Provider Press

Provider information

June 2017 / Vol. 22, No. 2

BlueCross BlueShield Minnesota

GRID OF HIGH IMPACT IDENTIFIED ISSUES

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

To alert providers to these identified issues, and to decrease providers' administrative burden of calling Provider Services or submitting appeals for these known issues, Blue Cross has published a grid of high impact identified issues on the Blue Cross provider website at **providers.bluecrossmn.com**. The grid will be updated as new high impact issues are identified and as existing issues statuses change.

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

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

The grid will include the following information:

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

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

NEED HELP UNDERSTANDING OUR NETWORKS?

Blue Cross has published two guides to help providers identify and understand our products. The Commercial Network Guide provides details regarding commercial products, including our narrow networks, and the Medicare Product Guide provides details about our Medicare products. Both guides are located on our website at **providers.bluecrossmn.com** under the "Education Center" section. The Medicare product guide is available under "Medicare Education" and the Commercial Network Guide has its own section in the Education Center.

Provider Press

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

Inside preview

FYI

PUBLICATIONS AVAILABLE ONLINE

The following is a list of Quick Points and Bulletins published from March to May 2017 that are available online at **providers.bluecrossmn.com**. As a reminder, Bulletins are mailed to all participating providers affected by the information. Quick Points are available only on our website unless noted otherwise in the bottom left corner of the publication.

QUICK POINTS	TITLE
QP5-17	Pharmacy Benefit Update – EpiPen, EpiPen Jr., Auvi-Q and Procysti
QP6-17	Appropriate Cover Sheet for Appeals and Claim Attachments
QP7-17	Submitting Eligibility and Benefit Transactions
QP8-17	Appointment Accessibility Survey
QP9-17	Change to Certification of Need Form for Special Transportation Services
QP10-17	Implementation of New Utilization Management Platform
QP11-17	Provider Services Extended Hours and Callback Technology
BULLETINS	**TITLE**
P7-17	Drug-Related Prior Authorization for Growth Hormone
P8-17	Prior Authorization Requirements for Breast MRI and Hip Arthroplasty
P9-17	A New Drug, Emflaza (deflazacort) Will Require Prior Authorization
P10-17	Changes in Medical Policy IV-122 Knee Arthroplasty
P11-17	Pre-Admission Requirement for Admissions Effective June 1, 2017
P12-17	A New Drug, Pharmaceutical Grade L-Glutamine Will Require Prior Authorization
P13-17	Added Reimbursement Policy for General Coding: Total Parenteral Nutrition Billing
P14-17	Medical Drug Management
P15-17	Change to Administration of Interpreter Services for MHCP Subscribers
P16-17	Changes in Medical Policy IV-107 Hip Arthroplasty (Hip Replacement) and Hip Resurfacing
P17-17	Addition of Drug Kisqali to the Self-Administered Oncology Prior Authorization with quantity Limit Program
P18-17	New Drug-Related Prior Authorization Requirements for Nusinerson (Spinraza)
P19-17	American Indian Tribal Fee Schedule foe Eligible Facility Services Provided to Purchased/Referred Care (PRC)-Eligible American Indians
P20-17	New Drug-Related Prior Authorization Criteria for QVAR
P21-17	New Drug-Related Prior Authorization with Quantity Limit for Entresto
P22-17	Identified Claims Processing Issues Grid
P23-17	Change to Administration of Interpreter Services for MHCP Subscribers
P24-17	AOR No longer Required for Noon-Covered Medicare Services for Platinum Blue Subscribers

FYI

MEMBER RIGHTS AND RESPONSIBILITIES

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

FYI

REMINDER: MEDICARE REQUIREMENTS FOR REPORTING PROVIDER DEMOGRAPHIC CHANGES

Blue Cross and Blue Shield of Minnesota (Blue Cross) has continually collaborated with providers in an effort to ensure accurate information is provided in all provider directories.

In accordance with Medicare requirements, Blue Cross is required to maintain accurate provider network directories for the benefit of our Subscribers. Blue Cross is hereby notifying all providers to submit a form to us when any of the following changes occur:

- Accepting new patients
- Demographic address and phone changes
- Office hours or other changes that affect availability
- Tax ID changes
- Practitioner additions or terminations
- Branch additions

Forms location

Based on what change has occurred, submit the appropriate form located on our website at **providers.bluecrossmn.com**. Select "Administrative Updates" in the "What's Inside" section to obtain instructions on completing the various forms or access this link: https://www.bluecrossmn.com/healthy/public/personal/home/providers/admin-updates.

How do we submit changes?

Send the appropriate form via fax as indicated below:
Fax: **651-662-6684, Attention: Provider Data Operations**

Questions?

If you have questions, please contact provider services at **(651) 662-5200** or **1-800-262-0820**.

FYI WHOM TO CONTACT?

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

CODING CORNER

AVOID DUPLICATE APPEALS

If you are questioning whether your appeal has been received or otherwise checking on the status of the review, be sure to indicate on the new appeal form that you are checking on the status of a previous appeal. This will help us from creating a duplicate appeal.

FYI

PROVIDER MANUAL UPDATES

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

MANUAL NAME	CHAPTER NUMBER AND TITLE	CHANGE
Provider Policy and Procedure Manual	Chapter 11, Coding Policies and Guidelines, all sub-sections	References to the Reimbursement Policies were added to all the sub-sections except Medical Services and Public Programs
Provider Policy and Procedure Manual	Chapter 1, At Your Service	Content change to Member Rights & Responsibilities
Blue Plus Manual	Chapter 1, Introduction to Blue Plus	Changed Provider Service hours of operation

2017 HOLIDAY SCHEDULE

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

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 7 a.m. to 6 p.m. Monday through Friday.

CODING CORNER

APPEAL PRIMER

As with any medical visit or procedure, the service(s) reflects an individual encounter and there are times or situations when the service(s) are denied. If you would like to appeal the denial be sure to check out the Appeal chapter, Chapter 10, of the Provider Policy and Procedure Manual. This chapter is dedicated to information on appeals and should be your first stop. The chapter starts (see below) with your rights as a provider and guide to accessing the correct section of the chapter to assure the most accurate and thorough information is submitted with the appeal.

"Providers are eligible to appeal:

- Post service claim appeals
- Pre authorization and Preadmission Notification denials
- Coding appeals

Because there are two basic types of appeals this chapter is divided into two appeal sections. The General Appeal Guideline section deals with all appeals that are not related to our coding software edits. The Coding Software Edit Appeals deals only with ClaimCheck and other coding related denials."

PHARMACY SECTION

PHARMACY UPDATES FOR QUARTER 2, 2017

Drug Formulary Changes

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

ADDITIONS TO FlexRx FORMULARY	ADDITIONS TO GenRx FORMULARY
CONTOUR NEXT ONE BLOOD GLUCOSE MONITORING SYSTEM	CONTOUR NEXT ONE BLOOD GLUCOSE MONITORING SYSTEM
EMEND ORAL SUSP	EMEND ORAL SUSP
EPINEPHRINE SOLN AUTO-INJECTOR (Mylan Products)	EPINEPHRINE SOLN AUTO-INJECTOR (Mylan Products)
KOATE	KOATE
REPATHA PUSHTRONEX SYSTEM	REPATHA PUSHTRONEX SYSTEM
SOOLANTRA	SOOLANTRA
STIOLTO RESPIMAT	

REMOVALS TO FlexRx FORMULARY	REMOVALS TO GenRx FORMULARY
BACTROBAN NASAL	CYCLOSPORINE MODIFIED
CENTANY	EPIPEN 2-PAK
CYCLOSPORINE MODIFIED	EPIPEN JR 2-PAK
EPIPEN 2-PAK	FUSILEV
EPIPEN JR 2-PAK	NILANDRON
FUSILEV	NITROSTAT
GENTAMICIN SULFATE OINT	SYNAGIS
NILANDRON	UVADEX
NITROSTAT	VALCYTE SOLN
PREDNISONE THERAPY PACK	
PRUDOXIN	
REMODULIN	
SYNAGIS	
UVADEX	
VALCYTE SOLN	
VOLTAREN GEL	

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PHARMACY SECTION

PHARMACY UPDATES FOR QUARTER 2, 2017 (cont. from previous page)

Drug Formulary Changes

The complete list of formulary changes can be found at:

FlexRx –

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

GenRx –

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

BasicRx –

BasicRx is a new drug formulary for the 2017 Blue Plus individual and family (non-grandfathered) health insurance plans. The complete 2017 BasicRx drug formulary can be found at:

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

UTILIZATION MANAGEMENT UPDATES

Blue Cross 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 April 1, 2017

BRAND NAME (generic name - if available)	Requirement		
ADLYXIN			ST
BASAGLAR		QL	
AFREZZA TITRATION PACK: 4 units/cartridge, 8 units/cartridge & 12 units/cartridge		QL	
FLECTOR		QL**	ST
LONSURF 15 mg/6.14 mg tablet	PA	QL	
NAMZARIC		QL	
PENNSAID 1.5% gel (diclofenac sodium)		QL**	ST¥
PENNSAID 2% solution		QL**	ST
RUBRACA	PA	QL	
SAVELLA tabs		QL**	ST
SAVELLA titration pack		QL**	ST
VOLTAREN gel (diclofenac sodium)		QL**	ST¥
XARTEMIS XR		QL	
ZUBSOLV		QL	

PA=Prior Authorization; QL=Quantity Limit; ST=Step Therapy
**PA currently in place; **QL currently in place; ***ST currently in place*
¥Generic available – the generic is also subject to prior authorization or step therapy

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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 from previous page)

Effective June 1, 2017

- The Benzodiazepine Quantity Limit Program will be implemented for the Medicaid line of business.

