



September 2018

# medical policy update **bulletin**

Medical Policy, Medical Benefit Drug Policy & Coverage Determination Guideline Updates

UnitedHealthcare respects the expertise of the physicians, health care professionals, and their staff who participate in our network. Our goal is to support you and your patients in making the most informed decisions regarding the choice of quality and cost-effective care, and to support practice staff with a simple and predictable administrative experience. The Medical Policy Update Bulletin was developed to share important information regarding UnitedHealthcare Medical Policy, Medical Benefit Drug Policy, Coverage Determination Guideline, Utilization Review Guideline, and Quality of Care Guideline updates.\*

\*Where information in this bulletin conflicts with applicable state and/or federal law, UnitedHealthcare follows such applicable federal and/or state law.

## Overview

This bulletin provides complete details on UnitedHealthcare Medical Policy, Medical Benefit Drug Policy, Coverage Determination Guideline (CDG), Utilization Review Guideline (URG), and/or Quality of Care Guideline (QOCG) updates. The inclusion of a health service (e.g., test, drug, device or procedure) in this bulletin indicates only that UnitedHealthcare has recently adopted a new policy and/or updated, revised, replaced or retired an existing policy; it does not imply that UnitedHealthcare provides coverage for the health service. In the event of an inconsistency or conflict between the information provided in this bulletin and the posted policy, the provisions of the posted policy will prevail. Note that most benefit plan documents exclude from benefit coverage health services identified as investigational or unproven/not medically necessary. Physicians and other health care professionals may not seek or collect payment from a member for services not covered by the applicable benefit plan unless first obtaining the member's written consent, acknowledging that the service is not covered by the benefit plan and that they will be billed directly for the service.



The complete library of UnitedHealthcare Medical Policies, Medical Benefit Drug Policies, CDGs, URGs, and QOCGs is available at [UHCprovider.com](http://UHCprovider.com) > Menu > Policies and Protocols > Commercial Policies > Medical & Drug Policies and Coverage Determination Guidelines.

### Tips for using the Medical Policy Update Bulletin:

- From the table of contents, click the policy title to be directed to the corresponding policy update summary.
- From the policy updates table, click the policy title to view a complete copy of a new, updated, or revised policy.

### Policy Update Classifications

#### New

New clinical coverage criteria and/or documentation review requirements have been adopted for a health service (e.g., test, drug, device or procedure)

#### Updated

An existing policy has been reviewed and changes have not been made to the clinical coverage criteria or documentation review requirements; however, items such as the clinical evidence, FDA information, and/or list(s) of applicable codes may have been updated

#### Revised

An existing policy has been reviewed and revisions have been made to the clinical coverage criteria and/or documentation review requirements

#### Replaced

An existing policy has been replaced with a new or different policy

#### Retired

The health service(s) addressed in the policy are no longer being managed or are considered to be proven/medically necessary and are therefore not excluded as unproven/not medically necessary services, unless coverage guidelines or criteria are otherwise documented in another policy

Note: The absence of a policy does not automatically indicate or imply coverage. As always, coverage for a health service must be determined in accordance with the member's benefit plan and any applicable federal or state regulatory requirements. Additionally, UnitedHealthcare reserves the right to review the clinical evidence supporting the safety and effectiveness of a medical technology prior to rendering a coverage determination.

