Provider Press

Provider information

December 2016 / Vol. 21, No. 3

BlueCross BlueShield Minnesota

MEASURING CONTINUITY AND COORDINATION OF CARE

Serious problems can occur for patients undergoing transitions across sites of care. The problems can affect the quality of care received and the effectiveness of health care services and treatment regimens. There are several ways that Blue Cross measures effective continuity and coordination of care for our members. The Healthcare Effectiveness Data and Information Set (HEDIS) provides some key metrics that may be used as markers for effective coordination of care across various specialties and care settings. For example, the All-Cause Readmission measure can be used to review whether plans, their network of providers, and members are taking appropriate actions to reduce readmissions. When coupled with other use-of-services and clinical quality data, readmission measure results can be used by plans to evaluate interventions related to care coordination and continuity of care, and to other factors that affect readmission rates.

There are several other HEDIS measures that study coordination of care, such as:

- Annual Monitoring for Patients on Persistent Medications
- Antidepressant Medication Management
- Cardiovascular Monitoring for People With Cardiovascular Disease and Schizophrenia
- Diabetes Monitoring for People With Diabetes and Schizophrenia
- Follow-Up After Hospitalization for Mental Illness
- Follow-Up Care for Children Prescribed ADHD Medication
- Metabolic Monitoring for Children and Adolescents on Antipsychotics
- Osteoporosis Management in Women Who Had a Fracture

Patient experience measures also provide some insight into how our members feel their care is coordinated across specialties and care settings. The Consumer Assessment of Healthcare Providers and Systems (CAHPS®) survey asks patients to report on and evaluate their experiences with health care. Each year members are asked a series of questions including, *"In the last 12 months, how often did your personal doctor seem informed and up-to-date about the care you got from these doctors or other health providers?"* The intent of this question is to measure members' experience with coordination of care. In addition, Blue Cross conducts surveys with our network providers related to continuity and coordination of care.

Particularly challenging to continuity and coordination are concepts such as access to care (availability of after-hours care, access to medical insurance, transportation to locations of care, ability to understand and navigate the health care system), continuity of care (a continuous relationship with a single provider over time, on-going familiarity and trust), and shared decision making (engaging patients in discussions of treatment options). As the study and evolution of care coordination progresses, Blue Cross encourages our provider network to collaborate with us to develop best practices in transitions of care to help keep Minnesotans healthy.

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/healthy/public/personal/home/providers/forms-and-publications.

Inside preview

FYI

PUBLICATIONS AVAILABLE ONLINE

The following is a list of Quick Points and Bulletins published from September 2016 to November 2016 that are available online at **providers.bluecrossmn.com**. As a reminder, Bulletins are mailed to all participating providers affected by the information. Quick Points are available only on our website unless noted otherwise in the bottom left corner of the publication.

QUICK POINTS	TITLE
QP24-16	Post-Cataract Care Units Billing
QP25-16	AMP Indicator Removed from Minnesota Health Care Programs (MHCP) Subscriber ID Cards
QP26-16	Claims Filing Rules for Air Ambulance Providers
QP27-16	Information Available in Provider Press Publication
QP28-16	Reminders for Providers who Provide Interpreter Services for MHCP Subscribers
QP29-16	Implementation of New Utilization Management Platform
QP30-16	How to Submit, Inquire, or Update a Pre-admission Notification on the Availity Web Portal
QP31-16	How to Submit, Inquire or Update a Pre-Admission Notification on the Availity Web Portal
QP32-16	High Complexity Case Unit
QP33-16	Centurion Contracts with BlueLink TPA for Claims Administration Services
BULLETINS	**TITLE**
P31R1-16	Revised: Prior Authorization for Acupuncture Services for Government Programs Subscribers
P44-16	Addition of a Drug (Viekira XR) to the Hepatitis C Second Generation Prior Authorization with Quantity Limit Program
P45-16	A New Drug, Ocrevus (ocrelizumab) Will Require Prior Authorization
P46-16	Changes in Medical Policy IV-87 Spinal Fusion: Lumbar
P47-16	New Drug-Related Prior Authorization Criteria for Botulinum Toxin, Remicade, Rituxan and Biologic Immunomodulators
P48-16	Criteria Changes to Certain Services on the Prior Authorization List for MHCP Subscribers
P49-16	New Drug-Related Prior Authorization Criteria with Quantity Limit for Zavesca
P50-16	Addition of a Drug (Xiidra) to the Ophthalmic Immunomodulators Prior Authorization with Quantity Limit Program
P51-16	Addition of a Drug (Belviq XR) to the Weight Loss Agents Prior Authorization with Quantity Limit Program
P52-16	DHS Guidelines for Mental Health-Targeted Case Management Services for MHCP Subscribers
P53-16	New Notification Requirement for Outpatient Dialysis Services for Commercial Products and Subscribers in Government Programs
P54-16	Added Reimbursement Policies
P55-16	Change in Coverage for Detoxification Services for Minnesota Health Care Programs Subscribers
P56-16	A New Drug, Dupilumab Will Require Prior Authorization
P57-16	Change in Medical Policy and Commercial Benefit Coverage of CT Colonography Colorectal Cancer Screening Test

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

PROVIDER MANUAL UPDATES

The following is a list of Blue Cross provider manuals that have been updated from September 2016 to November 2016. As a reminder, provider manuals are available online at **providers.bluecrossmn.com**. To view the manuals, select "Forms & publications," then "manuals." Updates to the manuals are documented in the "Summary of changes" section of the online manuals.

MANUAL NAME	CHAPTER NUMBER AND TITLE	CHANGE
Provider Policy and Procedure Manual	Chapter 2, Provider Agreements	Content changes to Required Notification for Termination of Provider Service Agreements
Blue Plus Manual	Chapter 3, Government Programs	All Care Coordination Delegation Guidelines Updated

CODING CORNER

CONSULTATION CODE REMINDER

CMS does not allow submission of inpatient and outpatient consultation codes for Medicare claims. However, this coding and submission will be followed only for our Medicare business. There is no change for all other lines of business. Blue Cross accepts all valid HIPAA medical codes. The consultation codes 99241-99245 and 99251-99255 are still valid CPT codes and as such will be accepted for our non-Medicare business. We expect that the documentation will support any code submitted.

A POPULAR REPETITION – THE NEXT HCPCS UPDATE

On January 1, 2017 we will again be accepting the HCPCS (Level I/CPT and Level II) medical code adds and revisions effective for that date. Likewise, we will reject all discontinued codes with a date of service of January 1, 2017 or after. A Provider Quick Points will be published before the effective date to reiterate this information but sorry, we can't include the codes.

OFFICE SUPPLIES HEADED HOME

Supplies in the clinic setting are generally included or part of the procedure or service. Codes 99070, A4649 and A4550 are always denied. Other supplies, such as Betadine or alcohol wipes, will also be denied. Generally, supplies are only allowed separately in conjunction with approved home health care. Thus Blue Cross will not allow separate charges for any take home supplies.

HEARING AID FITTING UNITS

Multiple units submitted with code V5011 (Fitting/orientation/checking of hearing aid) will not be allowed. Regardless if the service is unilateral or bilateral (one or both ears), units will be limited to only one unit (1).

2017 HOLIDAY SCHEDULE

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

Monday, January 2

Monday, May 29

Monday, July 3

Tuesday, July 4

Monday, September 4

Thursday, November 23

Friday, November 24

Monday, December 25

With the exception of the dates stated above, representatives answering the provider services numbers are available to assist you 8 a.m. to 5 p.m. Monday through Thursday, and 9 a.m. to 5 p.m. on Friday.

PHARMACY SECTION

PHARMACY UPDATES FOR QUARTER 4, 2016

Drug Formulary Changes

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

ADDITIONS TO FlexRx FORMULARY	REMOVALS FROM FlexRx FORMULARY
ADYNOVATE	CUPRIMINE
COAGADEX	DUTOPROL
CONCERTA	GLEEVEC
DEPEN TITRATABS	METHYLPHENIDATE HCL ER (methylphenidate hcl tab sa osm)
DOCETAXEL (NON-ALCOHOL FORMULA)	NASONEX
NARCAN	ORTHO TRI-CYCLEN LO
PRADAXA	TEGRETOL-XR
UPTRAVI	
ADDITIONS TO GenRx FORMULARY	**REMOVALS FROM GenRx FORMULARY**
ADYNOVATE	CUPRIMINE
COAGADEX	DUTOPROL
CONCERTA	GLEEVEC
DEPEN TITRATABS	METHYLPHENIDATE HCL ER (methylphenidate hcl tab sa osm)
DOCETAXEL (NON-ALCOHOL FORMULA)	NASONEX
NARCAN	ORTHO TRI-CYCLEN LO
UPTRAVI	TEGRETOL-XR

Effective September 1, 2016, Roche brand diabetic products were removed from the FlexRx and GenRx formularies. Only Ascensia/Bayer brand diabetic products are covered.

The complete list of formulary changes can be found at:

FlexRx -
https://www.myprime.com/content/dam/prime/memberportal/forms/2016/FullyQualified/Other/ALL/BCBSMN/COMMERCIAL/MNFLEXRX/MN_FlexRx_Formulary_Update.pdf

GenRx -
https://www.myprime.com/content/dam/prime/memberportal/forms/2016/FullyQualified/Other/ALL/BCBSMN/COMMERCIAL/MNGENRX/MNSM_Formulary_Update.pdf

PHARMACY SECTION

UTILIZATION MANAGEMENT UPDATES

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:

Effective October 1, 2016

BRAND NAME (generic name - if available)	Requirement		
BEVESPI		QL	
BRIVIACT			ST
CORLANOR	PA	QL	
DORYX MPC	PA		
JENTADUETO XR 2.5-1000 mg		QL	
KUVAN	PA	QL	
LAZANDA 300 mcg	PA	QL	
LENVIMA 18 mg therapy pack	PA	QL	
LIDODERM (lidocaine) 5% patch	PA	QL	
NORTHERA 100 mg	PA	QL	
NORTHERA 200 mg & 300 mg	PA	QL	
ONZETRA		QL	
TIVICAY 10 & 25 mg		QL	
TRUVADA 100-150 mg, 133-200 mg, 167-250 mg		QL	
VENCLEXTA 10 mg	PA	QL	
VENCLEXTA 100 mg	PA	QL	
VENCLEXTA 50 mg	PA	QL	
VENCLEXTA starter pack	PA	QL	
XTAMPZA ER		QL	ST
ZINBRYTA		QL	ST

PA = Prior Authorization QL = Quantity Limit; ST = Step Therapy

In addition, information on upcoming changes to select Utilization Management programs are included below. The medical policy database will be updated to reflect these changes.

Effective December 1, 2016

- Buprenorphine and Buprenorphine/Naloxone for Opioid Dependence Prior Authorization program will be inactivated for the Commercial and Medicaid lines of business. The Buprenorphine and Buprenorphine/Naloxone for Opioid Dependence Quantity Limit program will remain in place for the Commercial and Medicaid lines of business.