Effective July 1, 2017

- Ketorolac Quantity Limit Program will change the maximum allowed quantity from 21 tablets in 5 days to 20 tablets in 5 days to follow FDA labeling.
- The Insulin Combinations Step Therapy and Quantity Limit Program will be implemented for the Commercial lines of business.
- The Lidocaine Transdermal Prior Authorization and Quantity Limit Program will be renamed to Topical Lidocaine Prior Authorization and Quantity Limit Program and will include the addition of lidocaine ointment 5% as a target.

A complete listing of all utilization management updates can be found at:
FlexRx –
https://www.myprime.com/content/dam/prime/memberportal/forms/2017/FullyQualified/Other/ALL/BCBSMN/COMMERCIAL/MNFLEXRX/MN_FlexRx_UM_Updates.pdf

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

BasicRx –
https://www.myprime.com/content/dam/prime/memberportal/forms/2017/FullyQualified/Other/ALL/BCBSMN/COMMERCIAL/MNHIMBSCRX/MN_Exh_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 **provider.bluecrossmn.com** and select "Forms and Publications" then "Manuals." Topics in the manual include, but are not limited to, formulary exceptions, quantity limits and step therapy.

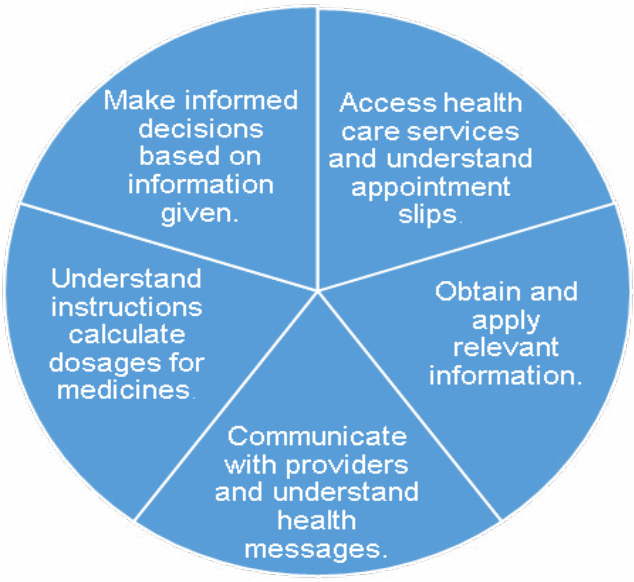
Similar Pharmacy Management for the Federal Employee Program (FEP) members can be found on the Fepblue.org website. FEP members have a different PBM (Caremark) and will have different formulary list and procedures for prior authorizations and quantity limits than listed above. This information can be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

HEALTH LITERACY

HEALTH LITERACY – A UNIVERSAL PRECAUTIONS APPROACH

According to the Agency for Health Care Research and Quality (AHRQ), low health literacy is linked to higher risk of death, more emergency room visits and longer hospitalizations. Years of education or having a high reading ability does not necessarily mean someone will also have high health literacy (HL).

Skills Needed for Health Literacy



The chart above reflects just some of the skills that are needed to effectively manage one's health and the health care environment. Are there other skills that are needed for patients visiting your clinic?

The health industry is complex and anyone can struggle to understand a diagnosis, treatment options, medication regimens, etc. That is exactly why the AHRQ proposes adopting a universal precautions approach when it comes to addressing barriers and implications of health literacy.

AHRQ outlines the aims of health literacy universal precautions:

- Simplifying health communication and confirming understanding for all patients to reduce the risk of miscommunication
- Making the office environment and health care system easier to navigate
- Supporting patients' efforts to improve their health

The AHRQ Health Literacy Universal Precautions Toolkit, 2nd edition, can help you reach the aims of reducing the complexity of health care, increasing patient understanding of health information and enhancing support for patients of all health literacy levels.

The Joint Commission, stresses the importance of health literacy, health communication, and cultural competencies as an element of quality health care. In their report, What Did the Doctor Say?: Improving Health Literacy to Protect Patient Safety, the Commission states:

"If a patient does not understand the implications of her or his diagnosis and the importance of prevention and treatment plans, or cannot access health care services because of communications problems, an untoward event may occur. The same is true if the treating physician does not understand the patient or the cultural context within which the patient receives critical information."

FYI

UPCOMING SURVEYS

We Need Your Feedback. Your Opinion Matters to Us!
As a participating provider in the Blue Cross networks, we rely on you to provide quality care and service to our Members – your patients. We also need to hear from you, our partners, on your experience with different aspects of the health care system.

Your Provider Service Agreement supports the collaboration between Blue Cross and Providers to maintain the best quality of care for the patients we both serve. NCQA accreditation and its standards are one of many ways that our partnership helps support this delivery of quality care and patient satisfaction. Blue Cross is asking its provider partners to assist in the important requirements of NCQA by completing a survey, if you are randomly selected. By responding to this important survey, you will directly impact the high value placed in the care you deliver to patients through your partnership with Blue Cross.

Below is a list of surveys that will be going out over the next few months. These surveys can come in a variety of formats, so please keep an eye out for a mailed, telephone, fax, or email survey. A strong response rate provides us with a clearer picture of our network's experience and expectations so we can more confidently identify opportunities to improve your satisfaction with Blue Cross.

SURVEY PURPOSE	SURVEY MODE	EXPECTED IN THE FIELD
Access to Care - This survey studies the network's ability to provide timely appointment access based on provider specialty and subscriber need (urgent, routine, new patient, or existing patient). This study helps us identify if we have adequate network access to meet the needs of our subscribers.	Mailed and Email	April - May
Utilization Management - This survey studies practitioners' satisfaction with utilization management policies and procedures, including the appeals process.	Email	Aug - Sept
Accuracy of Provider Directory - This survey measures the accuracy of practitioner and hospital information available to subscribers on our online provider directory.	Fax	Sept - Dec
Coordination of Medical and/or Behavioral Care - This survey studies the frequency and effectiveness of continuity and coordination of care across different avenues of care.	Telephone	Oct - Nov

Questions?

If you have questions, please contact provider service at **(651) 662-5200** or **1-800-262-0820**.

IMPROVING PATIENT EXPERIENCE

CONTINUITY AND COORDINATION OF CARE - A PATIENT'S PERSPECTIVE *A Qualitative Study*

Keeping care coordinated across multiple care providers can be challenging. As a part of our ongoing efforts to improve continuity and coordination of care for our members, Blue Cross and Blue Shield of Minnesota (Blue Cross) was interested in exploring patients' experiences and perspectives on how well medical care is coordinated in situations involving more than one care provider. To accomplish this, Blue Cross sponsored eight patient focus groups lead by an independent consulting group. Focus groups were held across Minnesota in St. Cloud (2 groups), Duluth (2 groups), and Minneapolis (4 groups).

Participants were at least 18 years of age and must have either received care from at least two providers or have managed medical care for another person who had seen more than one doctor. Participants completed a pre-session homework assignment, asking them to tell a story about a time when they (or someone they care for – perhaps a child or another adult) went to see a provider other than their usual primary care doctor. This exercise helped ground participants in a particular event for the purposes of the group discussion and to focus on a key topic for the sessions. Observations reported are qualitative and limited to a non-statistical sample.

KEY TAKEAWAY #1 – The current level of care coordination is not fully meeting patients' needs

To patients, coordinated care seems more an exception than a rule. The ratio of positive-to-negative stories shared during the sessions and in the homework results, depicted patients feeling the onus of coordinated care to be on them versus the provider. When participants recalled experiencing coordinated care a level of surprise and delight was expressed, stating that they felt "taken care of." Participants recognized that systems use different EMRs; however, the expectation for information sharing is a growing sentiment and especially important in health care. Participants believe that the technology exists to deliver immediate information exchange (as occurs in other areas of their lives).

I have three different MyChart accounts because I've gotten care from providers that are in three different networks…They are not connected to each other. I look at them all the time. My primary care is with Provider X. The only information about me on that one is from when I see him. Provider Y is the orthopedic surgeon who did my hips. Then Provider Z, I was hit by a car when I was on my bike in March and everything related to that accident is on that one. The log-in is all the same. They are different websites, and they don't share information with each other and it drives me nuts. I was in a really bad bike accident and I thought my primary care doctor would have the information from that. He didn't have a clue.

~ Focus group participant

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IMPROVING PATIENT EXPERIENCE

CONTINUITY AND COORDINATION OF CARE - (continued)

KEY TAKEAWAY #2 – Patients believe that utilizing technology to create one information hub with a patient focus is the ultimate solution to better coordinated care

Patients are already relying heavily on digital resources to inform and manage their health and medical issues. Of those that use patient portals, they believe that they are under-utilized and under-developed. In particular, they want more connections, more capabilities, and more information providing broader perspectives on health, wellness, and behavior modification.

Some of the doctors I found are really receptive to that online resource and some of them not at all, so there's a disconnect between consistent usage of it. Some of them are right away saying, 'Are you on MyChart?' I'll say, 'Yep.' Then they'll say, 'OK, I can message you through there, just check in.' Schedule your appointment through there. Others will not mention it or if I ask about it they'll say, 'Well, if something hasn't improved in three weeks, call in.' I've tried to connect to a doctor through that and I don't get a response it's because they're not really using it.

~ Focus group participant

In general, participants did not want to keep hard copies of medical information, in preference of utilizing electronic mechanisms for sharing information. The majority of participants in all sessions were open to signing a universal authorization to release information about their health that could be shared with all their providers. In fact only two individuals had ever refused to give approval for release of their medical information when prompted by office staff.