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<b>UPDATED</b>		
<a href="#">Chromosome Microarray Testing (Non-Oncology Conditions)</a>	Oct. 1, 2018	<ul style="list-style-type: none"> <li>Updated coverage rationale; modified language to clarify:               <ul style="list-style-type: none"> <li>[The listed services are] proven <b>and</b> medically necessary</li> <li>[The listed service is] unproven <b>and</b> not medically necessary</li> </ul> </li> <li>Updated list of applicable ICD-10 diagnosis codes to reflect annual code edits:               <ul style="list-style-type: none"> <li>Added Q93.51, Q93.59, and Q93.82</li> <li>Removed Q93.5</li> </ul> </li> </ul>
<a href="#">Computed Tomographic Colonography</a>	Sep. 1, 2018	<ul style="list-style-type: none"> <li>Updated coverage rationale:               <ul style="list-style-type: none"> <li>Replaced references to “patients” with “individuals”</li> <li>Modified language pertaining to clinical evidence/study findings to indicate:                   <ul style="list-style-type: none"> <li>There is insufficient evidence to support the use of computed tomographic colonography in the diagnosis of Crohn’s disease and diverticulitis</li> <li>The technology is not currently supported in Crohn’s disease due to the potential of false-negative findings</li> <li>While it is more promising in individuals with diverticulitis, further studies are needed to determine the safety and efficacy of computed tomographic colonography as a follow-up diagnostic tool for these conditions</li> </ul> </li> </ul> </li> <li>Updated supporting information to reflect the most current description of services, clinical evidence, CMS information, and references</li> </ul>
<a href="#">Core Decompression for Avascular Necrosis</a>	Oct. 1, 2018	<ul style="list-style-type: none"> <li>Updated list of applicable CPT codes; added 21299</li> <li>Updated supporting information to reflect the most current clinical evidence and references</li> </ul>
<a href="#">Functional Endoscopic Sinus Surgery (FESS)</a>	Sep. 1, 2018	<ul style="list-style-type: none"> <li>Updated coverage rationale:               <ul style="list-style-type: none"> <li>Modified language to clarify [the listed service is] proven and medically necessary</li> <li>Replaced reference to “patients” with “individuals”</li> </ul> </li> <li>Updated supporting information to reflect the most current description of services, clinical evidence, and references</li> </ul>
<a href="#">Hepatitis Screening</a>	Oct. 1, 2018	<ul style="list-style-type: none"> <li>Updated coverage rationale; modified language to clarify the [the listed services are] proven <b>and</b> medically necessary</li> <li>Updated list of applicable ICD-10 diagnosis codes to reflect annual code edits:               <ul style="list-style-type: none"> <li>Added F12.23, F12.93, O30.131, O30.132, O30.133, O30.139, O30.231, O30.232, O30.233, O30.239, O30.831, O30.832, O30.833, O30.839, O86.00, O86.01, O86.02, O86.03, O86.04, O86.09, T74.51XA, T74.51XD, T74.51XS, T74.52XA, T74.52XD, T74.52XS, T76.51XA, T76.51XD, T76.51XS, T76.52XA, T76.52XD, T76.52XS, Z20.821, Z62.813, and Z91.42</li> <li>Replaced:                   <ul style="list-style-type: none"> <li>“O0.0211” with “O00.211”</li> </ul> </li> </ul> </li> </ul>

## Medical Policy Updates

Policy Title	Effective Date	Summary of Changes
<b>UPDATED</b>		
<a href="#">Hepatitis Screening</a> (continued)	Oct. 1, 2018	<ul style="list-style-type: none"> <li>▪ "00.0212" with "000.212"</li> <li>▪ "00.0219" with "000.219"</li> </ul>
<a href="#">High Frequency Chest Wall Compression Devices</a>	Oct. 1, 2018	<ul style="list-style-type: none"> <li>• Updated coverage rationale:               <ul style="list-style-type: none"> <li>○ Replaced language indicating:                   <ul style="list-style-type: none"> <li>▪ "High-frequency chest wall compression (HFCWC), as a form of chest physical therapy, is unproven and not medically necessary for diagnoses <i>other than cystic fibrosis and bronchiectasis</i>" with "high-frequency chest wall compression (HFCWC), as a form of chest physical therapy, is unproven and not medically necessary for <i>all other</i> diagnoses [not listed in the policy as proven/medically necessary]"</li> </ul> </li> <li>○ Modified language pertaining to clinical evidence/study findings to indicate there is insufficient clinical evidence to conclude that the use of HFCWC therapy improves health outcomes, such as decreased morbidity and mortality rates, in individuals with conditions other than those listed as proven</li> </ul> </li> <li>• Removed list of applicable CPT codes: 94669</li> <li>• Updated supporting information to reflect the most current description of services, clinical evidence, CMS information, and references</li> </ul>
<a href="#">Lithotripsy for Salivary Stones</a>	Sep. 1, 2018	<ul style="list-style-type: none"> <li>• Updated coverage rationale:               <ul style="list-style-type: none"> <li>○ Replaced reference to:                   <ul style="list-style-type: none"> <li>▪ "Patients" with "participants"</li> <li>▪ "<i>Patient</i> sample sizes" with "sample sizes"</li> </ul> </li> </ul> </li> <li>• Updated supporting information to reflect the most current description of services, clinical evidence, and references</li> </ul>
<a href="#">Nerve Graft to Restore Erectile Function During Radical Prostatectomy</a>	Sep. 1, 2018	<ul style="list-style-type: none"> <li>• Updated supporting information to reflect the most current CMS information and references; no change to coverage rationale or list of applicable codes</li> </ul>
<a href="#">Neurophysiologic Testing and Monitoring</a>	Sep. 1, 2018	<ul style="list-style-type: none"> <li>• Updated and reorganized coverage rationale:               <ul style="list-style-type: none"> <li>○ Replaced references to "patient(s)" with "individual(s)"</li> <li>○ Modified language pertaining to clinical evidence/study findings for:                   <ul style="list-style-type: none"> <li>▪ Non-invasive automatic, portable, or automated point of care nerve conduction monitoring systems; replaced language indicating:                       <ul style="list-style-type: none"> <li>- "Studies of these devices are primarily small case series <i>comparing portable with conventional nerve conduction studies in the same patient; studies that did use controls did not always report the patients' conditions</i>" with "studies of these devices are primarily small case series or uncontrolled or poorly controlled comparison studies"</li> </ul> </li> <li>▪ Quantitative sensory testing to indicate:</li> </ul> </li> </ul> </li> </ul>