(continued on next page)

UTILIZATION MANAGEMENT STATEMENT

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

PHARMACY SECTION

UTILIZATION MANAGEMENT UPDATES - continued

Effective January 1, 2017

- Proton Pump Inhibitor Quantity Limit Program will have a quantity limit change for Prilosec/omeprazole 20 mg capsules.
- The quantity limit will change from 2 capsules per day to 1 capsule per day.
- For impacted patients, providers are encouraged to consider dosing, move patients to omeprazole 40 mg capsules, re-evaluate the need for proton pump inhibitor therapy, or consider OTC products as alternatives.

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

FlexRx -
https://www.myprime.com/content/dam/prime/memberportal/forms/2016/FullyQualified/Other/ALL/BCBSMN/COMMERCIAL/MNFLEXRX/MN_FlexRx_UM_Updates.pdf

GenRx -
https://www.myprime.com/content/dam/prime/memberportal/forms/2016/FullyQualified/Other/ALL/BCBSMN/COMMERCIAL/MNGENRX/MNSM_GenRx_UM_Updates.pdf

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

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

Additional information regarding Pharmacy is also located in the Provider Policy and Procedure Manual. To access the manual go online to 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 information for the Federal Employee Program (FEP) members can be found on the Fepblue.org website. FEP members have a different PBM (Caremark) and will have different formulary list and procedures for prior authorizations and quantity limits than listed above. This information can be found by scrolling down to "Pharmacy Benefits" and selecting "Finding out more."

QUALITY IMPROVEMENT

PCC QUALITY OF CARE COMPLAINT REPORT

Providers are required to complete the Blue Plus Quality of Care Complaint report for all written and verbal complaints from Blue Plus, Prepaid Medical Assistance Program and MinnesotaCare subscribers on a quarterly basis, per Minnesota Department of Health regulations. Complaints logged at the provider offices are to be investigated and resolved by the provider's office whenever possible.

These complaints are reported to Blue Plus in January, April, July and October for the preceding three months. The Primary Care Clinic (PCC) must submit a quarterly report even if the facility does not receive any complaints for the quarter. Your contract outlines the procedures required for your Quality of Care (QOC) PCC complaint reporting adherence agreement.

Complaints should no longer be directed to the attention of a single designated person. Sending your PCC QOC complaint report form to any source not listed below may delay the processing of your PCC QOC complaint report.

To access the PCC Blue Plus Quality of Care Complaint Report Form, go to **providers.bluecrossmn.com** and select "Forms & publications," then "forms - clinical operations."

Submit quarterly PCC QOC reports using one of these methods:

Email: pcc.complaint@bluecrossmn.com

Secure fax line: **(651) 662-4004**

Mail: Blue Plus
Attn: Quality & Compliance Dept.
R472
P.O. Box 64179
St. Paul, MN 55164-0179

FYI WHO TO CONTACT?

HELPFUL PHONE NUMBERS	
BLUELINE (voice response unit)	**(651) 662-5200 or 1-800-262-0820**
BlueCard® member benefits or eligibility	**1-800-676-BLUE (2583)**
FEP® (voice response unit)	**(651) 662-5044 or 1-800-859-2128**
Availity	**1-800-282-4548**
Provider services	**(651) 662-5200 or 1-800-262-0820**
Please verify these numbers are correctly programmed into your office phones.	
For phone numbers, fax numbers and addresses for Care Management programs and services please refer to the Provider Policy and Procedure Manual, Chapter 1 "How to Contact Us" section.	

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 the link below:
https://www.bluecrossmn.com/healthy/public/personal/home/providers/admin-updates.

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

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

FYI

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 subscribers. 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. Subscribers 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 subscriber's compliance with the treatment plan
- Lack of clarity about subscriber's treatment plan

Providers may also receive a letter including the subscriber's goals and/or gaps in care to inform the provider on what Blue Cross is working on with the subscriber 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 Subscriber's Health Care Practitioners to make a healthy difference in the health of its Subscribers.

In addition to Condition/Disease Management, Wellness coaching will be offered as part of Care Management beginning January 1, 2017. Wellness coaching helps subscribers 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 subscribers 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. Subscribers who receive wellness coaching services receive support from a dedicated coach, however they 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 subscribers, however, participation is optional. Subscriber eligibility for condition/disease management is determined by their Benefit Plan.

FYI

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 2015 has been completed and the results are below. We encourage providers to discuss the benefits of completing an advance directive with all of our adult members.

	TOTAL MEMBERS IN SAMPLE	ADVANCE DIRECTIVES PRESENT OR DISCUSSED	CHANGE FROM 2015 AUDIT
Medicare/Medicaid Eligible (MSHO)	400	262 (66%)	Increase of 4% from 62%
Medicaid	563	25 (4%)	Decrease of 6% from 10%
TOTAL	963	287 (30%)	Increase of 2% from 28%

BODY MASS INDEX (BMI) and COUNSELING for OBESITY

Documentation of a member's BMI is the first step towards addressing the prevalence of obesity in our society. Blue Plus completed a review of a sample of Blue Plus members' medical records with dates of service in 2015 to evaluate documentation of BMI value and counseling for obesity. Just over one-third of members defined as obese (BMI 30 or >) had documentation of a discussion with their provider concerning their weight management.

	TOTAL MEMBERS	BMI DOCUMENTED	BMI 30 > (IF DOCUMENTED)	BMI 30 OR >, ADVISED ON WEIGHT MANAGEMENT	CHANGE FROM 2015 AUDIT
Medicare/Medicaid Eligible (MSHO)	400	287 (72%)	126 (44%)	54 (43%)	BMI documented: Increase of 11% from 61%. BMI 30 or >: Increase of 6% from 38%. Advised on wt. mgmt. if BMI 30 or >: Increase of 34% from 9%
Medicaid	563	512 (91%)	227 (44%)	78 (34%)	BMI documented: Decrease of 1% from 92%. BMI 30 or >: Increase of 1% from 43%. Advised on wt. mgmt. if BMI 30 or >: Decrease of 5% from 39%
TOTAL	963	799 (83%)	353 (44%)	132 (37%)	BMI documented: Increase of 2% from 81%. BMI 30 or >: Increase of 2% from 42%. Advised on wt. mgmt. if BMI 30 or >: Increase of 5% from 32%

(continued on next page)

FYI

BLUE PLUS MEDICAL RECORD DOCUMENTATION REVIEW - continued

TOBACCO USE ASSESSMENT AND COUNSELING

A sample of medical records was reviewed to determine tobacco use among our Blue Plus members and discussions promoting tobacco cessation during a provider visit in 2015. While tobacco use appears to be routinely assessed at least once during 2015, only half of our members have documentation of provider efforts in addressing this health concern.

	TOTAL MEMBERS	ASSESSED FOR TOBACCO USE	TOBACCO USE	DISCUSSION AND/OR RX ASSISTANCE	CHANGE FROM 2015 AUDIT
Medicare/Medicaid Eligible (MSHO)	400	373 (93%)	30 (8%)	22 (73%)	Assessed use remained the same at 93% Tobacco use decreased .5% from 8.5% Discussion/Assistance to quit increased 31% from 42%
Medicaid	563	495 (88%)	147 (30%)	65 (44%)	Assessed use increased 2% from 86% Tobacco use decreased 2% from 32% Discussion/Assistance to quit decreased 10% from 54%
TOTAL	963	868 (90%)	177 (20%)	87 (49%)	Assessed use increased 1% from 89% Tobacco use decreased 4% from 24% Discussion/Assistance to quit decreased 4% from 53%

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

FYI

TRANSITION OF ADOLESCENT CARE TO ADULT PRIMARY CARE

If you know of families with subscribers reaching adulthood or young adults looking to transition to an adult primary care practitioner, we can help. 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.

HEALTH LITERACY

HEALTH LITERACY - BETTER INFORMATION, BETTER OUTCOMES

When it comes to health literacy we all play a role.

Nearly 9 out of 10 Americans have difficulty using everyday health information. Limited health literacy is linked to poorer health outcomes, increased health disparities and several health care safety issues, such as medication errors. Improving health literacy for all Americans has been identified as one of the 20 necessary actions to improve health care quality on a national scale by the Institute of Medicine in Priority Areas for National Action: Transforming Health Care Quality, a publication in the Quality Chasm Series.

The Minnesota Action Plan to Improve Health Literacy, released March 2016, on the Minnesota Health Literacy Partnership **website** outlines six priorities with actionable strategies to improve health literacy across the state. Strategies range from improving patient-centered resources to enhancing education opportunities at all levels to investing in language and cultural resources. An executive summary of the plan is available **here.**

Truly embracing the strategies outlined in the Minnesota Action Plan to Improve Health Literacy will require long-term commitments and collaboration on the part of the over 40 co-sponsors and broader health community. No single action and no single entity can tackle the issue of health literacy alone. This plan is an important step toward building a healthier Minnesota where people are better able to understand health information and protect and improve their health and wellness.

A new **toolkit** created by the Minnesota Health Literacy Partnership is now available and considered a companion to the Minnesota Action Plan. In this toolkit you will find resources such as training, guides and assessments to complement the strategies in the Minnesota Action Plan.

The Minnesota Health Literacy Partnership has developed a variety of free resources to help educate individuals and health care professionals about the importance of health literacy.

- HeLP MN Seniors
- Presentations and Training Materials
- Papers and Articles
- Teach-back Program Materials

For more information on health literacy and how you can implement the Action Plan strategies within your practice, please contact Alisha Odhiambo at: Alisha.Odhiambo@bluecrossmn.com.

FYI

MINNESOTA'S CHLAMYDIA EPIDEMIC

Healthcare Providers' help is needed to impact the rising Chlamydia rates in Minnesota. Chlamydia rates increased 61% in the past decade (2005-2015) and were 80% (21,238) of all sexually transmitted diseases reported in Minnesota in 2015.

Health study results (HEDIS data) indicates Blue Cross and Blue Shield of Minnesota (Blue Cross) continues to lag behind other Minnesota health plans when it comes to Chlamydia screening. In 2015 and 2016 Blue Cross HEDIS data fell below the national Medicaid 25th percentile. Blue Cross is actively reaching out to members to encourage them to participate in preventative care and we also encourage our providers to follow the recommended guidelines for chlamydia screening.

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

The Minnesota Department of Health (MDH) has a broad-based, multifaceted approach to decrease the upward trend of Chlamydia. MDH is an active member in the Minnesota Chlamydia Partnership (MCP), along with Blue Cross. The MCP supports the development of resources to improve Chlamydia screening rates and supports Minnesota healthcare providers in achieving lower Chlamydia rates.

Another entity supporting the efforts to decrease Chlamydia in Minnesota is Stratis Health. They are an independent nonprofit organization leading collaboration and innovation in health care quality. Stratis Health previously collaborated with Blue Cross and other Minnesota health plans to implement a performance improvement project to decrease the incidence of Chlamydia by promoting Chlamydia screening. A Chlamydia Toolkit for providers was created and is available on the Stratis Health website.

ACTION ITEMS FOR PROVIDERS:

- Request a **quarterly member list for screening follow-up** by contacting Bonnie Gagliardi in the Health Management Quality Department at Bonnie.Gagliardi@bluecrossmn.com,

- Obtain a **Chlamydia Provider Toolkit** at: http:www.stratishealthorg/pip/documents/Chlamydia_toolkit.pdf (Or search on "Chlamydia Provider Toolkit" at http://www.stratishealth.org/index.html), and

- Visit the **Minnesota Chlamydia Partnership** website at: http://www.health.state.mn.us/divs/idepc/diseases/chlamydia/mcp/index.html.