It was clear that patients who experienced coordination of care elicited greater trust in their providers and supported increased patient engagement in the care process. We know technology can help patients and providers stay connected with each other, allowing providers to continue exchanging information across the care continuum while keeping the patient at the center of care, but not responsible for all aspects of continuity and coordination of their care.

How is your organization leveraging different technologies to improve the patient experience and promote coordination of care? What solutions have you found to be most effective?

CODING CORNER

REIMBURSEMENT POLICY REFERENCES/UPDATES TO CHAPTER 11

Since 2015, individual reimbursement policy documents have been developed and posted on the Blue Cross website (www.bluecrossmn.com) on the Provider's self-service access page, as a separate tab under 'Tools and Resources.' Many of these policies reflected reimbursement procedures that were described in Chapter 11 of the Blue Cross Provider Policy and Procedure Manual (PPPM).

So now is the time to update Chapter 11 of the PPPM. Most subchapters have been updated. For those that have, you will now see an overview document and table the shows the policy number(s) and name, description, included medical codes, and comments if applicable. For example, the anesthesia section table starts with:

POLICY SECTION, NUMBER AND TITLE	POLICY DESCRIPTION	CODES LISTED IN POLICY (HCPCS, ICD, REVENUE)	COMMENTS
Anesthesia - 001 – Anesthesia	This policy addresses coverage and reimbursement for anesthesia services with the exception of moderate or conscious sedation which is addressed in a separate anesthesia policy 002 – Administration of Conscious Sedation.	Modifiers: AA, AD, QK, QS, QX, QY, QZ, P1, P2, P3, P4, P5, P6 ICD Diagnosis: Z41.1 HCPCS: 00100-01999, 92960, 99100, 99116, 99135, 99140, 99360	Cross Reference policy: Anesthesia -002 – Administration of Conscious Sedation.

NAVIGATING REIMBURSEMENT POLICIES

Now back to the Reimbursement Policies on the Blue Cross website. There is a new document that will be added under the REIMBURSEMENT POLICIES section under 'Tools and Resources' on the Provider's self-service access page. The Reimbursement Policy Summary is designed to help with policy searches. For example, you are looking for the policy that addresses S0302 but you do not know under which policy to find the code. Open up the summary document and search for S0302. You will find that code in one policy.

POLICY SECTION, NUMBER AND TITLE	POLICY DESCRIPTION	CODES LISTED IN POLICY (HCPCS, ICD, REVENUE)	COMMENTS
General Coding - 051 – Child and Teen Check-ups	This policy addresses coding and coverage for Child and Teen Check-up (C&TC) services.	Modifier: SL, UC HCPCS: 83655, 90460, 90461, 90471, 90472, 90473, 90474, 92551, 92552, 92582, 92583, 96110, 99173, 99188, 99381, 99382, 99383, 99384, 99385, 99391, 99392, 99393, 99394, 99395, 99420, S0302, V5008	Coverage is a health plan responsibility for Blue Plus® Minnesota Health Care Program (MHCP) groups.

FYI

GAPS IN CARE

Blue Cross is committed to offering choice, access and convenience to subscribers who need an annual wellness visit and/or have an open gap in care for preventive screenings (diabetes A1c, diabetes eye exam, diabetes nephropathy, breast cancer screening, colorectal cancer screening). Beginning in June, 2017, Blue Cross will be offering various approaches to help subscribers get their preventive screenings:

1. We'll send subscribers a letter regarding their needed screenings, encouraging them to schedule them with appropriate primary care and specialty providers. In addition, Blue Cross will be partnering with a vendor that will offer mobile unit/in home services to subscribers who have not historically completed select preventive screenings.

2. Subscribers may also have the opportunity to do a colorectal cancer screening and/or diabetes kidney screening kit in the comfort of their own home. Blue Cross will be sending in home test kits to subscribers who are not attributed to a specific PCP, as well as to subscribers who have completed in-home test kits before who had results within normal range.

We know subscribers are more likely to complete preventive screenings when their primary care provider asks them to, either under a doctor's care or through other opportunities such as a health fair, getting an immunization from a local pharmacist, or following through with an offer for such care from their health plan. We appreciate the encouragement you provide to your patients/our subscribers to actively participate in staying healthy and completing preventive screens. Thank you for your support.

If you have questions, comments or feedback email
ProviderStars@bluecrossmn.com

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

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: 4/17/17 Notification Posted: 2/24/17

Policies developed

None

Policies revised

Magnetic Resonance Imaging (MRI) of the Breast, V-07

- **NOTE:** This policy applies to members who are enrolled in Blue Advantage Prepaid Medical Assistance Program (PMAP), MinnesotaCare, Secure Blue (MSHO), and Minnesota Senior Care Plus (MSC+) Programs Only.

I. Screening Uses

MRI of the breast may be considered MEDICALLY NECESSARY for screening on an annual basis if ONE of the following criteria is met indicating high risk:

- **Personal history**
  - Previous diagnosis of breast cancer, including lobular carcinoma in situ, atypical hyperplasia, and neoplasia; OR
  - Previous diagnosis of ovarian cancer; OR
  - Received radiation therapy to the chest between the ages of 10 and 30 years old; OR
  - Presence of mutation in BRCA1 or BRCA2; OR
  - Presence of another genetic syndrome linked to high risk breast cancer including ONE of the following: TP53 (Li-Fraumeni syndrome), PTEN (Cowden syndrome, Bannayan-Riley-Ruvalcaba syndrome), CDH1, STK11 (Peutz-Jeghers syndrome), ATM, CHEK2, and PALB2;

  OR
- **Family history** of breast cancer indicating high risk defined as:
  - First, second, or third degree relative with a genetic syndrome linked to high risk breast cancer including mutation in BRCA1 or BRCA2, TP53 (Li-Fraumeni syndrome), PTEN (Cowden syndrome, Bannayan-Riley-Ruvalcaba syndrome), CDH1, STK11 (Peutz-Jeghers syndrome), ATM, CHEK2, and PALB2 but member untested; OR
  - Two or more first-degree relatives or two or more first and second-degree relatives meeting ONE of the following criteria:
    - Breast cancer, diagnosed before menopause; OR
    - Breast cancer in one relative diagnosed at any age AND ovarian cancer in one relative diagnosed at any age;

  OR
- **Risk model assessment** indicates lifetime risk of 20% or greater of developing breast cancer as identified by models largely defined by family history (e.g. Gail, Claus, Tyrer-Cuzick, BRCAPRO).

II. Diagnosis or Detection Uses

MRI of the breast may be considered MEDICALLY NECESSARY for patients with a diagnosis of breast cancer when ONE of the following criteria are met:

- For the detection of a suspected occult breast primary tumor in patients with axillary nodal adenocarcinoma (i.e., negative mammography and physical exam); OR
- For patients with a new diagnosis of breast cancer to evaluate the contralateral breast when clinical and

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mammographic findings are normal; OR

- To confirm the clinical diagnosis of rupture of silicone breast implants; OR
- For preoperative tumor mapping of the involved (ipsilateral) breast to evaluate the presence of multicentric disease in patients with clinically localized breast cancer who are candidates for breast-conservation therapy; OR
- For presurgical planning in patients with local advanced breast cancer before and after completion of neoadjuvant chemotherapy to permit tumor localization and characterization; OR
- To determine the presence of pectoralis major muscle/chest wall invasion in patients with posteriorly located tumors; OR
- To evaluate a documented abnormality of the breast before obtaining an MRI-guided biopsy when there is documentation that other methods, such as palpation or ultrasound are not able to localize the lesion for biopsy.

III. MRI of the breast is considered INVESTIGATIVE for all other indications due to the lack of evidence demonstrating an impact on improved health outcomes including but not limited to:

- For screening in an individual of average risk;
- For the detection of breast cancer when the sensitivity of mammography is limited, e.g. due to the following:
  - Dense breasts;
  - Breast implants;
  - Scarring after treatment for breast cancer;
- For diagnosis of low-suspicion findings on conventional testing not indicated for immediate biopsy and referred for short-interval follow-up;
- For diagnosis of suspicious breast lesion in order to avoid biopsy;
- To monitor the integrity of silicone gel-filled breast implants when there are no signs or symptoms of rupture.

Policies revised

Immunoglobulin Therapy, II-51

I. Intravenous Immunoglobulin (IVIG) Initial Review

Use of intravenous immunoglobulin (IVIG) may be considered MEDICALLY NECESSARY for ANY of the following indications:

- **Primary Immunodeficiencies**
  - Common variable immune deficiency (CVID), when the following criteria are met:
    - Significant and recurrent infections (e.g., recurrent pneumonias, frequent episodes of bacterial sinusitis, and not just isolated chronic sinusitis); AND
    - Onset of symptoms after two (2) years of age; AND
    - Abnormally low serum levels of IgM and/or IgA (at least 2 standard deviations below the age-adjusted mean); AND
    - Abnormally low serum levels of IgG as demonstrated by ONE of the following:

      1. Total serum IgG level < 400 mg/dL; OR

      2. At least 2 standard deviations below the normal age-adjusted mean; AND
    - A demonstrated impaired response to immunization with protein AND/OR polysaccharide antigens:

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1. For protein antigens: Serum antibody titers to tetanus and/or diphtheria should be obtained before immunization with tetanus and/or diphtheria vaccine and then three to four weeks after immunization. An abnormal response is defined as less than a four-fold rise in antibody titer.
2. For polysaccharide antigens: Serum antibody titers to pneumoccoccus should be obtained before immunizations and then three to six weeks after immunization with a polyvalent pneumococcal polysaccharide vaccine (such as Pneumovax). An abnormal response is defined as less than a four-fold rise in titer;

AND

- Exclusion of other possible causes of hypogammaglobulinemia.