## Medical Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
<b>UPDATED</b>			
<a href="#">Neurophysiologic Testing and Monitoring</a> (continued)	Sep. 1, 2018	<ul style="list-style-type: none"> <li>- Definitive conclusions for quantitative sensory testing including monofilament testing, pressure-specified sensory testing, computer assisted sensory examinations, and CPT testing cannot be determined due to limited evidence that this testing impacts patient management</li> <li>- Further research is needed to validate the clinical utility of quantitative sensory testing</li> <li>• Updated supporting information to reflect the most current description of services, clinical evidence, FDA and CMS information, and references</li> </ul>	
<a href="#">Osteochondral Grafting</a>	Sep. 1, 2018	<ul style="list-style-type: none"> <li>• Updated supporting information to reflect the most current clinical evidence and references; no change to coverage rationale or list of applicable codes</li> </ul>	
<a href="#">Percutaneous Vertebroplasty and Kyphoplasty</a>	Sep. 1, 2018	<ul style="list-style-type: none"> <li>• Updated supporting information to reflect the most current clinical evidence, CMS information, and references</li> </ul>	
<a href="#">Sensory Integration Therapy and Auditory Integration Training</a>	Sep. 1, 2018	<ul style="list-style-type: none"> <li>• Updated coverage rationale:               <ul style="list-style-type: none"> <li>○ Replaced reference to "patient" with "individual"</li> <li>○ Modified language pertaining to clinical evidence/study findings for auditory integration training (AIT); removed language indicating AIT is based on the unproven theory that some disorders are caused by hearing or listening deficiencies</li> </ul> </li> <li>• Updated supporting information to reflect the most current description of services, clinical evidence, FDA information, and references</li> </ul>	
<a href="#">Vagus Nerve Stimulation</a>	Sep. 1, 2018	<ul style="list-style-type: none"> <li>• Updated coverage rationale:               <ul style="list-style-type: none"> <li>○ Replaced reference(s) to:                   <ul style="list-style-type: none"> <li>▪ "Patient(s)" with "individual(s)"</li> <li>▪ "Patient selection criteria" with "selection criteria"</li> </ul> </li> <li>○ Added reference link to the policy titled <i>Bariatric Surgery</i> for information on vagus nerve blocking for the treatment of obesity</li> </ul> </li> <li>• Updated supporting information to reflect the most current clinical evidence, FDA and CMS information, and references</li> </ul>	
<b>REVISED</b>			
<a href="#">Bariatric Surgery</a>	Nov. 1, 2018	<ul style="list-style-type: none"> <li>• Revised coverage rationale:               <ul style="list-style-type: none"> <li>○ Removed reference to "primary/secondary" procedures</li> <li>○ Modified language to clarify:</li> </ul> </li> </ul>	<p><b>The following bariatric surgical procedures are proven and medically necessary in adults for treating Extreme Obesity:</b></p> <ul style="list-style-type: none"> <li>• Gastric bypass (Roux-en-Y; gastrojejunal anastomosis)</li> <li>• Adjustable gastric banding (laparoscopic adjustable silicone gastric banding) – Refer to the <i>U.S. Food and Drug Administration</i> section of the</li> </ul>