FYI

REVIEW UM CRITERIA

Blue Cross and Blue Plus utilization management (UM) programs use written utilization review criteria to make medical necessity determinations. Upon request, any Blue Cross or Blue Plus 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 the Blue Cross website at **providers.bluecrossmn.com**.

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: 10/17/16 Notification Posted: 08/26/16

Policies developed

None

Policies revised

Air Ambulance (II-160)

I. Air ambulance transportation services performed by either a rotary wing aircraft (RW) (e.g., helicopter); **or** fixed wing aircraft (FW), may be considered MEDICALLY NECESSARY when **all** of the following criteria are met:

- Aircraft is specially designed and equipped for transporting the sick or injured including customary patient care equipment and supplies, safety and lifesaving equipment; **and**
- The ambulance crew consists of at least two attendants. One of these attendants must be duly qualified to provide the medical care required during transport; **and**
- The patient's medical condition requires immediate and rapid ambulance transportation that cannot be provided by ground ambulance due to either of the following:
  - The point of pick-up is inaccessible by ground vehicle (this condition could be met in Hawaii, Alaska, and in other remote or sparsely populated areas of the continental United States); **or**
  - Great distances or other obstacles (for example, heavy traffic) are involved in getting the patient to the nearest hospital with appropriate facilities;

  AND
- Patient is transported to nearest appropriate facility meeting all of the following:
  - Hospital is capable of providing the required level and type of care for the patient's illness; and
  - Physician is available to treat the member's condition; and
  - A bed is available.
- The patient's condition is such that the time needed to transport by ground, or the instability of transportation by ground, poses a threat to the patient's survival or seriously endangers the member's health. These include but are not limited to:
  - Intracranial bleeding which requires neurosurgical intervention;
  - Cardiogenic shock;
  - Burns requiring treatment in a burn center;
  - Conditions requiring treatment in a hyperbaric oxygen unit;
  - Multiple severe injuries;
  - Life-threatening trauma.

II. Transfer of a patient from one hospital to another may be considered MEDICALLY NECESSARY if medical appropriateness criteria are met and the transferring hospital does not have adequate facilities to provide the medical services needed by the patient (e.g. burn unit, cardiac care unit, trauma unit).

III. Transport from a hospital capable of treating a patient because the patient and/or patient's family prefer a specified

MEDICAL AND BEHAVIORAL HEALTH POLICY UPDATE

hospital or physician is considered NOT MEDICALLY NECESSARY.

- The use of extra attendants is covered when a member's benefit permits extra attendants.
- If no transport of a member occurs no covered service is rendered. Therefore, payment will not be made to the ambulance company. This applies to situations in which the member refuses to be transported, even if medical services are provided prior to loading the member onto the ambulance.
- Additional air mileage may be allowed in situations where additional mileage is incurred due to circumstances beyond the pilot's control. These circumstances include, but are not limited to, the following:
  - Military base and other restricted zones, air-defense zones, and similar FAA restrictions and prohibitions;
  - Hazardous weather;
  - Variances in departure patterns and clearance routes required by an air traffic controller.
- If the air transport meets the criteria for medical necessity, claims for air transports may account for all mileage from the point of pickup, including where applicable: ramp to taxiway, taxiway to runway, take-off run, air miles, roll out upon landing, and taxiing after landing. Documentation must include each of these factors.
- If no transport of a member occurs, no covered service is rendered. Therefore, when multiple ground and/or air ambulance providers respond, payment may be made only to the ambulance provider that actually furnishes the transport. Ambulance providers that arrive on the scene but do not furnish a transport are not due payment.
- Conventional air services, nonemergency transport, one way fixed or rotary wing transport are non-covered air ambulance services.
- Ambulance transportation is a benefit under many, but not all, of the Plan's programs. When a benefit, coverage is made in accordance with all appropriate contractual provisions and limitations.
- This policy addresses general guidelines applicable to air ambulance services. It should be used as a reference source in conjunction with the member's benefits, the network provider's agreement with the Plan, and any applicable ambulance billing guidelines. This policy, the member's benefits, the network provider's agreement with the Plan, and any applicable ambulance billing guidelines are referred to in this policy as air ambulance criteria.

Bariatric Surgery (IV-19)

I. Adult Patient Selection Criteria

- The surgical treatment of morbid obesity may be considered MEDICALLY NECESSARY for patients 18 years of age or older who meet ALL the following criteria:
  - Body mass index (BMI) of **ONE** of the following:
    - BMI of ≥ 40 kg/m2 OR
    - BMI of 35 kg/m2 to < 40 kg/m2 with **AT LEAST ONE** of the following comorbid conditions:

      1. Hypertension refractory to standard drug regimens; OR
      2. Cardiovascular disease; OR
      3. Type 2 diabetes mellitus (HbA1C of 7 or greater, or requiring medication); OR
      4. Obstructive sleep apnea requiring continuous positive airway pressure (CPAP) or other related treatment;
      5. Obesity-hypoventilation syndrome (OHS): OR
      6. Pickwickian syndrome (a combination of OSA and OHS); OR
      7. Nonalcoholic fatty liver disease (NAFLD); OR
      8. Nonalcoholic steatohepatitis (NASH);

MEDICAL AND BEHAVIORAL HEALTH POLICY UPDATE

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 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:
    1. Behavior modification program supervised by a qualified professional; AND
    2. Consultation with a dietician or nutritionist; AND
    3. Exercise regimen (unless contraindicated) to improve pulmonary reserve prior to surgery, supervised by exercise therapist or other qualified professional; AND
    4. Reduced-calorie diet program supervised by dietician or nutritionist;

    OR
  - Prior to surgery, the patient has actively participated in a nutrition and exercise program with a substantial face-to-face component that meets **all** of the following criteria:
    1. Program is supervised by a physician, physician's assistant, nurse practitioner/advanced practice nurse or registered dietician; AND
    2. Participation takes place for a cumulative total of 6 months or longer in duration and occurs within 1 year prior to surgery; AND
    3. Components of the program include visits with dieticians and/or nutritionists,
       - 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 must be 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 (2015); AND
- The physician requesting authorization for the surgery must confirm that the patient's treatment plan includes a surgical preparatory program addressing all the following components in order to improve outcomes related to the surgery and to establish the patient's ability to comply with postoperative medical care and dietary restrictions:
  - Preoperative and postoperative 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.

II. Adolescent Patient Selection Criteria

- The surgical treatment of morbid obesity may be considered MEDICALLY NECESSARY for patients <18 years of age who meet **ALL** the following criteria:

MEDICAL AND BEHAVIORAL HEALTH POLICY UPDATE

- BMI-**ONE** of the following:
  - BMI ≥ 50 kg/m2 ; OR
  - BMI of 40 kg/m2 to < 50 kg/m2 with documentation of **AT LEAST ONE** of the following comorbid conditions
    1. Type 2 diabetes (HbA1C of 7 or greater, or requiring medication); OR
    2. Obstructive sleep apnea requiring CPAP or other related treatment; OR
    3. Hypertension, refractory to standard treatment; OR
    4. Pseudotumor cerebri; OR
    5. Polycystic ovarian syndrome (PCOS); OR
    6. Nonalcoholic steatohepatitis (NASH);

  AND
- Absence of a previous history of genetic or syndromic obesity, such as PraderWilli 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 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:
    1. Behavior modification program supervised by qualified professional; AND
    2. Consultation with a dietician or nutritionist; AND
    3. Exercise regimen (unless contraindicated) to improve pulmonary reserve prior to surgery, supervised by exercise therapist or other qualified professional; AND
    4. Reduced-calorie diet program supervised by dietician or nutritionist;

    OR
  - Prior to surgery, the patient has actively participated in a nutrition and exercise program with a substantial face-to-face component that meets **all** of the following criteria:
    1. Program is supervised by a physician, physician's assistant, nurse practitioner/advanced practice nurse or registered dietician; AND
    2. Participation takes place for a cumulative total of 6 months or longer in duration and occurs within 1 year prior to surgery; AND
    3. Components of the program include visits with dieticians and/or nutritionists,
       - 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;

MEDICAL AND BEHAVIORAL HEALTH POLICY UPDATE

AND

- The patient must be 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. §245.4871, subd. 27 (2015). The evaluation must also address the following issues:
  - Patient's ability to provide informed assent without coercion; AND
  - Family and social support; AND
  - Assessment of the use of any pharmacologic agents (e.g., anti-psychotic medications) that may contribute to obesity;

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 in order to improve outcomes related to the surgery and to establish the patient's ability to comply with postoperative medical care and dietary restrictions:
  - Preoperative and postoperative 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. Surgical Procedures

- The following surgical procedures may be considered MEDICALLY NECESSARY in the treatment of morbid obesity when the previous patient selection criteria for adults or adolescents have been met:
  - Open gastric bypass using a RouxenY anastomosis with an alimentary or Roux limb of ≤ 150 cm
  - Laparoscopic gastric bypass using a RouxenY anastomosis
  - Adjustable gastric banding, consisting of an adjustable external band placed around the stomach (i.e., LapBand® 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 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
  - Gastric bypass using a Billroth II type of anastomosis, known as the minigastric 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/m2 including but not limited to solely as a cure for type 2 diabetes mellitus

MEDICAL AND BEHAVIORAL HEALTH POLICY UPDATE

- 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:
  - AspireAssist® Weight Loss Therapy System
  - Duodenaljejunal sleeve
  - Intragastric balloon therapy
  - Primary Obesity Surgery, Endoluminal (POSE)
  - StomaphyX™

IV. Reoperation Criteria

- **Revision** bariatric surgery **OR conversion** of one type of bariatric surgery to a different procedure may be considered MEDICALLY NECESSARY 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); **AND**
    - BMI
      1. Adult patient currently has a BMI ≥ 40 kg/m2 OR a BMI of 35 kg/m to < 40 kg/m2 with an obesity related comorbid condition as described in section I; OR
      2. Adolescent patient currently has a BMI ≥ 50 kg/ m2 OR a BMI of 40 kg/ m2 to < 50 kg/ m2 with an obesity related comorbid condition as described in section II;

      AND
    - At least two (2) years have elapsed since the original bariatric surgery.