OR

- IgG subclass deficiency, when the following criteria are met:
  - Significant and recurrent infections (e.g., recurrent pneumonias, frequent episodes of bacterial sinusitis, and not just isolated chronic sinusitis); AND
  - Abnormally low serum levels of one or more IgG subclasses (at least 2 standard deviations below the age-adjusted mean) in patients with normal levels of total IgG and IgM; AND
  - A demonstrated impaired response to immunization with protein AND/OR polysaccharide antigens:
    1. For protein antigens: Serum antibody titers to tetanus and/or diphtheria should be obtained before immunization with tetanus and/or diphtheria vaccine and then three to four weeks after immunization. An abnormal response is defined as less than a four-fold rise in antibody titer
    2. For polysaccharide antigens: Serum antibody titers to pneumoccoccus should be obtained before immunization and then three to six weeks after immunization with a polyvalent pneumococcal polysaccharide vaccine (such as Pneumovax). An abnormal response is defined as less than a four-fold rise in titer.

OR

- All other primary humoral immunodeficiencies, including but not limited to:
  X-linked agammaglobulinemia (XLA or Bruton's agammaglobulinemia);
  - Congenital agammaglobulinemia;
  - Primary hypogammaglobulinemia;
  - X-linked immunodeficiency;
  - Hyper-IgM syndrome;
  - Immunodeficiency with thrombocytopenia and eczema (Wiskott-Aldrich syndrome);
  - Hyper-IgE syndrome;
  - Severe combined immune deficiency (SCID);
  - Cellular immunodeficiency with immunoglobulins (Nezelof syndrome);
  - Thymic hypoplasia (DiGeorge's syndrome);
  - Ataxia telangiectasia (Louis-Bar syndrome).

  AND ONE of the following:
  - Agammaglobulinemia, as evidenced by ONE of the following:

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1. Total serum IgG < 200 mg/dL; OR
2. Patients with an abnormal Bruton tyrosine kinase (BTK) gene/absence of BTK protein; OR
3. Absence of B lymphocytes.

OR

- Hypogammaglobulinemia and ALL of the following:
  1. Significant and recurrent infections (e.g., recurrent pneumonias, frequent episodes of bacterial sinusitis, and not just isolated chronic sinusitis); AND
  2. Total serum IgG < 700 mg/dL or at least 2 standard deviations below the age-adjusted mean; AND
  3. A demonstrated impaired response to immunization with protein AND/OR polysaccharide antigens:
     - For protein antigens: Serum antibody titers to tetanus and/or diphtheria should be obtained before immunization with tetanus and/or diphtheria vaccine and then three to four weeks after immunization. An abnormal response is defined as less than a four-fold rise in antibody titer
     - For polysaccharide antigens: Serum antibody titers to pneumoccoccus should be obtained before immunization and then three to six weeks after immunization with a polyvalent pneumococcal polysaccharide vaccine (such as Pneumovax). An abnormal response is defined as less than a four-fold rise in titer
- **Secondary Immunodeficiencies**
  - Pediatric human immunodeficiency virus (HIV) infection with hypogammaglobulinemia; OR
  - Acquired hypogammaglobulinemia and/or significant and recurrent infections associated with ONE of the following:
    - B-cell chronic lymphocytic leukemia;
    - Multiple myeloma;
    - Waldenstrom's macroglobulinemia (lymphoplasmacytic lymphoma);
    - Post-CD20 therapy.
- **Organ and Stem-Cell Transplantation**
  - Prior to solid organ transplantation, for treatment of patients at high risk of antibody-mediated rejection, including highly sensitized patients and those receiving an ABO incompatible organ; OR
  - Following organ transplantation, for treatment of antibody-mediated rejection; OR
  - Following hematopoietic stem-cell transplantation, for treatment of related immunodeficiencies
- **Hematologic Disorders**
  - Idiopathic thrombocytopenic purpura (ITP); OR
  - Antenatal/Neonatal alloimmune thrombocytopenia; OR
  - Warm antibody autoimmune hemolytic anemia, refractory to corticosteroids and splenectomy; OR
  - Pure red cell aplasia due to parvovirus B19; OR
  - Hemolytic disease of the fetus and newborn (erythroblastosis fetalis); OR
  - HIV-associated thrombocytopenia; OR

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- Post-transfusion purpura.

- **Neurologic Disorders**
  - Acute inflammatory demyelinating polyneuropathy (Guillain-Barre syndrome); OR
  - Chronic inflammatory demyelinating polyneuropathy (CIDP); OR
  - Myasthenia gravis, when ONE of the following criteria are met:
    - Myasthenic crisis (i.e., an acute episode of respiratory muscle weakness); OR
    - Myasthenia gravis in patients wtih chronic debilitating disease (e.g., restricted daily activities and symptomatic at rest or worse) despite treatment with cholinesterase inhibitors, or complications from or failure of steroids and/or azathioprine;

    OR
  - Multifocal motor neuropathy in patients with conduction block and anti-GM1 antibodies; OR
  - Stiff-person syndrome (Moersch-Woltman syndrome), after incomplete response to conventional therapy (e.g., benzodiazepines, baclofen); OR
  - Lambert-Eaton myasthenic syndrome (LEMS)
- **Rheumatic and Inflammatory Disorders**
  - Kawasaki disease (mucocutaneous lymph node syndrome); OR
  - Dermatomyositis that has not responded to treatment with prednisone and immunosuppressant therapy (e.g., azathioprine, methotrexate); OR
  - Polymyositis that has not responded to treatment with prednisone and immunosuppressant therapy (e.g., azathioprine, methotrexate)
- **Dermatologic Disorders**
  - Autoimmune Mucocutaneous Blistering Diseases, for treatment of the following conditions in patients with severe, progressive disease despite treatment with conventional medical therapy (e.g., corticosteroids, azathioprine, cyclophosphamide):
    - Pemphigus vulgaris;
    - Pemphigus foliaceus;
    - Bullous pemphigoid;
    - Mucous membrane pemphigoid;
    - Bullous systemic lupus erythematosus (SLE);
    - Epidermolysis bullosa acquisita

    OR
  - Toxic epidermal necrolysis (TEN)
- **Other Disorders**
  - Toxic shock syndrome due to staphylococcal or streptococcal infection, refractory to conventional therapy.

II. Subcutaneous Immunoglobulin (SCIG) Initial Review

Use of subcutaneous immunoglobulin (SCIG) therapy may be considered MEDICALLY NECESSARY for ANY of the following indications:

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- **Primary Immunodeficiencies**
  - Common variable immune deficiency (CVID), when the following criteria are met:
    - Significant and recurrent infections (e.g., recurrent pneumonias, frequent episodes of bacterial sinusitis, and not just isolated chronic sinusitis); AND
    - Onset of symptoms after two (2) years of age; AND
    - Abnormally low serum levels of IgM and/or IgA (at least 2 standard deviations below the age-adjusted mean); AND
    - Abnormally low serum levels of IgG as demonstrated by ONE of the following:

      1. Total serum IgG level < 400 mg/dL; OR

      2. At least 2 standard deviations below the normal age-adjusted mean;

      AND

      - A demonstrated impaired response to immunization wtih protein AND/OR polysaccharide antigens:

        1. For protein antigens: Serum antibody titers to tetanus and/or diphtheria should be obtained before immunization with tetanus and/or diphtheria vaccine and then three to four weeks after immunization. An abnormal response is defined as less than a four-fold rise in antibody titer

        2. For polysaccharide antigens: Serum antibody titers to pneumoccoccus should be obtained before immunizations and then three to six weeks after immunization with a polyvalent pneumococcal polysaccharide vaccine (such as Pneumovax). An abnormal response is defined as less than a four-fold rise in titer;

      AND

      - Exclusion of other possible causes of hypogammaglobulinemia.

      OR

  - IgG subclass deficiency, when the following criteria are met:
    - Significant and recurrent infections (e.g., recurrent pneumonias, frequent episodes of bacterial sinusitis, and not just isolated chronic sinusitis); AND
    - Abnormally low serum levels of one or more IgG subclasses (at least 2 standard deviations below the age-adjusted mean) in patients with normal levels of total IgG and IgM; AND
    - A demonstrated impaired response to immunization with protein AND/OR polysaccharide antigens:
      - For protein antigens: Serum antibody titers to tetanus and/or diphtheria should be obtained before immunization with tetanus and/or diphtheria vaccine and then three to four weeks after immunization. An abnormal response is defined as less than a four-fold rise in antibody titer
      - For polysaccharide antigens: Serum antibody titers to pneumoccoccus should be obtained before immunization and then three to six weeks after immunization with a polyvalent pneumococcal polysaccharide vaccine (such as Pneumovax). An abnormal response is defined as less than a four-fold rise in titer.

    OR

  - All other primary humoral immunodeficiencies, including but not limited to:
    - X-linked agammaglobulinemia (XLA or Bruton's agammaglobulinemia);

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- Congenital agammaglobulinemia;
- Primary hypogammaglobulinemia;
- X-linked immunodeficiency;
- Hyper-IgM syndrome;
- Immunodeficiency with thrombocytopenia and eczema (Wiskott-Aldrich syndrome);
- Hyper-IgE syndrome;
- Severe combined immune deficiency (SCID);
- Cellular immunodeficiency with immunoglobulins (Nezelof syndrome);
- Thymic hypoplasia (DiGeorge's syndrome);
- Ataxia telangiectasia (Louis-Bar syndrome).

  AND ONE of the following: Agammaglobulinemia, as evidenced by ONE of the following:

  1. Total serum IgG < 200 mg/dL; OR
  2. Patients with an abnormal Bruton tyrosine kinase (BTK) gene/absence of BTK protein; OR
  3. Absence of B lymphocytes.