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<b>REVISED</b>			
<a href="#">Bariatric Surgery</a> (continued)	Nov. 1, 2018	<ul style="list-style-type: none"> <li>▪ [The listed services are] proven <b>and</b> medically necessary</li> <li>▪ [The listed services are] unproven <b>and</b> not medically necessary</li> <li>○ Added language to indicate:               <ul style="list-style-type: none"> <li>▪ Revisional Bariatric Surgery using one of the procedures identified [in the policy] is proven and medically necessary when due to a technical failure or major complication from the initial bariatric procedure; a technical failure or major complication includes, but is not limited to, the following:                   <ul style="list-style-type: none"> <li>- Bowel perforation, including band erosion</li> <li>- Band migration (slippage) that cannot be corrected with manipulation or adjustment (records must demonstrate that manipulation or adjustment to correct band slippage has been attempted)</li> <li>- Leak</li> <li>- Obstruction (confirmed by imaging studies)</li> </ul> </li> </ul> </li> </ul>	<p>policy</p> <ul style="list-style-type: none"> <li>• Gastric sleeve procedure (also known as laparoscopic vertical gastrectomy or laparoscopic sleeve gastrectomy)</li> <li>• Vertical banded gastroplasty (gastric banding; gastric stapling)</li> <li>• Biliopancreatic bypass (Scopinaro procedure)</li> <li>• Biliopancreatic diversion with duodenal switch</li> </ul> <p><b>Bariatric surgery using one of the procedures identified above for treating obesity is proven and medically necessary when ALL of the following criteria are met:</b></p> <ul style="list-style-type: none"> <li>• Class III obesity (Extreme Obesity) [Body Mass Index (BMI) &gt; 40 kg/m<sup>2</sup>]; <b>or</b></li> <li>• Class II obesity (BMI 35-39.9 kg/m<sup>2</sup>) in the presence of one or more of the following co-morbidities:               <ul style="list-style-type: none"> <li>○ Type 2 diabetes; or</li> <li>○ Cardiovascular disease [e.g., stroke, myocardial infarction, poorly controlled hypertension (systolic blood pressure-greater than 140 mm Hg or diastolic blood pressure 90 mm Hg or greater, despite pharmacotherapy)]; or</li> <li>○ History of coronary artery disease with a surgical intervention such as cardiopulmonary bypass or percutaneous transluminal coronary angioplasty; or</li> <li>○ Obstructive Sleep Apnea (OSA) confirmed on polysomnography with an AHI or RDI of <math>\geq 30</math>; or</li> <li>○ History of cardiomyopathy;</li> </ul> </li> </ul> <p><b>and</b></p> <ul style="list-style-type: none"> <li>• The individual must also meet the following criteria:               <ul style="list-style-type: none"> <li>○ Documentation of a motivated attempt of weight loss through a structured diet program, prior to bariatric surgery, which includes physician or other health care provider notes and/or diet or weight loss logs from a structured weight loss program for a minimum of 6 months; and</li> <li>○ Psychosocial-behavioral evaluation to provide screening and identification of risk factors or potential postoperative challenges that may contribute to a poor postoperative outcome.</li> </ul> </li> </ul> <p><b>The bariatric surgical procedures identified above are proven and medically necessary in adolescents for treating Extreme Obesity and who have:</b></p>