Policies inactivated

Systems Pathology Testing for Predicting Risk of Recurrence in Prostate Cancer (VI-35)

Thermal Capsulorrhaphy (IV-31)

Policies Effective: 11/21/16 Notification Posted: 09/30/16

Policies developed

None

Policies revised

Genetic Cancer Susceptibility Panels (VI-56)

- **NOTE: Testing for hereditary breast and ovarian cancer syndrome (BRCA1 and BRCA2 genes) is not addressed in this policy. Please refer to policy VI-16: Genetic Testing for Hereditary Breast and/or Ovarian Cancer Syndrome (BRCA1 and BRCA2 Genes).**

MEDICAL AND BEHAVIORAL HEALTH POLICY UPDATE

I. Multigene cancer susceptibility panels may be considered MEDICALLY NECESSARY when **ALL** of the following are met:
- Pretest genetic counseling by a cancer genetics professional independent of the laboratory performing the test documents a family history/pedigree consistent with an inherited cancer or cancer syndrome; **AND**
- The genetic disorder is associated with one or more cancers; **AND**
- The risk of cancer from the genetic disorder cannot be identified through biochemical or other testing; **AND**
- The panel is limited to genes that have proven utility for clinical management of the specific cancer or cancer syndrome in question; **AND**
- Results of testing will impact the medical management of the individual (e.g., increased screening or surveillance

II. Multigene cancer susceptibility panels are considered INVESTIGATIVE for all other indications, including but not limited to the following, due to a lack of clinical evidence demonstrating an impact on improved health outcomes:
- Panel includes genes for which there is no proven utility for clinical management of a specific cancer or cancer syndrome. These include but are not limited to:
  - CancerNext™ Expanded
  - ColoNext™ (colon cancer)
  - DecisionDx-GBM (central nervous system tumors)
  - RenalNext™ (kidney cancer)
  - GeneDx Colorectal Cancer Panel
  - iGene Cancer Panel
  - University of Washington ColoSeq™
  - VistaSeq Hereditary Cancer Panel
- Testing done in the absence of pretest genetic counseling by a cancer genetics professional independent of the laboratory performing the test
- Panel is offered as a direct access (also known as direct to consumer) test
- Panel testing in the general population as a screening tool
- All other uses of genetic cancer susceptibility panel testing which do not meet criteria as stated above.

Genetic Testing for Hereditary Breast and/or Ovarian Cancer Syndrome (BRCA1 and BRCA2) (VI-16)

- **Note: This medical policy describes medically necessary indications for the distinct BRCA1 and BRCA2 codes listed under Procedure Codes below. BRCA1 and BRCA2 components of a multi-gene panel will be eligible for coverage when the member meets medical necessity criteria. Codes for other genetic tests included in the panel will be denied.**

I. Genetic testing of BRCA1 and BRCA2 may be considered MEDICALLY NECESSARY for an individual with a close blood relative who has a known deleterious mutation in BRCA1 and/or BRCA2. Individuals who meet this criterion are candidates for BRCA single-site (known family variant) analysis.

II. Genetic testing of BRCA1 and/or BRCA2 may be considered MEDICALLY NECESSARY for an individual with a **personal history** of one or more of the following:
- Breast cancer
- Ovarian cancer

MEDICAL AND BEHAVIORAL HEALTH POLICY UPDATE

- Fallopian tube cancer
- Primary peritoneal cancer
- Pancreatic cancer at any age meeting one of the following:
  1. One or more close blood relative(s) with breast cancer at age 50 or younger;
  2. One or more close blood relative(s) with ovarian, fallopian tube, or primary peritoneal cancer at any age;
  3. Two or more close blood relatives with breast, pancreatic or prostate cancer (Gleason score of 7 or greater) at any age;
  4. Ashkenazi Jewish ancestry
- Prostate cancer (Gleason score of 7 or greater at any age) meeting one of the following:
  1. One or more close blood relative(s) with breast cancer at age 50 or younger;
  2. One or more close blood relative(s) with ovarian, fallopian tube, or primary peritoneal cancer at any age;
  3. Two or more close blood relatives with breast, pancreatic or prostate cancer (Gleason score of 7 or greater) at any age.

III. Genetic testing of BRCA1 and/or BRCA2 may be considered MEDICALLY NECESSARY for an individual with **no personal history of cancers listed in section II of this policy** who:

- Has received pre-test genetic counseling by a healthcare professional who has the appropriate genetics training and experience and is independent of the laboratory performing the test; **AND**
- Has a reasonable likelihood of a mutation based on pre-test genetic counseling; **AND**
- An appropriate affected family member is unavailable for testing (e.g., affected relative refuses testing or relative is deceased); **AND**
- Meets 1 or 2 below:
  1. A first- or second-degree blood relative meets any of the criteria in section II of this policy; OR
  2. A third-degree blood relative with breast cancer and/or ovarian, fallopian tube, or primary peritoneal cancer; AND who has **either** of the following:
     - Two or more close blood relatives from the same side of the family with breast cancer (at least one with breast cancer diagnosed at age 50 or younger); OR
     - Two or more close blood relatives from the same side of the family with ovarian, fallopian tube or primary peritoneal cancer.

IV. BRCA1 and/or BRCA2 testing is considered INVESTIGATIVE for all other indications, including but not limited to laboratory testing for mutations in BRCA1 and/or BRCA2 in the general population due to a lack of clinical evidence demonstrating its impact on improved health outcomes.

V. Genetic testing for hereditary breast and/or ovarian cancer syndrome using multi-gene sequencing panels is considered INVESTIGATIVE due to a lack of clinical evidence demonstrating its impact on improved health outcomes. Examples of currently available tests using next generation sequencing to assess cancer susceptibility include but are not limited to:

- BRCAvantagePlus™
- BRCAplus™, BreastNext™, GYNplus™, OvaNext™, PancNext™ and Cancer Next™
- BROCA Cancer Risk Panel

MEDICAL AND BEHAVIORAL HEALTH POLICY UPDATE

- DeCode Breast Cancer
- GeneDX Breast/Ovarian Cancer Panel, Breast Cancer High Risk Panel, Endometrial Cancer Panel, High/Moderate Risk Panel, Pancreatic Cancer Panel and Comprehensive Cancer Panel
- GYNplus™
- MyRisk™ Hereditary Cancer Test

Spinal Fusion: Lumbar (IV-87)

- **Note: When fusion at more than one level is planned, the criteria below apply to each level of lumbar fusion being considered. The criteria below also apply to lumbar fusion of a level adjacent to a prior lumbar fusion.**

I. Lumbar spinal fusion may be considered MEDICALLY NECESSARY for **ANY** of the following indications, when a correlative abnormality is confirmed by diagnostic imaging studies (e.g., xray, CT, MRI):

- Spinal tumor with spinal instability, epidural compression, or vertebral destruction; OR
- Spinal fracture with spinal instability or neural compression; OR
- Spinal infection (e.g., osteomyelitis, spinal tuberculosis, discitis) with spinal instability or vertebral destruction; OR
- Spinal instability after debridement for infection; OR
- Severe or rapidly progressive neurological deficit (e.g., motor loss, sensory loss, or cauda equina syndrome); OR
- Severe idiopathic scoliosis (Cobb angle >40 degrees); OR
- Symptomatic pseudarthrosis.

II. Lumbar spinal fusion may be considered MEDICALLY NECESSARY for **ANY** of the following degenerative conditions when **ALL** criteria are met:

- Diagnostic imaging (e.g., x-ray, CT, MRI), obtained within the previous 12 months, confirms **ONE** of the following conditions is present:

  1. Severe degenerative scoliosis or kyphosis (Cobb angle >30 degrees or sagittal imbalance >5 cm); OR
  2. Spondylolisthesis; OR
  3. Spinal stenosis with **ONE** of the following;
     - Spondylolisthesis; or
     - Spinal instability; or
     - Spinal instability is anticipated due to need for bilateral or wide decompression with facetectomy or resection of pars interarticularis;

     OR
  4. Recurrent, same-level disc herniation with neural structure compression;

  AND

- Documented unremitting pain and functional impairment despite at least 3 months of intensive conservative therapy during the previous 12 months, including **BOTH** of the following:

  1. Medical management with nonsteroidal anti-inflammatory drugs (NSAIDs) or other analgesic medications;

  AND

  2. Physical therapy, including strengthening exercises: 6 week course.
     NOTE: If a patient is unable to complete physical therapy (PT) due to progressively worsening pain and disability, the case will be reviewed on an individual basis (See Documentation Submission section).

III. Lumbar spinal fusion is considered INVESTIGATIVE if the **sole indication** is **ANY** of the following conditions:

- Initial disc herniation; OR
- Chronic nonspecific low back pain without radiculopathy; OR
- Degenerative disc disease; OR

MEDICAL AND BEHAVIORAL HEALTH POLICY UPDATE

- Initial discectomy/laminectomy for neural structure decompression; OR
- Facet syndrome.

- **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:
    - Written report, from a radiologist, describing findings from diagnostic spinal imaging studies.
    - For section II of the policy, if a patient is unable to complete physical therapy (PT) due to progressively, worsening symptoms of pain and disability, the case will be reviewed on an individual basis. Documentation must be submitted from the physical therapist describing the patient's inability to complete PT.

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 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/m2, 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 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.

II. Oncologic Applications

- Initial Treatment Strategy
  - PET or PET/CT may be considered MEDICALLY NECESSARY 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 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 INVESTIGATIVE as an **Initial Treatment Strategy (Diagnosis and Staging)** for all other nonsolid primary tumors and the following solid primary malignant tumors:
    - Prostate
    - Kidney

MEDICAL AND BEHAVIORAL HEALTH POLICY UPDATE

  - Bladder, urinary
  - Basal and squamous cell skin cancers
- **Subsequent Treatment Strategy**
  - PET or PET/CT may be considered MEDICALLY NECESSARY 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 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 INVESTIGATIVE when used as a **Subsequent Treatment Strategy (Restaging and Monitoring)** for all other nonsolid primary tumors and the following solid primary malignant tumors:
    - Prostate
    - Kidney
    - Bladder, urinary
    - Basal and squamous cell skin cancers Small cell lung
    - Pancreas
    - 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 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 INVESTIGATIVE for all other oncologic applications due to the 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 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 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.

MEDICAL AND BEHAVIORAL HEALTH POLICY UPDATE

- Diagnosis of chronic osteomyelitis.

- PET or PET/CT is considered INVESTIGATIVE for the diagnosis or evaluation of all other noncardiac 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.

Policies inactivated

None

Policies Effective: 12/19/16 Notification Posted: 10/28/16

Policies developed

Biologic Immunomodulators: Abatacept (Orencia®), Certolizumab Pegol (Cimzia®), Golimumab (Simponi Aria®), Tocilizumab (Actemra®), Ustekinumab (Stelara®), and Vedolizumab (Entyvio®) Il-170

- **NOTE: When abatacept (Orencia®), certolizumab pegol (Cimzia®), tocilizumab (Actemra®), and ustekinumab (Stelara®) will be self-administered by subcutaneous injection, please refer to applicable pharmacy benefit plan.**

I. Initial and Renewal Review for Oncologic Indications

Tocilizumab (Actemra®) may be considered MEDICALLY NECESSARY for **oncologic indications** when **ALL** of the following criteria are met:

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

  AND
- The dose is supported in the literature.

II. Initial Review for Non-Oncologic Indications

Abatacept (Orencia®), certolizumab pegol (Cimzia®), golimumab (Simponi Aria®), tocilizumab (Actemra®), ustekinumab (Stelara®), or vedolizumab (Entyvio®) may be considered MEDICALLY NECESSARY for **non-oncologic indications** when **ALL** of the following criteria are met:

- 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 patient has a diagnosis of ONE of the following for the respective requested agent:
  - **Abatacept (Orencia®)**
    - 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 6 years of age or older.
  - **Certolizumab pegol (Cimzia®)**
    - Moderately to severely active rheumatoid arthritis in a patient 18 years of age or older; OR
    - Moderately to severely active Crohn's disease in a patient 18 years of age or older; OR
    - Active psoriatic arthritis in a patient 18 years of age or older; OR
    - Active ankylosing spondylitis in a patient 18 years of age or older.