  OR

- Hypogammaglobulinemia and ALL of the following:
  1. Significant and recurrent infections (e.g., recurrent pneumonias, frequent episodes of bacterial sinusitis, and not just isolated chronic sinusitis); AND
  2. Total serum IgG < 700 mg/dL or at least 2 standard deviations below the normal age-adjusted mean; AND
  3. A demonstrated impaired response to immunization with protein AND/OR polysaccharide antigens:
     - For protein antigens: Serum antibody titers to tetanus and/or diphtheria should be obtained before immunization with tetanus and/or diphtheria vaccine and then three to four weeks after immunization. An abnormal response is defined as less than a four-fold rise in antibody titer
     - For polysaccharide antigens: Serum antibody titers to pneumoccoccus should be obtained before immunization and then three to six weeks after immunization with a polyvalent pneumococcal polysaccharide vaccine (such as Pneumovax). An abnormal response is defined as less than a four-fold rise in titer

III. Intravenous Immunoglobulin (IVIG) and Subcutaneous Immunoglobulin (SCIG) Renewal Review

Use of intravenous immunoglobulin (IVIG) or subcutaneous immunoglobulin (SCIG) 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 renewal request is for the same indication previously approved; AND
- The patient has shown positive clinical response (e.g., reduced number and/or severity of infections, decreased use/elimination of prophylactic antibiotics, functional improvement).

IV. Investigative Indications

All other uses of intravenous immunoglobulin (IVIG) OR subcutaneous immunoglobulin (SCIG) are considered INVESTIGATIVE, including but not limited to treatment of the following conditions, due to the lack of clinical evidence demonstrating an impact on improved health outcomes:

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- Acquired factor VIII inhibitors;
- Acute myocarditis;
- Adrenoleukodystrophy;
- Alzheimer's disease;
- Aplastic anemia;
- Asthma;
- Autism spectrum disorders;
- Behçet syndrome;
- Birdshot retinopathy;
- Chronic fatigue syndrome;
- Chronic sinus infections (unless the sinus infection is a symptom of one of the primary immunodeficiencies listed above. Chronic sinus infection is common in most primary immunodeficiencies listed, especially antibody deficiency with normal or near-normal immunoglobulins);
- Complex regional pain syndrome;
- Crohn's disease;
- Cystic fibrosis;
- Diabetes mellitus;
- Diamond-Blackfan anemia;
- Epilepsy;
- Fisher syndrome;
- Hemolytic uremic syndrome;
- Hemophagocytic lymphohistiocytosis;
- Immune optic neuritis;
- Immune-mediated neutropenia;
- Inclusion body myositis;
- Multiple sclerosis (relapsing-remitting and chronic, progressive);
- Necrotizing fasciitis;
- Nonimmune thrombocytopenia;
- Noninfectious uveitis;
- Opsoclonus-myoclonus;
- Other vasculitides besides Kawasaki disease, including polyarteritis nodosa, Goodpasture syndrome, and vasculitis associated with other connective tissue diseases;
- PANDAS (Pediatric Autoimmune Neuropsychiatric Disorders Associated with Streptococcal Infections);
- Paraneoplastic syndromes;
- Paraproteinemic neuropathy;
- POEMS syndrome (polyneuropathy, organeomegaly, endocrinopathy, monoclonal gammopathy, and skin changes);

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- Polyradiculoneuropathy (other than chronic inflammatory demyelinating polyneuropathy);
- Post-polio syndrome;
- Recurrent fetal loss;
- Recurrent otitis media;
- Refractory recurrent pericarditis;
- Refractory rheumatoid arthritis;
- Sepsis (neonatal or in adults);
- Thrombotic thrombocytopenic purpura.

• 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

- Clinical notes describing the diagnosis and clinical features of the diagnosis.
- For patients with primary humoral immunodeficiencies, including common variable immune deficiency (CVID) and IgG subclass deficiency (see medical necessity criteria specific to these conditions, in sections I and II above):
  - Clinical notes clearly documenting significant and recurrent infections (e.g., recurrent pneumonias, frequent episodes of bacterial sinusitis, and not just isolated chronic sinusitis); AND
  - Laboratory results including the patient's serum immunoglobulin levels AND the age-adjusted reference ranges for the laboratory performing the tests.

Renewal Review

- Documentation of prior approval for the requested agent for the same indication through the initial review process.
- Documentation supporting positive clinical response, such as substantial improvement in disease condition or a reduction in disease progression. Examples include clinical notes documenting reduced number and/or severity of infections, decreased use/elimination of prophylactic antibiotics, or functional improvement.

Gene Expression Profiling for the Management of Breast Cancer Treatment, VI-10

I. Use of Oncotype DX™, the Breast Cancer IndexSM, EndoPredict® or Prosigna™ to determine recurrence risk for deciding whether to initiate adjuvant chemotherapy may be considered MEDICALLY NECESSARY in patients with primary, invasive breast cancer who meet ALL the following criteria:

- Unilateral, non-fixed tumor; AND
- Breast tumor is estrogen receptor positive OR progesterone receptor positive; AND
- Breast tumor is human epidermal growth factor receptor 2 (HER2)-negative; AND
- Node-negative (lymph nodes with micrometastases [< 2 mm in size] are considered node negative for this policy statement) OR 1-3 involved ipsilateral axillary lymph nodes; AND
- Patient will be treated with adjuvant endocrine therapy (e.g., tamoxifen or aromatase inhibitors); AND
- Adjuvant chemotherapy is not precluded due to any other factor (e.g., significant co-morbidities).

II. All other uses of breast cancer gene expression assays are considered INVESTIGATIVE due to a lack of clinical evidence demonstrating an impact on improved health outcomes. This includes, but is not limited to:

- Use of gene expression assays for predicting breast cancer recurrence risk when the criteria above are not met

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(e.g., patient has tumor that is estrogen and progesterone negative, a tumor that is HER2 positive, or who has 4 or more involved ipsilateral axillary lymph nodes)

- Use of gene expression assays for predicting breast cancer recurrence risk in patients with noninvasive ductal carcinoma in situ
- Use of breast cancer gene expression assays not included in the medical necessity criteria for any indication

Continuous Glucose Monitoring Systems, VII-05

I. Professional (Short-Term) Continuous Glucose Monitoring (CGM) Systems

- Use of a professional (short-term) CGM system for 3 to 5 days may be considered MEDICALLY NECESSARY for patients with diabetes who meet ONE of the following criteria:
  - Diabetes is poorly controlled, as evidenced by unexplained hypoglycemic episodes, hypoglycemic unawareness, suspected postprandial hyperglycemia, or recurrent diabetic ketoacidosis; OR
  - Prior to insulin pump initiation to determine basal insulin levels.
- All other uses of a professional (short-term) CGM system are considered INVESTIGATIVE due to the lack of evidence demonstrating an impact on improved health outcomes.

II.Personal (Long-term or Real-Time) Continuous Glucose Monitoring (CGM) Systems

- Use of a personal (long-term or real-time) CGM system may be considered MEDICALLY NECESSARY for patients with diabetes who meet ONE of the following criteria:
  - Type 1 diabetes, when ALL of the following criteria are met:
    1. Insulin injections are required 3 or more times per day or an insulin pump is used for maintenance of glucose control; AND
    2. Adequate glycemic control has not been achieved despite frequent self-monitoring of blood glucose (4 or more fingersticks per day), as evidenced by at least ONE of the following:
       - Recurrrent, severe hypoglycemia (e.g., blood glucose levels less than 50 mg/dL) or hypoglycemia unawareness; OR
       - Frequent nocturnal hypoglycemia (e.g., blood glucose levels less than 50 mg/dL); OR
       - Discordant hemoglobin A1C and fingerstick blood glucose levels (i.e., patient with consistent normal fingerstick results, but high hemoglobin A1C levels).

    OR
  - During pregnancy, when ONE of the following criteria are met:
    1. Adequate glycemic control is not achieved as described above; OR
    2. Fasting hyperglycemia (greater than 150 mg/dL); OR
    3. Recurring episodes of severe hypoglycemia (less than 50 mg/dL).
- All other uses of a personal (long-term or real-time) CGM system are considered INVESTIGATIVE due to the lack of evidence demonstrating an impact on improved health outcomes.

III. Closed-Loop Continuous Glucose Monitoring (CGM) and Insulin Pump Systems (Artificial Pancreas Device Systems)

- Use of an FDA-approved closed-loop CGM and insulin pump system (artificial pancreas device system) with a low-glucose suspend feature (e.g., MiniMed 530G, 630G, or 670G System) may be considered MEDICALLY NECESSARY for patients with diabetes who meet ALL of the following criteria:

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- Type 1 diabetes; AND
- Meets FDA-approved age requirements for the specific system being used; AND
- Insulin injections are required 3 or more times per day or an insulin pump is used for maintenance of glucose control; AND
- Adequate glycemic control has not been achieved despite frequent self-monitoring of blood glucose (4 or more fingersticks per day), as evidenced by **at least ONE** of the following:
  1. Recurrrent, severe hypoglycemia (e.g., blood glucose levels less than 50 mg/dL) or hypoglycemia unawareness; OR
  2. Frequent nocturnal hypoglycemia (e.g., blood glucose levels less than 50 mg/dL); OR
  3. Discordant hemoglobin A1C and fingerstick blood glucose levels (i.e., patient with consistent normal fingerstick results, but high hemoglobin A1C levels).

- All other uses of a closed-loop CGM and insulin pump system (artificial pancreas device system) are considered INVESTIGATIVE due to the lack of evidence demonstrating an impact on improved health outcomes.

