelara®) will be self-administered by subcutaneous injection, please refer to applicable pharmacy benefit plan.

I. Initial Review

Ustekinumab 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 **ONE** of the following:
  - Moderate to severe plaque psoriasis; OR
  - Active psoriatic arthritis; OR
  - Moderately to severely active Crohn's disease.

  AND
- **ONE** of the following:
  - The patient is currently receiving the requested biologic immunomodulator; OR
  - The patient has previously failed another biologic immunomodulator with FDA approval for the same indication; OR
- The patient has used one conventional agent prerequisite for the indication (see table 2 below); OR
- The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to at least one conventional agent.

  AND
- The patient does not have any FDA labeled contraindications to therapy (see table 1 below); **AND**

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- The patient is not currently being treated with another biologic immunomodulator; **AND**
- For patients not currently receiving the requested biologic immunomodulator, the patient has been screened for latent tuberculosis (TB) and started on TB therapy if the patient tests positive; **AND**
- The dose is within the FDA labeled dose for the labeled indications (see table 3 below).

II. Renewal Review

Ustekinumab 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 the requested agent (see table 1 below); **AND**
- The patient is not currently being treated with another biologic immunomodulator; **AND**
- The dose is within the FDA labeled dose for the labeled indications (see table 3 below).

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

- **Table 1. FDA Labeled Contraindications**

AGENT	FDA LABELED CONTRAINDICATIONS
Ustekinumab	Hypersensitivity

- **Table 2. Conventional Agent Prerequisites**

FDA LABELED INDICATIONS	CONVENTIONAL AGENT PREREQUISITES
Psoriatic arthritis (PsA	methotrexate leflunomide minocycline sulfasalazine hydroxychloroquine

(continued on next page)

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Psoriasis (Ps)	methotrexate topical corticosteroids coal tar products anthralin calcipotriene calcitriol acitretin tazarotene cyclosporine methoxsalen tacrolimus pimecrolimus PUVA (phototherapy)
Crohn's disease (CD)	methotrexate aminosalicylates corticosteroids (including budesonide EC capsule) cyclosporine azathioprine 6-mercaptopurine metronidazole ciprofloxacin

- **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
Psoriasis – who are candidates for phototherapy or systemic therapy	<100 kg: 45 mg at weeks 0 and 4, then 45 mg every 12 weeks. >100 kg: 90 mg at weeks 0 and 4, then 90 mg every 12 weeks
Psoriatic Arthritis – monotherapy or in combination with methotrexate	45 mg at weeks 0 and 4, then 45 mg every 12 weeks Ps and PsA and >100 kg - 90 mg at weeks 0 and 4, then every 12 weeks
Crohn's Disease – after failure or intolerance to TNF or immunomodulators or corticosteroids	IV induction: 260 mg for those <55 kg, 390 mg for those 56 to 85 kg, and 520 mg for those >85 kg. SC maintenance: 90 mg at week 8, then every 8 weeks

IV (intravenous); SC (subcutaneous)

Documentation Submission:

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

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Initial Review

1. Clinical notes describing the diagnosis and clinical features of the diagnosis.
2. For patients not currently receiving the requested biologic immunomodulator, laboratory results for latent tuberculosis (TB) screening. If the test was positive, describe follow-up therapy.
3. Clinical notes describing current and past medications for the diagnosis, including response to the medications.
4. The dose being requested, including the patient's weight if the requested biologic immunomodulator and diagnosis require weight-based dosing. 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 the requested biologic immunomodulator through the initial review process.
2. Documentation supporting positive clinical response (e.g., slowing of disease progression or decrease in symptom severity and/or frequency).
3. Clinical notes describing current and past medications for the diagnosis, including response to the medications.
4. The dose being requested, including the patient's weight if the requested biologic immunomodulator and diagnosis require weight-based dosing. 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.

Vedolizumab II-182

I. Initial Review

Vedolizumab 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 **ONE** of the following:
  - Moderately to severely active Crohn's disease; OR
  - Moderately to severely active ulcerative colitis.

  AND
- **ONE** of the following:
  - The patient is currently receiving the requested biologic immunomodulator; OR
  - The patient has previously failed another biologic immunomodulator with FDA approval for the same indication; OR
  - The patient has used one conventional agent prerequisite for the indication (see table 2 below); OR
  - The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to at least one conventional agent.

  AND
- The patient does not have any FDA labeled contraindications to therapy (see table 1 below); **AND**

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- The patient is not currently being treated with another biologic immunomodulator; **AND**
- For patients not currently receiving the requested biologic immunomodulator, the patient has been screened for latent tuberculosis (TB) and started on TB therapy if the patient tests positive; **AND**
- The dose is within the FDA labeled dose for the labeled indications (see table 3 below).

II. Renewal Review

Vedolizumab 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 the requested agent (see table 1 below); **AND**
- The patient is not currently being treated with another biologic immunomodulator; **AND**
- The dose is within the FDA labeled dose for the labeled indications (see table 3 below).

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

• Table 1. FDA Labeled Contraindications

AGENT	FDA LABELED CONTRAINDICATIONS
Vedolizumab	Hypersensitivity

• Table 2. Conventional Agent Prerequisites

FDA LABELED INDICATIONS	CONVENTIONAL AGENT PREREQUISITES
Crohn's disease (CD) Ulcerative colitis (UC)	methotrexate aminosalicylates corticosteroids (including budesonide EC capsule) cyclosporine azathioprine 6-mercaptopurine metronidazole ciprofloxacin

MEDICAL AND BEHAVIORAL HEALTH POLICY UPDATE

- **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
Crohn's disease – after inadequate response, loss of response, or intolerance to TNF or immunomodulator or corticosteroid dependence with loss of response, inadequate response, or intolerance	300 mg at weeks 0, 2, and 6, then every 8 weeks Note: Discontinue if no therapeutic benefit by week 14.
Ulcerative colitis – after inadequate response, loss of response, or intolerance to TNF or immunomodulator or corticosteroid dependence with loss of response, inadequate response, or intolerance	300 mg at weeks 0, 2, and 6, then every 8 weeks Note: Discontinue if no therapeutic benefit by week 14.

Documentation Submission:

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

Initial Review

1. Clinical notes describing the diagnosis and clinical features of the diagnosis.
2. For patients not currently receiving the requested biologic immunomodulator, laboratory results for latent tuberculosis (TB) screening. If the test was positive, describe follow-up therapy.
3. Clinical notes describing current and past medications for the diagnosis, including response to the medications.
4. The dose being requested, including the patient's weight if the requested biologic immunomodulator and diagnosis require weight-based dosing. 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 the requested biologic immunomodulator through the initial review process.
2. Documentation supporting positive clinical response (e.g., slowing of disease progression or decrease in symptom severity and/or frequency).
3. Clinical notes describing current and past medications for the diagnosis, including response to the medications.
4. The dose being requested, including the patient's weight if the requested biologic immunomodulator and diagnosis require weight-based dosing. 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.

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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

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

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