MEDICAL AND BEHAVIORAL HEALTH POLICY UPDATE

- **Golimumab (Simponi Aria®)**
  - Moderately to severely active rheumatoid arthritis in a patient 18 years of age or older.
- **Tocilizumab (Actemra®)**
  - 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.
- **Ustekinumab (Stelara®)**
  - Moderate to severe plaque psoriasis in a patient 18 years of age or older (Note: If the prescriber is requesting 90 mg, the patient must have tried the 45 mg dose for at least 3 months and had an inadequate response); OR
  - Active psoriatic arthritis in a patient 18 years of age or older; OR
  - Moderately to severely active Crohn's disease in a patient 18 years of age or older.
- **Vedolizumab (Entyvio®)**
  - Moderately to severely active Crohn's disease in a patient 18 years of age or older; OR
  - Moderately to severely active ulcerative colitis 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 dose is within the FDA labeled dose for the labeled indications (see table 3 below).

III. Renewal Review for Non-Oncologic Indications

Abatacept (Orencia®), certolizumab pegol (Cimzia®), golimumab (Simponi Aria®), tocilizumab (Actemra®), ustekinumab (Stelara®), or vedolizumab (Entyvio®) may be considered MEDICALLY NECESSARY 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**
- The dose is within the FDA labeled dose for the labeled indications (see table 3 below).

IV. All other uses of abatacept (Orencia®), certolizumab pegol (Cimzia®), golimumab (Simponi Aria®), tocilizumab (Actemra®), ustekinumab (Stelara®), or vedolizumab (Entyvio®) are considered INVESTIGATIVE due to the lack of clinical evidence demonstrating an impact on improved health outcomes.

MEDICAL AND BEHAVIORAL HEALTH POLICY UPDATE

- **Table 1. FDA Labeled Contraindications**

AGENT	FDA LABELED CONTRAINDICTIONS
Abatacept (Orencia®)	None
Certolizumab pegol (Cimzia®)	None
Golimumab (Simponi Aria®)	None
Tocilizumab (Actemra®)	Hypersensitivity
Ustekinumab (Stelara®)	Hypersensitivity
Vedolizumab (Entyvio®)	Hypersensitivity

- **Table 2. Conventional Agent Prerequisites**

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

- **Table 3. Dosing for Non-Oncologic Indications**

AGENT	FDA LABELED INDICATIONS	DOSING
Abatacept (Orencia®)	RA – monotherapy or in combination with non-TNF DMARD PJIA – 6 years or older as monotherapy or in combination with methotrexate	**RA** – 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 **PJIA** – 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
Certolizumab pegol (Cimzia®)	CD – after inadequate response to conventional therapy RA PsA AS	**CD** – 400 mg at weeks 0, 2, and 4, then 400 mg every 4 weeks **RA** – 400 mg at weeks 0, 2, and 4, then 200 mg every other week or 400 mg every 4 weeks **PsA** – 400 mg at weeks 0, 2, and 4, then 200 mg every other week or 400 mg every 4 weeks **AS** – 400 mg at weeks 0, 2, and 4, then 200 mg every other week or 400 mg every 4 weeks
Golimumab (Simponi Aria®)	RA – in combination with methotrexate	**RA** – 2 mg/kg at weeks 0 and 4, then every 8 weeks
Tocilizumab (Actemra®)*	RA – inadequate response to 1 or more DMARDs PJIA – in patients 2 years or older SJIA – in patients 2 years or older	**RA** – IV: 4-8 mg/kg every 4 weeks. Not to exceed 800 mg per infusion SC: 162 mg weekly **PJIA** – IV: 10 mg/kg for those <30 kg, 8 mg/kg for those ≥30 kg every 4 weeks **SJIA** – IV: 12 mg/kg for those <30 kg, 8 mg/kg for those ≥30 kg every 2 weeks
Ustekinumab (Stelara®)	Ps – who are candidates for phototherapy or systemic therapy PsA – monotherapy or in combination with methotrexate CD – after failure or intolerance to TNF or immunomodulators or corticosteroids	**Ps** – ≤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** **PsA** – 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 **CD** – 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
Vedolizumab (Entyvio®)#	CD – after inadequate response, loss of response, or intolerance to TNF or immunomodulator or corticosteroid dependence with loss of response, inadequate response, or intolerance UC – after inadequate response, loss of response, or intolerance to TNF or immunomodulator or corticosteroid dependence with loss of response, inadequate response, or intolerance	**CD** – 300 mg at weeks 0, 2, and 6, then every 8 weeks **UC** – 300 mg at weeks 0, 2, and 6, then every 8 weeks

MEDICAL AND BEHAVIORAL HEALTH POLICY UPDATE

IV (intravenous); SC (subcutaneous)
* It is recommended that Actemra not be initiated in patients with an absolute neutrophil count (ANC) below 2000 per mm3, platelet count below 100,000 per mm3, or who have ALT or AST above 1.5 times the upper limit of normal (ULN). Actemra doses exceeding 800 mg per infusion are not recommended in RA patients
# discontinue if no therapeutic benefit by week 14
** Labeling supports efficacy in patients weighing >100 kg at the 45 mg dose but notes greater efficacy in those patients at the 90 mg dose.
^^ for co-existent moderate-to-severe plaque psoriasis >100 kg, dose is 90 mg initially then 4 weeks later, followed by 90 mg every 12 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 for Non-Oncologic Indications

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.
4. The dose being requested, including the patient's weight.

Renewal Review for Non-Oncologic Indications

1. Documentation supporting positive clinical response (e.g., slowing of disease progression or decrease in symptom severity and/or frequency).
2. Clinical notes describing current medications for the diagnosis.
3. The dose being requested, including the patient's weight.

Policies revised

Infliximab II-97

I. Initial Review

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

- 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 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**
- ONE of the following:
  - The patient has a diagnosis of perianal fissuring/chronic fistulizing Crohn's disease and is 18 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.

MEDICAL AND BEHAVIORAL HEALTH POLICY UPDATE

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 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 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 immunomodulator; **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).

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

- Age-related macular degeneration
- Alcoholic hepatitis
- Arthritis (other than rheumatoid arthritis, psoriatic arthritis, and juvenile idiopathic arthritis)
- Behcet syndrome
- Cancer cachexia
- Depression
- Diabetic macular edema
- Endometriosis
- Erythrodermic or exfoliative psoriasis

MEDICAL AND BEHAVIORAL HEALTH POLICY UPDATE

- 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 CONTRAINDICTIONS
Infliximab (Remicade®)	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
Psoriasis (Ps)	methotrexate topical corticosteroids coal tar products anthralin calcipotriene calcitriol acitretin tazarotene cyclosporine methoxsalen tacrolimus pimecrolimus PUVA (phototherapy)

(Continued on next page)

MEDICAL AND BEHAVIORAL HEALTH POLICY UPDATE

- **Table 2. Conventional Agent Prerequisites** (Continued from previous page)

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
Ankylosing spondylitis (AS)	NSAIDs (ibuprofen, ketoprofen, celecoxib)
OFF LABEL INDICATIONS	**CONVENTIONAL AGENT PREREQUISITES**
Juvenile idiopathic arthritis (JIA)	methotrexate leflunomide minocycline sulfasalazine hydroxychloroquine
Uveitis	ophthalmic corticosteroids (prednisolone, rimexolone) ophthalmic cycloplegic agents (atropine, homatropine, scopolamine, cyclopentolate) methotrexate azathioprine cyclosporine NSAIDs (ibuprofen, ketoprofen, celecoxib)

- **Table 3. Dosing**

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.
Uveitis	5 mg/kg at weeks 0, 2, and 6 followed by 5 mg/kg every 6 to 8 weeks.

MEDICAL AND BEHAVIORAL HEALTH POLICY UPDATE

*Some disease states allow for dosing up to 10 mg/kg if a patient is not responsive at a dose of 5 mg/kg.

- **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.
  4. The dose being requested, including the patient's weight.

  Renewal Review
  1. Documentation supporting positive clinical response (e.g., slowing of disease progression or decrease in symptom severity and/or frequency).
  2. Clinical notes describing current medications for the diagnosis.
  3. The dose being requested, including the patient's weight.

Rituximab II-47

I. Initial and Renewal Review for Oncologic Indications

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

- The patient does not have any FDA labeled contraindications to therapy (see table 1 below); AND
- 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
  - Chronic lymphocytic leukemia (CLL); 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
    - Chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL); or
    - Diffuse large B-cell lymphoma; or
    - Follicular lymphoma; or
    - Gastric mucosa-associated lymphoid tissue (MALT) lymphoma; or
    - Hairy cell leukemia; or
    - Lymphoblastic lymphoma; or

MEDICAL AND BEHAVIORAL HEALTH POLICY UPDATE

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

II. Initial Review for Non-Oncologic Indications

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

- 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 rituximab, the patient has been screened for hepatitis B infection and has begun therapy if appropriate; **AND**
- 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:
    - 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.

MEDICAL AND BEHAVIORAL HEALTH POLICY UPDATE

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 dose is within the FDA labeled dose for the labeled indications or is supported in literature for additional indications (see table 2 below).

MEDICAL AND BEHAVIORAL HEALTH POLICY UPDATE

III. Renewal Review for Non-Oncologic Indications

Rituximab may be considered MEDICALLY NECESSARY 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 rituximab is considered 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 LABELED CONTRAINDICATIONS
Rituximab (Rituxan®)	None

- **Table 2. Dosing for Non-Oncologic Indications**

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/m2 once weekly for 4 weeks. Subsequent courses have not been evaluated.
Microscopic polyangiitis (MPA)	375 mg/m2 once weekly for 4 weeks. Subsequent courses have not been evaluated.
OFF LABEL INDICATIONS	**DOSING**
Autoimmune hemolytic anemia (AIHA)	375 mg/m2 once weekly for 4 weeks
Chronic graft-versus-host disease (cGVHD)	375 mg/m2 once weekly for 4 weeks
Idiopathic/immune thrombocytopenic purpura (ITP)	375 mg/m2 once weekly for 4 weeks
Autoimmune mucocutaneous blistering diseases	375 mg/m2 once weekly for 4 weeks OR two 1000 mg infusions separated by 2 weeks
Neuromyelitis optica (NMO)	375 mg/m2 once weekly for 4 weeks OR two 1000 mg infusions separated by 2 weeks
Thrombotic thrombocytopenic purpura (TTP)	375 mg/m2 once weekly for 4 weeks
Dermatomyositis	375 mg/m2 once weekly for 4 weeks OR two 1000 mg infusions separated by 2 weeks
Polymyositis	375 mg/m2 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/m2 or 1000 mg prior to transplantation

MEDICAL AND BEHAVIORAL HEALTH POLICY UPDATE

- **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.
  4. The dose being requested, including the patient's weight.

  Renewal Review for Non-Oncologic Indications
  1. Documentation supporting positive clinical response (e.g., slowing of disease progression or decrease in symptom severity and/or frequency).
  2. Clinical notes describing current medications for the diagnosis.
  3. The dose being requested, including the patient's weight.