IV. Remote Glucose Monitoring Systems

- Use of a remote glucose monitoring system (e.g., my Sentry™) is considered INVESTIGATIVE due to the lack of evidence demonstrating an impact on improved health outcomes.

Panniculectomy/Excision of Redundant Skin or Tissue, IV-24

I. Panniculectomy

- Panniculectomy with or without abdominoplasty may be considered MEDICALLY NECESSARY when **both** of the following criteria are met:
  - The pannus/panniculus extends at or below the level of the symphysis pubis; AND
  - The treating physician has documented that the pannus/panniculus is associated with:
    - Chronic, or recurrent infection, intertrigo or skin necrosis refractory to medical management (e.g., antifungal, antibacterial, and moisture-absorbing agents; supportive garments, topically-applied skin barriers); OR
    - Chronic or recurrent ulcerations, accompanied by skin deterioration, that are nonresponsive to aggressive wound management.
- Panniculectomy with or without abdominoplasty may be considered MEDICALLY NECESSARY as an adjunct to a medically necessary procedure when needed for exposure to improve surgical access or wound healing following surgery.
- The following procedures are considered COSMETIC as they are performed primarily to enhance or otherwise alter physical appearance without correcting or improving a physiological function:
  - Panniculectomy with or without abdominoplasty not meeting the medical necessity criteria in the policy statements directly above;
  - Abdominoplasty;
  - Nonfunctional procedures performed in association with a medically necessary panniculectomy (e.g., transposition of the umbilicus, undermining to the costal margin, lateral contouring imbrications, lipectomy);
  - Repair of diastasis recti.

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II. Excision of Redundant Skin or Tissue of Other Anatomical Areas

- Excision of redundant skin or tissue of other anatomical areas including but not limited to the upper extremities (e.g., brachioplasty), lower extremities, buttocks, or genitalia may be considered MEDICALLY NECESSARY when at least one of the following are met:
  - The treating physician has documented that the redundant skin is associated with:
    - Chronic, or recurrent infection, intertrigo or skin necrosis refractory to medical management (e.g., antifungal, antibacterial, and moisture-absorbing agents; supportive garments, topically-applied skin barriers); OR
    - Chronic or recurrent ulcerations, accompanied by skin deterioration, that are nonresponsive to aggressive wound management; OR
    - Biopsy or removal of a premalignant or malignant skin lesion,
- Excision of redundant skin or tissue performed primarily to enhance or otherwise alter physical appearance is considered COSMETIC.

III. Suction-assisted protein lipectomy (SAPL) of the lower extremities is considered INVESTIGATIVE due to a lack of clinical evidence demonstrating its impact on improved health outcomes.

- Documentation Submission
  Documentation supporting the medical necessity criteria described in the policy must be included in prior authorization requests. In addition, photographs must be submitted for indications that cannot be sufficiently described. Several different views of the affected area are helpful. Photographs should be limited to the affected area.

Policies inactivated

Implantation of Intrastromal Corneal Ring Segments, IV-121

Policies Effective: 05/15/17 Notification Posted: 03/24/17

Policies developed

None

Policies revised

Transcatheter Uterine Artery Embolization (formerly titled Occlusion of Uterine Arteries) V-10

I. Transcatheter uterine artery embolization may be considered MEDICALLY NECESSARY for treatment of ANY of the following:

- Uterine fibroids, OR
- Postpartum uterine hemorrhage, OR
- Uterine arteriovenous malformations.

II. ONE repeat transcatheter embolization of uterine arteries may be considered MEDICALLY NECESSARY to treat persistent symptoms of uterine fibroids after an initial UAE.

III. Transcatheter uterine artery embolization is considered INVESTIGATIVE for all other indications, including but not limited to cervical ectopic pregnancy and adenomyosis, due to the lack of evidence demonstrating an impact on improved health outcomes.

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Knee Arthroplasty (Knee Replacement) IV-122

- **NOTE:** When bilateral knee arthroplasty is planned, whether simultaneous or staged, the criteria below apply to each knee joint being considered.

I. Total Knee Arthroplasty (Total Knee Replacement)

Total knee arthroplasty may be considered MEDICALLY NECESSARY when ALL of the following criteria are met:

- ONE of the following indications:
  1. Primary and secondary tumors of the distal femur or proximal tibia; OR
  2. Displaced fractures of the distal femur or proximal tibia; OR
  3. Failed previous knee fracture fixation; OR
  4. Failed previous unicompartmental knee arthroplasty; OR
  5. Failed previous knee osteotomy; OR
  6. Avascular necrosis (osteonecrosis) of the knee; OR
  7. Hemophilic arthropathy of the knee; OR
  8. Advanced knee joint disease due to osteoarthritis, rheumatoid arthritis, juvenile rheumatoid/idiopathic arthritis, or post-traumatic arthritis and ALL of the following criteria:
     - Diagnostic imaging and/or arthroscopic evidence, obtained within the previous 12 months, of severe cartilage damage or destruction (i.e., modified Outerbridge grade III or IV or Kellgren-Lawrence grade 3 or 4); AND
     - Clinically significant functional limitation resulting in impaired, age-appropriate activities of daily living and diminished quality of life; AND
     - Moderate to severe persistent knee pain despite at least 3 months of conservative non-surgical therapy during the previous 12 months, including BOTH of the following:
       a. Medical management with nonsteroidal anti-inflammatory agents (NSAIDs) or other analgesic medications; AND
       b. Physical therapy, including strengthening exercises: 6 week course

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

  AND
- No contraindications to the procedure, including:
  1. No active infection of the knee joint or active systemic bacteremia;
  2. No active skin infection or open wound within the planned surgical site of the knee;
  3. No known allergy to components of the knee implant (e.g., cobalt, chromium, aluminum).

II. Unicompartmental Knee Arthroplasty (Partial Knee Replacement)

Unicompartmental knee arthroplasty may be considered MEDICALLY NECESSARY for the treatment of advanced knee joint disease due to osteoarthritis, rheumatoid arthritis, juvenile rheumatoid/idiopathic arthritis, or post-traumatic arthritis, when ALL of the following criteria are met:

- Diagnostic imaging and/or arthroscopic evidence, obtained within the previous 12 months, of severe cartilage damage or destruction (i.e., modified Outerbridge grade III or IV or Kellgren-Lawrence grade 3 or 4) limited to a single compartment (i.e., medial, lateral, or patellofemoral); AND
- Involved knee demonstrates adequate alignment and ligamentous stability; AND
- Clinically significant functional limitation resulting in impaired, age-appropriate activities of daily living and diminished quality of life; AND
- Moderate to severe persistent knee pain localized to the affected compartment (i.e., medial, lateral, or patellofemoral) despite at least 3 months of conservative non-surgical therapy during the previous 12 months, including BOTH of the following:

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1. Medical management with nonsteroidal anti-inflammatory agents (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 due to progressively worsening pain and disability, the case will be reviewed on an individual basis by an internal physician reviewer (See Documentation Submission section).

AND

- No contraindications to the procedure, including:
  1. No active infection of the knee joint or active systemic bacteremia;
  2. No active skin infection or open wound within the planned surgical site of the knee;
  3. No known allergy to components of the knee implant (e.g., cobalt, chromium, aluminum).

III. Revision Knee Arthroplasty

Revision knee arthroplasty may be considered **MEDICALLY NECESSARY** for **ANY** of the following indications:

- Instability, fracture, or mechanical failure of the prosthetic components or aseptic loosening; **OR**
- Periprosthetic fractures; **OR**
- Fracture or dislocation of the patella; **OR**
- Infection of the prosthetic joint.

IV. Investigative Procedures

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

- Bicompartmental knee arthroplasty;
- Bi-unicompartmental knee arthroplasty;
- Unicondylar interpositional spacer.

- Documentation Submission

Documentation supporting the medical necessity criteria described in the policy must be included in the prior authorization, when prior authorization is required. In addition, the following documentation must also be submitted for total or unicompartmental knee arthroplasty due to advanced knee joint disease:

- Interpretive report within the past 12 months that describes the extent of articular cartilage damage, as determined by at least one of the following methods:
  1. Knee arthroscopy report that utilizes or can be correlated with the modified Outerbridge classification system of articular cartilage injury; OR
  2. Knee x-ray report that utilizes or can be correlated with the Kellgren-Lawrence grading system of osteoarthritis; OR
     Knee MRI report from a radiologist that utilizes or can be correlated with the modified Outerbridge or similar classification system related to articular injury and osteoarthritis. Further information on these classification
  3. systems is provided in the 'Definitions' and 'Policy' sections of this document;

  AND
- Clinical notes describing:
  1. Severity of knee pain; AND
  2. Functional limitations related to knee symptoms; AND
  3. Conservative non-surgical therapy:
     - Medical management with nonsteroidal anti-inflammatory agents (NSAIDs) or other analgesics; AND
     - Physical therapy. 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 by an internal physician reviewer. Documentation must include clinical notes from the physical therapist describing the patient's inability to complete PT.

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- For unicompartmental knee arthroplasty: an orthopedic assessment of knee alignment and ligamentous stability.

Genetic Testing for FMR1 Mutations (Including Fragile X Syndrome) VI-44

I. Genetic testing for FMR1 mutations may be considered MEDICALLY NECESSARY for the following patient populations:

- Individuals of either sex with intellectual disability, developmental delay, or autism spectrum disorder; OR
- Individuals seeking reproductive counseling who have a family history of fragile X syndrome or a family history of undiagnosed intellectual disability; OR
- Prenatal testing of fetuses of known carrier mothers; OR
- Affected individuals or their relatives who have had a positive cytogenetic fragile X test result who are seeking further counseling related to the risk of carrier status among themselves or their relatives; OR
- Women under the age of 40 with ovarian failure in whom fragile X-associated primary ovarian insufficiency is suspected; OR
- Individuals with neurologic symptoms consistent with fragile X- associated tremor/ataxia syndrome.