Genetic Testing for Cardiac Ion Channelopathies VI-19

I. Genetic testing of patients with suspected congenital long QT syndrome (LQTS) may be considered MEDICALLY NECESSARY:
- To determine future risk of LQTS in asymptomatic patients who meet either of the following:
  - A close blood relative (i.e., first-, second-, or third-degree relative) with a known LQTS mutation; OR
  - A close blood relative (i.e., first-, second-, or third-degree blood relative) diagnosed with LQTS by clinical means whose genetic status is unavailable;

  OR
- When signs and/or symptoms are present indicating a moderate-to-high pretest probability* of LQTS, but a definitive diagnosis cannot be made without genetic testing.

  * Determining the pretest probability of LQTS is not standardized. An example of a patient with a moderate- to-high pretest probability of LQTS is a patient with a Schwartz score of 2-3.

II. Genetic testing for catecholaminergic polymorphic ventricular tachycardia (CPVT) may be considered MEDICALLY NECESSARY:
- To determine future risk of CPVT in asymptomatic patients who meet either of the following:
  - A close blood relative (i.e., first-, second-, or third-degree relative) with a known CPVT mutation; OR
  - A close blood relative diagnosed with CPVT by clinical means whose genetic status is unavailable;

OR
- When signs or symptoms of CPVT are present but a definitive diagnosis cannot be made without genetic testing.

III. Genetic testing for Brugada syndrome (BrS) may be considered MEDICALLY NECESSARY when patients meet one or more of the following:
- To determine future risk of BrS in asymptomatic patients who have a close blood relative (i.e., first-, second-, or third-degree relative) with a known BrS mutation;

  OR
- When signs or symptoms consistent with BrS are present but a definitive diagnosis cannot be made without genetic testing.

MEDICAL AND BEHAVIORAL HEALTH POLICY UPDATE

IV. Genetic testing for short QT syndrome (SQTS) may be considered MEDICALLY NECESSARY for asymptomatic patients who have a close blood relative (i.e., first-, second-, or third-degree relative) with a known mutation for SQTS.

V. Genetic testing is considered INVESTIGATIVE for all other indications including but not limited to genetic testing for LQTS, CPVT, BrS or SQTS not meeting the criteria outlined above or to determine prognosis or direct therapy in patients with known channelopathies. There is a lack of evidence demonstrating an impact on improved health outcomes.

Implantable Cardioverter-Defibrillator IV-84

I. <u>Transvenous Implantable Cardioverter-Defibrillators</u>

Adult Patients

- FDA-approved implantable cardioverter-defibrillators (ICDs) may be considered MEDICALLY NECESSARY in adults (18 years of age or older) who meet any of the following criteria:
  - History of life-threatening clinical event (e.g., cardiac arrest) due to ventricular fibrillation (VF) or sustained ventricular tachycardia (VT) neither of which is due to reversible or transient causes; **OR**
  - Spontaneous sustained VT, in patients with structural heart disease; **OR**
  - Spontaneous sustained VT, in patients without structural heart disease, that is not amenable to other treatments; **OR**
  - Syncope of undetermined origin with clinically relevant, hemodynamically significant, sustained VT or VF induced at electrophysiological study; **OR**
  - Ischemic cardiomyopathy at least 40 days post-MI with left ventricular ejection fraction (LVEF) less than or equal to 30%, and are in New York Heart Association (NYHA) Class I; **OR**
  - Ischemic dilated cardiomyopathy (IDCM) with NYHA Class II or III heart failure, at least 40 days post-MI, and measured left ventricular ejection fraction (LVEF) less than or equal to 35%; **OR**
  - Non-ischemic dilated cardiomyopathy (NIDCM) with LVEF less than or equal to 35% after reversible causes have been excluded, and the response to optimal medical therapy has been adequately determined; **OR**
  - Nonsustained VT due to prior MI, LVEF less than or equal to 40%, and inducible VF or sustained VT at electrophysiological study; **OR**
  - Hypertrophic cardiomyopathy (HCM) with one or more of the following risk factors and judged to be at high risk for sudden cardiac death (SCD) by a physician experienced in the care of patients with HCM:
    1. Prior cardiac arrest;
    2. Family history of HCM-related SCD in at least one first-degree relative younger than 50 years;
    3. 1 or more runs of VT at heart rates of 120 beats per minute or greater;
    4. Unexplained syncope within the previous 12 months inconsistent with neurocardiogenic origin;
    5. Abnormal blood pressure response to exercise in the presence of other SCD risk factors or modifiers;
    6. LV wall thickness greater than or equal to 30 mm.
- FDA-approved ICDs may be considered MEDICALLY NECESSARY for the prevention of sudden cardiac death (SCD) after diagnosis of any one of the following cardiac ion channelopathies and the criteria for high risk of SCD are met:

MEDICAL AND BEHAVIORAL HEALTH POLICY UPDATE

- Long QT syndrome (LQTS), with a history of cardiac arrest or recurrent syncope while on beta blocker therapy
- Brugada syndrome (BrS) with history of cardiac arrest; or documented spontaneous VT with or without syncope, or induced sustained VT
- Catecholaminergic polymorphic ventricular tachycardia (CPVT) with a history of cardiac arrest, recurrent syncope, documented VT that is nonresponsive to optimal medical management or with left cardiac sympathetic denervation
- Short QT syndrome (SQTS) with history of cardiac arrest, documented spontaneous VT with or without syncope; or family history of SCD

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

Pediatric Patients

- FDA-approved implantable cardioverter-defibrillators (ICD)s may be considered MEDICALLY NECESSARY in children and adolescents (<18 years of age) who meet any of the following criteria:
  - Survivors of cardiac arrest, after reversible causes have been excluded; **OR**
  - Symptomatic, sustained ventricular tachycardia in association with congenital heart disease in patients who have undergone hemodynamic and electrophysiologic evaluation; **OR**
  - Congenital heart disease with recurrent syncope of undetermined origin in the presence of either ventricular dysfunction or inducible ventricular arrhythmias; **OR**
  - Hypertrophic cardiomyopathy (HCM) with 1 or more of the following risk factors for sudden cardiac death (SCD) and judged to be a high risk for (SCD) by a physician experienced in the care of patients with HCM:
    1. Family history of HCM-related SCD in at least one first-degree relative younger than 50 years;
    2. LV hypertrophy based on age-specific norms;
    3. Unexplained syncope within the previous 12 months inconsistent with neurocardiogenic origin.
- FDA-approved ICDs may be considered MEDICALLY NECESSARY for the prevention of sudden cardiac death (SCD) after diagnosis of any one of the following cardiac ion channelopathies and the criteria for high risk of SCD are met:
  - Long QT syndrome (LQTS), with a history of cardiac arrest or recurrent syncope while on beta blocker therapy
  - Brugada syndrome (BrS) with history of cardiac arrest; or documented spontaneous VT with or without syncope or induced sustained VT
  - Catecholaminergic polymorphic ventricular tachycardia (CPVT) with a history of cardiac arrest, recurrent syncope, documented VT that is nonresponsive to optimal medical management or with left cardiac sympathetic denervation
  - Short QT syndrome (SQTS) with history of cardiac arrest, documented spontaneous VT with or without syncope; or family history of SCD
- The use of implantable cardioverter-defibrillator (ICD)s is considered INVESTIGATIVE for all other indications in children and adolescents due to a lack of clinical evidence demonstrating an impact on improved health outcomes.

II. <u>Subcutaneous Implantable Cardioverter-Defibrillators</u>

- FDA-approved subcutaneous ICDs, (S-ICD) may be considered MEDICALLY NECESSARY for adults or children who have an indication for ICD implantation for any of the above reasons and meet all of the following criteria:

MEDICAL AND BEHAVIORAL HEALTH POLICY UPDATE

- Have a contraindication to a transvenous ICD due to one or more of the following:
  1. Lack of adequate vascular access;
  2. Compelling reason to preserve existing vascular access (ie, need for chronic dialysis; younger patient with anticipated long-term need for ICD therapy); OR
  3. History of need for explantation of a transvenous ICD due to a complication, with ongoing need for ICD therapy;

  AND
- Have no indication for antibradycardia pacing; **AND**
- Do not have ventricular arrhythmias that are known or anticipated to respond to antitachycardia pacing.

- Subcutaneous implantable cardioverter-defibrillators are considered INVESTIGATIVE for all other indications due to a lack of clinical evidence demonstrating an impact on improved health outcomes.

Botulinum Toxin II-16

I. <u>Abobotulinum Toxin A (Dysport®) Initial Review</u>

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

- The patient does not have any FDA labeled contraindications to therapy (see table 1 below); **AND**
- The patient has a diagnosis of ONE of the following:
  - Blepharospasm associated with dystonia, including benign essential blepharospasm or VII (facial) nerve disorders, in a patient 12 years of age or older; OR
  - Cervical dystonia (spasmodic torticollis; applicable whether congenital, due to child birth injury, or traumatic injury) **AND** BOTH of the following:
    - The patient's cervical dystonia must be associated with sustained head tilt or abnormal posturing with limited range of motion in the neck; AND
    - The patient has a history of recurrent involuntary contraction(s) of one or more of the muscles of the neck (e.g., sternocleidomastoid, splenius, trapezius, or posterior cervical muscles).

    OR
  - Hemifacial spasm **AND** ONE of the following:
    - The patient has tried one conventional agent prerequisite (e.g., carbamazepine, baclofen, and benzodiazepines); OR
    - The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to at least one conventional agent.

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

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

MEDICAL AND BEHAVIORAL HEALTH POLICY UPDATE

AND

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

II. Abobotulinum Toxin A (Dysport®) Renewal Review

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

- The patient has been previously approved for therapy through the initial review process; **AND**
- Abobotulinum toxin A treatment has resulted in a reduction of symptom severity and/or frequency from baseline (prior to therapy); **AND**
- 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 labeled indications or supported in literature for additional indications.

III. Incobotulinum Toxin A (Xeomin®) Initial Review

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

- The patient does not have any FDA labeled contraindications to therapy (see table 1 below); **AND**
- The patient has a diagnosis of ONE of the following:
  - Blepharospasm associated with dystonia, including benign essential blepharospasm or VII (facial) nerve disorders, in a patient 18 years of age or older who was previously treated with onabotulinum toxin A (Botox®); OR
  - Cervical dystonia (spasmodic torticollis; applicable whether congenital, due to child birth injury, or traumatic injury) **AND** BOTH of the following:
    - The patient's cervical dystonia must be associated with sustained head tilt or abnormal posturing with limited range of motion in the neck; AND
    - The patient has a history of recurrent involuntary contraction(s) of one or more of the muscles of the neck (e.g., sternocleidomastoid, splenius, trapezius, or posterior cervical muscles).

    OR
  - Spasticity of the upper limb.

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

IV. Incobotulinum Toxin A (Xeomin®) Renewal Review

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

- The patient has been previously approved for therapy through the initial review process; **AND**
- Incobotulinum toxin A treatment has resulted in a reduction of symptom severity and/or frequency from baseline (prior to therapy); **AND**
- 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 labeled indications or supported in literature for additional indications.

V. Onabotulinum Toxin A (Botox®) Initial Review

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

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

MEDICAL AND BEHAVIORAL HEALTH POLICY UPDATE

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

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

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

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

    OR
  - Esophageal achalasia **AND** ONE of the following:
    - The patient has not responded to pneumatic dilation or myotomy; OR
    - The patient is not a good candidate for pneumatic dilation or myotomy.

    OR
  - Hemifacial spasm **AND** ONE of the following:
    - The patient has tried one conventional agent prerequisite (e.g., carbamazepine, baclofen, and benzodiazepines); OR
    - The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to at least one conventional agent.

MEDICAL AND BEHAVIORAL HEALTH POLICY UPDATE

OR

- Overactive bladder **AND** ALL of the following:
  - The patient has symptoms of urge urinary incontinence, urgency, and frequency; AND
  - Conservative therapies including bladder training, pelvic floor muscle exercises, and fluid management have been inadequate; AND
  - ONE of the following:
    1. The patient has failed two conventional agent prerequisites, including one anticholinergic agent (e.g., oxybutynin, tolterodine, trospium, darifenacin, solifenacin, or fesoterodine) AND mirabegron; OR
    2. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to at least one anticholinergic agent AND mirabegron.

OR

- Palmar or axillary hyperhidrosis **AND** ONE of the following:
  - The patient has failed aluminum chloride 20% solution; OR
  - The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to aluminum chloride 20% solution.

OR

- Sialorrhea **AND** ONE of the following:
  - The patient has failed one conventional agent prerequisite (e.g., oral hyoscine, atropine drops, glycoprrolate, or amitriptyline); OR
  - The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to at least one conventional agent.

OR

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

OR

- Spasticity of the lower limb; OR
- Spasticity of the upper limb; OR
- Strabismus, including persistent cranial VI nerve palsy of one month or longer, in a patient 12 years of age or older **AND** ALL of the following:
  - The patient has had an inadequate response to corrective lenses; AND

MEDICAL AND BEHAVIORAL HEALTH POLICY UPDATE

- The patient has had an inadequate response to any other additional, patient appropriate, conservative corrective therapies (e.g., exercises); AND
- The patient has good vision in both eyes; AND
- Eye movements are not restricted; AND
- The patient has small to moderate angle of esotropia; AND
- There is a potential for the patient to experience binocular vision.

OR

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

AND

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

VI. Onabotulinum Toxin A (Botox®) Renewal Review

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

- The patient has been previously approved for therapy through the initial review process; **AND**
- ONE of the following:
  - The patient has a diagnosis of chronic migraine headache **AND** ONE of the following:
    - Onabotulinum toxin A treatment has resulted in a reduction of 7 or more headache days per month from baseline (prior to therapy); OR
    - Onabotulinum toxin A treatment has resulted in a reduction of 100 or more headache hours per month from baseline (prior to therapy).

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

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 labeled indications or supported in literature for additional indications.

VII. Rimabotulinum Toxin B (Myobloc®) Initial Review

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

- The patient does not have any FDA labeled contraindications to therapy (see table 1 below); **AND**
- The patient has a diagnosis of ONE of the following:
  - Cervical dystonia (spasmodic torticollis; applicable whether congenital, due to child birth injury, or traumatic injury) **AND** BOTH of the following:

MEDICAL AND BEHAVIORAL HEALTH POLICY UPDATE

- The patient's cervical dystonia must be associated with sustained head tilt or abnormal posturing with limited range of motion in the neck; AND
- The patient has a history of recurrent involuntary contraction(s) of one or more of the muscles of the neck (e.g., sternocleidomastoid, splenius, trapezius, or posterior cervical muscles).
  OR
- Oromandibular dystonia (e.g., orofacial dyskinesia, Meige syndrome); OR
- Sialorrhea **AND** ONE of the following:
  - The patient has failed one conventional agent prerequisite (e.g., oral hyoscine, atropine drops, glycoprrolate, or amitriptyline); OR
  - The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to at least one conventional agent.

AND

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

VIII. Rimabotulinum Toxin B (Myobloc®) Renewal Review

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

- The patient has been previously approved for therapy through the initial review process; AND
- Rimabotulinum toxin B treatment has resulted in a reduction of symptom severity and/or frequency from baseline (prior to therapy); **AND**
- 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 labeled indications or supported in literature for additional indications.

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

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

- Bell's palsy
- Benign prostatic hyperplasia
- Chronic low back pain
- Chronic motor tic disorder, and tics associated with Tourette syndrome (motor tics)
- Depressive disorders
- Detrusor sphincteric dyssynergia
- Essential tremor
- Facial wound healing
- Gastroparesis
- Headaches, except as noted above for chronic migraine headache
- Hirschsprung's disease

MEDICAL AND BEHAVIORAL HEALTH POLICY UPDATE

- Internal anal sphincter (IAS) achalasia
- Interstitial cystitis
- Joint pain
- Lateral epicondylitis
- Mechanical neck disorders
- Myofascial pain syndrome
- Neuropathic pain after neck dissection
- Pain after hemorrhoidectomy or lumpectomy
- Prevention of pain associated with breast reconstruction after mastectomy
- Raynaud's disease/Raynaud's phenomenon
- Tinnitus
- Trigeminal neuralgia

- **Table 1. FDA Labeled Contraindications**

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

- **Table 2. Dosing**

FDA LABELED INDICATIONS	ONABOTULINUM TOXIN A (BOTOX®)	ABOBOTULINUM TOXIN A (DYSPORT®)	RIMABOTULINUM TOXIN B (MYOBLOC®)	INCOBOTULINUM TOXIN A (XEOMIN®)
Blepharospasm	Recommended initial dose is 1.25 to 2.5 units into each of 3 sites per affected eye[e]	40-120 units per eye		Recommended initial dose should be same as onabotulinum toxin A[i]. Max dose is 35 units/eye[b].
Cervical dystonia	Patient specific dosing 198-300 units divided among selected muscles[c,d]	Recommended initial dose is 500 units[b,g]	Recommended dose 2,500 to 5,000 units divided among selected muscles[h]	Recommended dose is 120 units[b]
Primary axillary hyperhidrosis	Recommended dose is 50 units per axilla			
Chronic migraine prophylaxis	Recommended dose is 155 units[b]			
Detrusor overactivity associated with a neurologic condition	Recommended and max dose is 200 units[a]			

(Continued on next page)

MEDICAL AND BEHAVIORAL HEALTH POLICY UPDATE

- **Table 2. Dosing** (Continued from previous page)

FDA LABELED INDICATIONS	ONABOTULINUM TOXIN A (BOTOX®)	ABOBOTULINUM TOXIN A (DYSPORT®)	RIMABOTULINUM TOXIN B (MYOBLOC®)	INCOBOTULINUM TOXIN A (XEOMIN®)
Overactive bladder	Recommended and max dose is 100 units[a]			
Strabismus	Recommended initial dose ranges from 1.25 to 5 units depending on prism diopters[f]			
Upper limb spasticity	Patient specific dosing 75-400 units divided among selected muscles[b,c]	1 to 2 injection(s) per muscle at a dose of 100-400 units[m]. Patients may require up to 500-1000 units to respond.		1 to 4 injection sites per muscle at a dose of 5 to 200 units depending on muscle type – no sooner than every 12 weeks
Lower limb spasticity	Recommended and max dose is 300-400 units[b]	Recommended dose is 10-15 units/kg (unilateral) and 20-30 units/kg (bilateral)[m]. Max dose is 1000 units.		
OFF LABEL INDICATIONS				
Achalasia	20-25 units injected into each of 4 quadrants for a total of 80-100 units[j]			
Chronic anal fissure	10 units injected into each side of the fissure (20 units total into internal sphincter)			
Cerebral palsy (spasticity)	Up to 200 units per treatment	24-30 units/kg[k]		
Focal limb dystonia	5-20 units for small muscles and muscles of forearm[l]			
Laryngeal dystonia (spasmodic dysphonia)	1.25-25 units			
Oromandibular dystonia	2-100 units in each muscle		30-100 units divided among selected muscles	
Sialorrhea	5-100 units (per side) parotid gland; 5-30 units (per side) submandibular gland		1000 units (per side) parotid gland; 250 units (per side) submandibular gland	
Torsion dystonia	140 units (customized to patient)			
Hemifacial spasm	12 to 25 units divided among selected muscles	28 to 220 units divided among selected muscles		
Primary palmar hyperhidrosis	Recommended dose is 50 units per palm			
Other conditions (spasticity)	Max dose is 400 units			

MEDICAL AND BEHAVIORAL HEALTH POLICY UPDATE

a-reinjection no sooner than 12 weeks from prior bladder injection

b-recommended retreatment schedule is every 12 weeks

c-dosing range from clinical trials

d-in trials, effect lasted approximately 3 months for most patients

e-cumulative dose in 30 days should not exceed 200 units. Effects generally last 3 months.

f-maximum single injection for any one muscle is 25 units. Evaluate dose efficacy in 7-14 days.

g-reducing dose injected into sternocleidomastoid muscle may reduce dysphagia. Total single treatment dose should be between 250 and 1000 units. Doses above 1000 units not evaluated.

h-in patients with a prior history of tolerating botulinum toxin. Use lower initial dose for treatment naïve. Duration of effect lasted 12-16 weeks at doses of 5,000 to 10,000 units in clinical trials.

i-if Botox dose unknown, initial dose should be between 1.25 and 2.5 units/injection site. Dose should not exceed 70 units (35 units/eye).

j-symptoms typically reappear after 6 months (50% of patients)

k-total dose is 120 units per treatment session, higher doses do not provide additional efficacy.

l-subsequent injections should be given at 2-4 month intervals

m-retreat every 12 to 16 weeks or longer as needed based on response with doses between 500-1000 units

- **Documentation Submission:**
  Documentation supporting the medical necessity criteria descried 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. Clinical notes describing current and past treatments for the diagnosis.
  3. The dose being requested, including the patient's weight.

  Renewal Review
  1. For chronic migraine headache, information from the medical record and/or headache diary/log entries quantifying a reduction in migraine frequency or duration compared to baseline.
  2. For all diagnoses other than chronic migraine headache, documentation supporting reduction of symptom severity and/or frequency from baseline.
  3. The dose being requested, including the patient's weight.

Hyperhidrosis Treatments II-55

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

I. Treatment for All Types of Hyperhidrosis

- In addition to use of a treatment considered medically necessary for a specific focus of hyperhidrosis as described in section II, treatment of primary hyperhidrosis (axillary, palmar, plantar, or craniofacial) may be considered MEDICALLY NECESSARY in patients with one or more of the following indications:
  - Medical complication secondary to hyperhidrosis including one or more of the following:
    1. Tingling and discoloration (acrocyanosis) of the hands;
    2. Recurrent skin maceration with bacterial or fungal infections;
    3. Recurrent secondary infections;
    4. Persistent eczematous dermatitis despite medical treatment with topical dermatological or systemic anticholinergic agents; **OR**
  - Significant disruption of professional/personal life or significant functional impairment as a result of hyperhidrosis, as documented in the medical record.