II. Testing for FMR1 mutations for all other indications including but not limited to population-based screening or testing in individuals not meeting one or more of the criteria above, is considered INVESTIGATIVE due to the lack of clinical evidence demonstrating its impact on improved health outcomes.

Psychological and Neuropsychological Testing X-45

I. Specific considerations for determinations regarding psychological testing include the following:

- Psychological testing may be considered MEDICALLY NECESSARY when ALL of the following criteria are met:
  1. Testing is supervised and interpreted by a physician, or PhD or master's-level licensed psychologist who is appropriately licensed according to applicable state law following a face-to-face evaluation; AND
  2. Testing is used to rule-in or rule out the presence of at least one of the following:
     - A thought disorder, severe emotional distress or other psychiatric diagnosis when this information is not available from one or more comprehensive medical or behavioral health evaluations with the member and other sources as appropriate (e.g. family members, other health care providers, school records);
     - An intellectual disability or intellectual developmental disorder;
     - Psychological comorbidities in patients with attention-deficit/hyperactivity disorder (ADHD) when signs or symptoms are suggestive of other mental health or neurocognitive disorders. ADHD alone does not typically require cognitive testing unless such disorders are suspected. Provider interpretation of brief rating scales of up to one hour is considered medically necessary.

     AND
  3. A specific diagnostic or treatment question still exists which cannot be answered without the results of psychological testing; AND
  4. The results of the testing will impact the medical/psychiatric/psychological treatment of the patient; AND
  5. Testing instruments and time allotted for each instrument are appropriate for and limited to the unique clinical presentation of the individual; AND
  6. The most current versions of validated and reliable psychological testing instruments are utilized, or if an older version is used, there is specific rationale for use of that version.
- Psychological testing is considered NOT MEDICALLY NECESSARY for all other indications including but limited to the following:
  1. Use of testing for screening or solely for exploratory purposes in the absence of signs/symptoms of a specific behavioral health condition for which testing is essential
  2. Diagnosis and management of ADHD in the absence of signs or symptoms suggestive of other mental health or

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neurocognitive disorders

3. Preoperative evaluation prior to a surgical procedure in the absence of signs or symptoms of a co-occurring psychiatric or neurocognitive condition
4. Testing instruments and requested hours for test administration, scoring, interpretation, and generating reports are outside established standards of practice
5. Testing is performed while an individual is abusing substances or having acute withdrawal symptoms
6. Testing performed consists of brief self-administered or self-scored inventories or screening tests including but not limited to the Beck Depression Inventory, Beck Anxiety Inventory, Eating Attitudes Test (EAT-26) Hamilton Rating Scale for Depression or Patient Health Questionnaire (PHQ-9)
7. Testing is predominately for career aptitude, vocational or academic/educational planning
8. Testing in the setting of a court referral or solely for forensic purposes
9. Testing for research purposes

II. Specific considerations for determinations regarding neuropsychological testing include the following:

- Neuropsychological testing may be considered MEDICALLY NECESSARY when ALL of the following criteria are met:
  1. Testing is supervised and interpreted by a physician or PhD who is appropriately licensed according to applicable state law following a face-to-face evaluation; AND
  2. Testing is used to rule-in or rule-out the presence of a specific neurocognitive disorder or other specific neurological or psychiatric diagnosis when this information is not available from one or more comprehensive medical or behavioral health evaluations with the member and other sources as appropriate (e.g. family members, other health care providers, school records); AND
  3. The results of the testing will impact the medical/psychiatric/psychological treatment of the patient; AND
  4. Presence of a clinical condition which may require the use of neuropsychological testing, including but not limited to:
     - Cerebrovascular disease/stroke when there is evidence of cognitive or neurologic impairment
     - Complex neuropsychiatric or neurodevelopmental condition (e.g., autism spectrum disorder, intellectual disability, or psychosis when neurological signs are known or suspected.
     - Confirmed space-occupying brain lesion including but not limited to brain abscess, brain tumor or arteriovenous malformations within the brain
     - Demyelinating disorders including multiple sclerosis
     - Encephalopathy including acquired immunodeficiency syndrome (AIDS) encephalopathy, human immunodeficiency virus (HIV) encephalopathy, hepatic encephalopathy, Lyme disease encephalopathy (including neuroborreliosis), Wernicke's encephalopathy or systemic lupus erythematosus (SLE) encephalopathy
     - Extrapyramidal disease (e.g. Parkinson's, Huntington's disease)
     - Genetic disorder that may result in cognitive or neurologic impairment (e.g., Turner, Klinfelter, Rett, Fragile X or 22q11.2 deletion [velocardiofacial or DiGeorge] syndromes, Duchenne muscular dystrophy, neurofibromatosis type 1)
     - In-born errors of metabolism (e.g., lysosomal or peroxisomal storage disease, Hurler syndrome, adrenal leukodystrophy)
     - Hypoxic or anoxic brain injury
     - Neonatal or antenatal complication (e.g., respiratory distress, preeclampsia, in utero exposure to illicit drugs, alcohol, tobacco, environmental toxins)
     - Neurotoxin exposure (e.g. lead poisoning, cranial irradiation, chemotherapeutic agents)

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  - Seizure disorder including patients with epilepsy and patients being considered for epilepsy surgery
  - Systemic medical condition known to be associated with cerebral dysfunction in adults or children (e.g., renal disease, cardiac anomalies or congenital heart conditions requiring surgical repair, liver disease and autoimmune disorders such as lupus erythematosus or celiac disease)
  - Traumatic brain injury (TBI)
- Neuropsychological testing is considered NOT MEDICALLY NECESSARY for all other indications including but limited to the following:
  1. Use of testing for screening or solely for exploratory purposes in the absence of signs or symptoms of a neuropsychological/neurological condition
  2. Diagnosis and management of attention-deficit/hyperactivity disorder (ADHD) in the absence of signs or symptoms suggestive of other mental health or neurocognitive disorders which meet requirements for testing
  3. Requested hours for test administration, scoring, interpretation, and generating reports are outside established standards of practice
  4. Testing is performed while an individual is abusing substances or having acute withdrawal symptoms
  5. Testing is predominately for career aptitude, vocational or academic/educational planning
  6. Testing in the setting of court referral or solely for forensic purposes
  7. Testing for research purposes

Policies inactivated

None

Policies Effective: 06/19/17 Notification Posted: 04/28/17

Policies developed

Nusinersen, II-171

I. Initial Review

Nusinersen 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 type I spinal muscular atrophy (SMA), as evidenced by ALL of the following:
  1. Genetic testing confirms diagnosis of SMA, including loss of, or defect in, the SMN1 gene (NOTE: laboratory documentation must be provided); AND
  2. ONE of the following:
     - SMA-associated symptoms before 6 months of age; OR
     - Genetic testing confirms 2 copies of the SMN2 gene (NOTE: laboratory documentation must be provided);

  AND
- Laboratory testing confirms ALL of the following measurements are within the normal age-adjusted reference range for the laboratory performing the test (NOTE: laboratory documentation must be provided):
  1. Platelet count (e.g., 150,000–450,000/µL); AND
  2. Prothrombin time (e.g., 11–13.5 seconds or international normalized ratio [INR] of 0.8–1.1) or activated partial thromboplastin time (e.g., 25–35 seconds) by coagulation laboratory testing; AND
  3. Urinary protein concentration (e.g., ≤0.2 g/L) by quantitative spot urine protein testing;

  AND
- Nusinersen is prescribed by or in consultation with a neurologist; AND

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- The dose is within the FDA labeled dose (see table 2 below).

II. Renewal Review

Nusinersen 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., improvement in motor function or stabilization of motor function loss); AND
- The patient does not have any FDA labeled contraindications to therapy (see table 1 below); AND
- Laboratory testing confirms ALL of the following measurements are within the normal age-adjusted reference range for the laboratory performing the test (NOTE: laboratory documentation must be provided):
  1. Platelet count (e.g., 150,000–450,000/µL); AND
  2. Prothrombin time (e.g., 11–13.5 seconds or international normalized ratio [INR] of 0.8–1.1) or activated partial thromboplastin time (e.g., 25–35 seconds) by coagulation laboratory testing; AND
  3. Urinary protein concentration (e.g., ≤0.2 g/L) by quantitative spot urine protein testing;

  AND
- Nusinersen is prescribed by or in consultation with a neurologist; AND
- The dose is within the FDA labeled dose (see table 2 below).

III. All other uses of nusinersen are considered INVESTIGATIVE, including but not limited to treatment of SMA not meeting the criteria above, due to the lack of clinical evidence demonstrating an impact on improved health outcomes.

- **Table 1. FDA Labeled Contraindications**

AGENT	FDA LABELED CONTRAINDICATIONS
Nusinersen	None

- **Table 2. Dosing**

FDA LABELED INDICATIONS	DOSING
Spinal muscular atrophy (SMA)	12 mg (5 mL) per administration Initiate treatment with 4 loading doses. The first 3 loading doses should be administered at 14-day intervals. The 4th loading dose should be administered 30 days after the 3rd dose. A maintenance dose should be administered once every 4 months thereafter.

- Documentation Submission:

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

  Initial Review

  1. Clinical notes describing the diagnosis and clinical features of the diagnosis.
  2. Laboratory documentation confirming genetic diagnosis of SMA, including loss of, or defect in, the *SMN1* gene.
  3. Laboratory documentation confirming ALL of the following measurements are within the normal age-adjusted reference range for the laboratory performing the test:

     a. Platelet count

     b. Prothrombin time or activated partial thromboplastin time by coagulation laboratory testing

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c. Urinary protein concentration by quantitative spot urine protein testing

4. The dose being requested. If the requested dose is higher or more frequent than the dosing guidelines provided in the table above, a clear explanation for the medical necessity of the requested dose MUST be submitted, including prior dosing (strength and frequency) associated with inadequate response.