MEDICAL AND BEHAVIORAL HEALTH POLICY UPDATE

II. Treatments for Specific Foci of Hyperhidrosis

- **Axillary**
  - The following treatments may be considered MEDICALLY NECESSARY:
    1. Aluminum chloride 20% solution;
    2. Endoscopic transthoracic sympathectomy (ETS) or surgical excision of axillary sweat glands when BOTH of the following have failed:
       - Aluminum chloride 20% solution administered for a minimum of one month; **AND**
       - Botulinum toxin therapy.
  - The following treatments are considered INVESTIGATIVE:
    1. Axillary liposuction;
    2. Axillary coagulation of lymph glands;
    3. Microwave treatment.
- **Palmar**
  - The following treatments are considered MEDICALLY NECESSARY:
    1. Aluminum chloride 20% solution;
    2. Endoscopic transthoracic sympathectomy (ETS) when BOTH of the following have failed:
       - Aluminum chloride 20% solution administered for a minimum of one month; AND
       - Botulinum toxin therapy.
  - The following treatments are considered INVESTIGATIVE:
    1. Microwave treatment.
- **Plantar**
  - Aluminum chloride 20% solution may be considered MEDICALLY NECESSARY.
  - The following treatments are considered INVESTIGATIVE:
    1. Endoscopic transthoracic sympathectomy;
    2. Microwave treatment.
- **Craniofacial**
  - The following treatments may be considered MEDICALLY NECESSARY:
    1. Aluminum chloride 20% solution;
    2. Endoscopic transthoracic sympathectomy (ETS) when aluminum chloride 20% solution administered for a minimum of one month has failed.
  - The following treatments are considered INVESTIGATIVE:
    1. Microwave treatment.

Autologous Chondrocyte Implantation of Focal Articular Cartilage Lesions IV-113

I. Autologous chondrocyte implantation (ACI) may be considered MEDICALLY NECESSARY 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:

MEDICAL AND BEHAVIORAL HEALTH POLICY UPDATE

- 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 cm2 (centimeters squared); AND
- Focal, full thickness (Modified Outerbridge grade III or IV) unipolar lesions of the patella or on 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 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 INVESTIGATIVE, due to a lack of evidence demonstrating an impact on improved health outcomes.

IV. Matrix-induced autologous chondrocyte implantation (ACI) is considered INVESTIGATIVE for all indications due to a lack of evidence demonstrating an impact on improved health outcomes.

Intravenous Human Epidermal Growth Factor Receptor 2 (HER2) Targeted Agents II-158

I. Trastuzumab (Herceptin®) Initial and Renewal Review
Trastuzumab may be considered MEDICALLY NECESSARY when **ALL** of the following criteria are met:

- The patient does not have any FDA labeled contraindications to therapy; **AND**
- ONE of the following:
  - **HER2-Positive Breast Cancer**
    - The patient has a diagnosis of breast cancer; AND
    - HER2 overexpression or HER2 amplification in the tumor tissue has been confirmed by ONE of the following HER2 test results:
      1. Immunohistochemistry (IHC) assay is 3+; or
      2. In situ hybridization (ISH) assay shows an average HER2 copy number ≥6.0 signals/cell; or
      3. ISH assay shows a HER2/chromosome 17 enumeration probe (CEP17) ratio ≥2.0.

      AND
    - ONE of the following:
      1. Trastuzumab will be used as neoadjuvant therapy; or
      2. Trastuzumab will be used as adjuvant therapy; or
      3. Trastuzumab will be used for treatment of recurrent or metastatic breast cancer.

    OR
  - **HER2-Positive Central Nervous System Cancer**
    - The patient has a diagnosis of leptomeningeal metastases from breast cancer; AND
    - HER2 overexpression or HER2 amplification in the tumor tissue has been confirmed by ONE of the following

MEDICAL AND BEHAVIORAL HEALTH POLICY UPDATE

HER2 test results:

1. IHC assay is 3+; or
2. ISH assay shows an average HER2 copy number ≥6.0 signals/cell; or
3. ISH assay shows a HER2/chromosome 17 enumeration probe (CEP17) ratio ≥2.0.

AND

- Trastuzumab will be administered intrathecally.

OR

- **Advanced or Metastatic HER2-Positive Gastric, Esophageal, and Esophagogastric Junction Cancer**
  - The patient has a diagnosis of advanced or metastatic gastric, esophageal, or esophagogastric junction adenocarcinoma; AND
  - HER2 overexpression or HER2 amplification in the tumor tissue has been confirmed by ONE of the following HER2 test results:
    1. IHC assay is 3+; or
    2. ISH assay shows an average HER2 copy number ≥6.0 signals/cell; or
    3. ISH assay shows a HER2/chromosome 17 enumeration probe (CEP17) ratio ≥2.0.

    AND
  - Trastuzumab will be used as first-line therapy in combination with systemic chemotherapy (e.g., cisplatin and capecitabine or 5-fluorouracil).

  OR
- **HER2-Positive Non-Small Cell Lung Cancer**
  - The patient has a diagnosis of non-small cell lung cancer; AND
  - HER2 mutation in the tumor tissue has been confirmed by genetic testing.

AND

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

II. Pertuzumab (Perjeta®) Initial and Renewal Review

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

- The patient does not have any FDA labeled contraindications to therapy; AND
- ONE of the following:
  - **Neoadjuvant Treatment for HER2-Positive Breast Cancer**
    - The patient has a diagnosis of locally advanced, inflammatory, or early stage breast cancer; AND
    - HER2 overexpression or HER2 amplification in the tumor tissue has been confirmed by ONE of the following HER2 test results:
      1. Immunohistochemistry (IHC) assay is 3+; or
      2. In situ hybridization (ISH) assay shows an average HER2 copy number ≥6.0 signals/cell; or
      3. ISH assay shows a HER2/CEP17 ratio ≥2.0.

      AND
    - ONE of the following:

MEDICAL AND BEHAVIORAL HEALTH POLICY UPDATE

1. Tumor is ≥2 cm in diameter; or
2. Tumor is node positive (clinically evident by palpitation or imaging).

AND

- Pertuzumab will be used in combination with trastuzumab and a taxane (e.g., paclitaxel or docetaxel) (NOTE: If the taxane is discontinued due to toxicity, treatment with pertuzumab and trastuzumab may continue); AND
- Pertuzumab will be used prior to surgical resection of the tumor.

OR

- **Adjuvant Treatment for HER2-Positive Breast Cancer**
  - The patient has a diagnosis of early stage or locally advanced breast cancer; AND
  - HER2 overexpression or HER2 amplification in the tumor tissue has been confirmed by ONE of the following HER2 test results:
    1. IHC assay is 3+; or
    2. ISH assay shows an average HER2 copy number ≥6.0 signals/cell; or
    3. ISH assay shows a HER2/CEP17 ratio ≥2.0.

    AND
  - ONE of the following:
    1. Tumor is ≥2 cm in diameter; or
    2. Tumor is node positive (clinically evident by palpitation or imaging).

    AND
  - Pertuzumab will be used in combination with trastuzumab and a taxane (e.g., paclitaxel or docetaxel) (NOTE: If the taxane is discontinued due to toxicity, treatment with pertuzumab and trastuzumab may continue); AND
  - Pertuzumab was not used as neoadjuvant therapy.

  OR
- **Recurrent or Metastatic HER2-Positive Breast Cancer**
  - The patient has a diagnosis of recurrent or metastatic breast cancer; AND
  - HER2 overexpression or HER2 amplification in the tumor tissue has been confirmed by ONE of the following HER2 test results:
    1. IHC assay is 3+; or
    2. ISH assay shows an average HER2 copy number ≥6.0 signals/cell; or
    3. ISH assay shows a HER2/CEP17 ratio ≥2.0.

    AND
  - ONE of the following:
    1. Pertuzumab will be used as first-line therapy in combination with trastuzumab and a taxane (e.g., paclitaxel or docetaxel) (NOTE: If the taxane is discontinued due to toxicity, treatment with pertuzumab and trastuzumab may continue); or
    2. Pertuzumab will be used as second-line therapy in combination with trastuzumab in patients previously treated with chemotherapy and trastuzumab in the absence of pertuzumab.

MEDICAL AND BEHAVIORAL HEALTH POLICY UPDATE

AND

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

III. Ado-Trastuzumab Emtansine (Kadcyla®) Initial and Renewal Review
Ado-trastuzumab emtansine may be considered MEDICALLY NECESSARY when **ALL** of the following criteria are met:

- The patient does not have any FDA labeled contraindications to therapy; AND
- **Recurrent or Metastatic HER2-Positive Breast Cancer**
  - The patient has a diagnosis of recurrent or metastatic breast cancer; AND
  - HER2 overexpression or HER2 amplification in the tumor tissue has been confirmed by ONE of the following HER2 test results:
    - Immunohistochemistry (IHC) assay is 3+; or
    - In situ hybridization (ISH) assay shows an average HER2 copy number ≥6.0 signals/cell; or
    - ISH assay shows a HER2/CEP17 ratio ≥2.0.

    AND
  - ONE of the following:
    - Ado-trastuzumab emtansine will be used in patients previously treated with trastuzumab and a taxane (e.g., paclitaxel or docetaxel), separately or in combination; or
    - Ado-trastuzumab emtansine will be used as first-line therapy in patients not suitable for treatment with trastuzumab, pertuzumab, and a taxane (e.g., paclitaxel or docetaxel).

    AND
  - Ado-trastuzumab emtansine will be used as single agent therapy.

AND

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

IV. All other uses of trastuzumab, pertuzumab, or ado-trastuzumab emtansine are considered INVESTIGATIVE due to the lack of clinical evidence demonstrating an impact on improved health outcomes.

Policies inactivated

Abatacept (Orencia®) II-161

Transcutaneous Transducer Garments (TTG) E-21

Intraepidermal Nerve Fiber Density Testing L-4

Pharmacogenomic and Metabolite Markers for Patients Treated with Azathioprine L-49

Anaplastic Lymphoma Kinase (ALK) Gene Rearrangements by Fluorescence in Situ Hybridization Testing (FISH) in Non-Small Cell Lung Cancer L-87

Excision Repair Cross-Complementing Factor 1 (ERCC1) Analysis for Non-Small Cell Lung Cancer L-88

Policies reviewed with no changes in August 2016, September 2016, and October 2016:

Amino Acid-Based Elemental Formulas II-69

Autologous Hematopoietic Stem-Cell Transplantation for Malignant Astrocytomas and Gliomas II-120

Bronchial Thermoplasty IV-117

MEDICAL AND BEHAVIORAL HEALTH POLICY UPDATE

MEDICAL AND BEHAVIORAL HEALTH POLICY UPDATE

Single-Nucleotide Polymorphism (SNP) Breast Cancer Risk Assessment VI-32
Spinal Manipulation Under Anesthesia II-116
Sublingual Immunotherapy Drops for Allergy Treatment II-169
Testing of Fetal Nucleic Acids in Maternal Blood for Detection of Fetal Aneuploidy VI-43
Transesophageal Endoscopic Therapies for Gastroesophageal Reflux Disease (GERD) II-31
Vagus Nerve Stimulation and Blocking Therapies II-75
Wheelchairs VII-04
Wound Healing: Electrostimulation and Electromagnetic Therapy II-85
Wound Healing: Non-Contact Ultrasound Treatment II-88

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

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

Advisors/Faith Bauer, CPC, CPC-H, CPC-P; Betty Jo Haggerty and Alex Dirlam-Langlay.

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