Renewal Review

1. Documentation of prior approval for nusinersen through the initial review process.
2. Documentation supporting positive clinical response (e.g., improvement in motor function or stabilization of motor function loss).
3. Laboratory documentation confirming ALL of the following measurements are within the normal age-adjusted reference range for the laboratory performing the test:

   a. Platelet count

   b. Prothrombin time or activated partial thromboplastin time by coagulation laboratory testing

   c. Urinary protein concentration by quantitative spot urine protein testing
4. The dose being requested. If the requested dose is higher or more frequent than the dosing guidelines provided in the table above, a clear explanation for the medical necessity of the requested dose MUST be submitted, including prior dosing (strength and frequency) associated with inadequate response.

Policies revised

Hematopoietic Stem-Cell Transplantation for Chronic Lymphocytic Leukemia and Small Lymphocytic Lymphoma, II-122

- Allogeneic hematopoietic stem-cell transplantation may be considered MEDICALLY NECESSARY to treat chronic lymphocytic leukemia or small lymphocytic lymphoma in patients with histologic transformation or other confirmation of disease progression after standard first-line therapy.
- Allogeneic hematopoietic stem-cell transplantation is considered INVESTIGATIVE to treat chronic lymphocytic leukemia or small lymphocytic lymphoma when the criteria above are not met.
- Autologous hematopoietic stem-cell transplantation is considered INVESTIGATIVE to treat chronic lymphocytic leukemia or small lymphocytic lymphoma.

Hip Arthroplasty (Hip Replacement) and Hip Resurfacing, IV-107

- **NOTE:** When bilateral hip arthroplasty is planned, whether simultaneous or staged, the criteria below apply to each hip joint being considered.

I. <u>Total Hip Arthroplasty (Total Hip Replacement)</u>

Total hip arthroplasty may be considered MEDICALLY NECESSARY when ALL of the following criteria are met:

- ONE of the following indications:
  1. Primary and secondary tumors of the proximal femur; OR
  2. Displaced femoral neck fracture; OR
  3. Failed previous hip fracture fixation; OR
  4. Developmental dysplasia of the hip (DDH) in skeletally mature patients; OR
  5. Avascular necrosis (osteonecrosis) of the hip; OR
  6. Hemophilic arthropathy of the hip; OR
  7. Advanced hip joint disease and ALL of the following criteria:

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- Diagnostic imaging, obtained within the previous 12 months, confirms ONE of the following:
  a. Severe cartilage damage or destruction (i.e., modified Outerbridge grade III or IV or Kellgren-Lawrence grade 3 or 4) due to osteoarthritis or post-traumatic arthritis of the hip; OR
  b. Advanced rheumatoid arthritis of the hip (e.g., marginal erosions, joint destruction, acetabular protrusio);
  AND
- Clinically significant functional limitation resulting in impaired, age-appropriate activities of daily living and diminished quality of life; AND
- Moderate to severe persistent hip pain resulting in limited ROM and antalgic gait, despite at least 3 months of conservative non-surgical treatment during the previous 12 months, including BOTH of the following:
  a. Medical management with nonsteroidal anti-inflammatory agents (NSAIDs) or other analgesic medications; **AND**
  b. Physical therapy, including strengthening exercises: 6 week course.
  NOTE: If a patient is unable to complete physical therapy (PT) due to progressively worsening pain and disability, the case will be reviewed on an individual basis by an internal physician reviewer (See Documentation Submission section).

AND

- No contraindications to the procedure, including:
  1. No active infection of the hip joint or active systemic bacteremia;
  2. No active skin infection or open wound within the planned surgical site of the hip;
  3. No known allergy to components of the hip implant (e.g., cobalt, chromium, aluminum).

II. Revision Hip Arthroplasty

Revision hip arthroplasty may be considered MEDICALLY NECESSARY for ANY of the following indications:

- Instability of the prosthetic components or aseptic loosening; OR
- Periprosthetic fracture; OR
- Periprosthetic osteolysis; OR
- Infection of the prosthetic joint; OR
- Implant component failure or FDA recall of the implant.

III. Total Hip Resurfacing

Total hip resurfacing may be considered MEDICALLY NECESSARY as an alternative to total hip arthroplasty when ALL of the following criteria are met:

- Patient has normal proximal femoral bone geometry and bone quality; AND
- ONE of the following conditions is present:
  1. Avascular necrosis with <50% involvement of the femoral head; OR
  2. Advanced hip joint disease due to osteoarthritis, rheumatoid arthritis, or post-traumatic arthritis when ALL criteria for total hip arthroplasty, as described in section I, have been met.

- Documentation Submission

Documentation supporting the medical necessity criteria described in the policy must be included in the prior authorization, when prior authorization is required. In addition, the following documentation must also be submitted for total hip arthroplasty OR total hip resurfacing due to the following indications:

- Osteoarthritis or posttraumatic arthritis of the hip:

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1. Interpretive report within the past 12 months that describes the extent of articular cartilage damage, as determined by at least one of the following methods:
   - Hip x-ray report that utilizes or can be correlated with the Kellgren-Lawrence grading system of osteoarthritis; OR
   - Hip MRI report from a radiologist that utilizes or can be correlated with the modified Outerbridge or similar classification system related to articular cartilage injury and osteoarthritis. NOTE: Further information on these classification systems is provided above;

AND

2. Clinical notes describing:
   - Severity of hip pain; AND
   - Functional limitations related to hip symptoms; AND
   - Conservative non-surgical therapy:
     a. Medical management with nonsteroidal anti-inflammatory agents (NSAIDs) or other analgesics; AND
     b. Physical therapy. 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 by an internal physician reviewer. Documentation must include clinical notes from the physical therapist describing the patient's inability to complete PT.

- Rheumatoid arthritis of the hip:
  1. Interpretive report within the past 12 months that describes the extent of damage to the hip joint; AND
  2. Clinical notes describing:
     - Severity of hip pain; AND
     - Functional limitations related to hip symptoms; AND
     - Conservative non-surgical therapy:
       a. Medical management with NSAIDs or other analgesics; AND
       b. Physical therapy. If a patient is unable to complete PT due to progressively worsening symptoms of pain and disability, the case will be reviewed on an individual basis by an internal physician reviewer. Documentation must include clinical notes from the physical therapist describing the patient's inability to complete PT.
- For total hip resurfacing: an orthopedic assessment of proximal femoral bone geometry and bone quality.

Genetic Testing Genetic Testing Hereditary Breast/Ovarian Cancer Syndrome (BRCA1/BRCA2), VI-16

- **NOTE:** Panel testing for risk of other hereditary cancer syndromes is addressed in policy VI-56: Genetic Cancer Susceptibility Panels.

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
- Fallopian tube cancer
- Primary peritoneal cancer

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- 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 meets ALL of the following:

- Has received pre-test genetic counseling from a board-eligible or board-certified genetic counselor, clinical geneticists, or healthcare professional working under the supervision of a physician 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. Genetic testing for hereditary breast and/or ovarian cancer using a multi-gene sequencing panel ***that includes BRCA1/BRCA2 genes*** is considered MEDICALLY NECESSARY when an individual meets **all** of the following:

- Pretest genetic counseling by a board-eligible or board-certified genetic counselor, clinical geneticist, or healthcare professional working under the supervision of a physician and who is independent of the laboratory performing the test documents a family history/pedigree demonstrating a reasonable likelihood for one of the following cancer syndromes (associated genes in parentheses):
  - Bannayan-Riley-Ruvalcaba syndromes, Cowden syndrome, PTEN hamartoma syndrome *(PTEN)*
  - Hereditary diffuse gastric cancer syndrome *(CDH1)*
  - Li Fraumeni syndrome *(TP53)*
  - Lynch syndrome/hereditary non-polyposis colorectal cancer *(MSH2, MLH1, MSH6, MUYH, PMS2, PMS1, EPCAM)*

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- *PALB2* genetic mutation associated with increased risk of breast cancer *(PALB2)*
- Peutz-Jeghers syndrome *(STK11)*

AND

- The panel is limited to genes that have proven utility for clinical management of hereditary breast and/or ovarian cancer; AND
- Results of testing will impact the medical management of the individual (e.g., increased screening or surveillance).

V. Genetic testing for hereditary breast and/or ovarian cancer as either a single-gene or multi-gene panel test is considered INVESTIGATIVE for all other indications including but not limited to the following due to a lack of clinical evidence demonstrating an effect on health outcomes:

- Testing performed in the absence of pretest genetic counseling by a cancer genetics professional independent of the laboratory performing the test
- Testing offered as a direct access (also known as direct to consumer)
- Testing in the general population as a screening tool
- All other testing for risk of hereditary breast and/or ovarian cancer that do not meet criteria as stated above.

• Documentation Submission

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

1.Documentation of a known deleterious mutation in genes addressed in this policy in a close blood relative; OR

2.Diagnosis of individual with personal history of cancers addressed in this policy; OR

3.For a patient without a personal history of cancer, verification of the following:

- Pre-test genetic counseling, as defined above, by a healthcare professional who has the appropriate genetics training and experience and is independent of the laboratory performing the test.
- Documentation of the gene or genes for which testing is requested, accompanied by a statement that the individual's personal and family history has been reviewed and that based on that history, testing of the indicated gene(s) is appropriate.

Policies inactivated

None

Policies reviewed with no changes in February 2017, March 2017, and April 2017:

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

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