## Medical Policy Updates

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<b>REVISED</b>			
<a href="#">Bariatric Surgery</a> (continued)	Nov. 1, 2018	<ul style="list-style-type: none"> <li>- Staple-line failure</li> <li>- Mechanical band failure</li> <li>▪ Revisional Bariatric Surgery for any other indication, including but not limited to inadequate weight loss due to a member's noncompliance with prescribed postoperative nutrition and exercise, is unproven and not medically necessary</li> <li>▪ Single-anastomosis duodenal switch [also known as duodenal switch with single anastomosis, or stomach intestinal pylorus sparing surgery (SIPS)] is unproven and not medically necessary for treating obesity</li> <li>○ Removed language indicating surgical adjustment or alteration of a prior bariatric procedure is proven and/or medically necessary for complications of the original surgery, such as stricture, obstruction, pouch dilatation, erosion, band slippage when the complication causes abdominal pain, inability to eat or drink or causes vomiting of prescribed meals</li> <li>○ Replaced language indicating</li> </ul>	<ul style="list-style-type: none"> <li>• Achieved greater than 95% of estimated adult height based on documented individual growth pattern; <b>and</b></li> <li>• A minimum Tanner stage of 4; <b>and</b></li> <li>• Meet the following medical necessity criteria:             <ul style="list-style-type: none"> <li>○ Class III obesity (Extreme Obesity) [Body Mass Index (BMI) &gt; 40 kg/m<sup>2</sup>] with mild Obstructive Sleep Apnea; or</li> <li>○ Class II obesity (BMI 35-39.9 kg/m<sup>2</sup>) in the presence of one or more of the following co-morbidities:                 <ul style="list-style-type: none"> <li>▪ Type 2 diabetes; or</li> <li>▪ Cardiovascular disease [e.g., stroke, myocardial infarction, poorly controlled hypertension (systolic blood pressure-greater than 140 mm Hg or diastolic blood pressure 90 mm Hg or greater, despite pharmacotherapy)]; or</li> <li>▪ History of coronary artery disease with a surgical intervention such as cardiopulmonary bypass or percutaneous transluminal coronary angioplasty; or</li> <li>▪ BMI 35-39.9 kg/m<sup>2</sup> with moderate to severe Obstructive Sleep Apnea; or</li> <li>▪ History of cardiomyopathy;</li> </ul> </li> </ul> </li> <li><b>and</b></li> <li>• The individual must also meet the following criteria:             <ul style="list-style-type: none"> <li>○ Documentation of a motivated attempt of weight loss through a structured diet program, prior to bariatric surgery, which includes physician or other health care provider notes and/or diet or weight loss logs from a structured weight loss program for a minimum of 6 months; and</li> <li>○ Psychosocial-behavioral evaluation to provide screening and identification of risk factors or potential postoperative challenges that may contribute to a poor postoperative outcome.</li> </ul> </li> </ul> <p><b>Note:</b> See additional information in the <i>Description of Services</i> section of the policy for growth and BMI charts.</p> <p><b>Bariatric surgical procedures in a person who has not attained an adult level of physical development and maturation as described above are unproven and not medically necessary.</b> Potential safety issues must be addressed in studies with sufficient sample size and adequate follow-up times necessary to demonstrate the impact of the surgery on physical, sexual and reproductive maturation and the long term improvement of co-morbidities in this age group.</p>

## Medical Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
<b>REVISED</b>			
<a href="#">Bariatric Surgery</a> (continued)	Nov. 1, 2018	<p>“further studies are needed to determine the safety and efficacy of [the listed unproven/not medically necessary] procedures as a treatment option for obesity” with “further studies are needed to determine the <i>long-term</i> safety and efficacy of [the listed unproven/not medically necessary] procedures as a treatment option for obesity”</p> <ul style="list-style-type: none"> <li>Added definition of “Revisional Bariatric Surgery”</li> <li>Updated supporting information to reflect the most current description of services, clinical evidence, and references</li> </ul>	<p><b>Bariatric surgery as the primary treatment for gynecological abnormalities, osteoarthritis, gallstones, urinary stress incontinence, gastroesophageal reflux (including for Barrett’s esophagus or gastroparesis) or other obesity-associated diseases that generally do not lead to life threatening consequences is unproven and not medically necessary.</b></p> <p>There is insufficient published clinical evidence to support bariatric surgery for the definitive treatment of gynecological abnormalities, osteoarthritis, gallstones, urinary stress incontinence or as treatment for gastroesophageal reflux and other obesity-associated diseases. Bariatric surgery will frequently ameliorate symptoms of these co-morbidities; however, the primary purpose of bariatric surgery in obese persons is to achieve weight loss.</p> <p><b>Robotic-assisted gastric bypass surgery is proven and medically necessary as equivalent but not superior to other types of minimally invasive bariatric surgery.</b></p> <p><b>Revisional Bariatric Surgery using one of the procedures identified above is proven and medically necessary when due to a technical failure or major complication from the initial bariatric procedure.</b></p> <p>A technical failure or major complication includes, but is not limited to, the following:</p> <ul style="list-style-type: none"> <li>Bowel perforation, including band erosion</li> <li>Band migration (slippage) that cannot be corrected with manipulation or adjustment. (Records must demonstrate that manipulation or adjustment to correct band slippage has been attempted.)</li> <li>Leak</li> <li>Obstruction (confirmed by imaging studies)</li> <li>Staple-line failure</li> <li>Mechanical band failure</li> </ul> <p><b>Revisional Bariatric Surgery for any other indication, including but not limited to inadequate weight loss due to a member’s noncompliance with prescribed postoperative nutrition and exercise, is unproven and not medically necessary.</b></p> <p><b>The following procedures are unproven and not medically necessary for treating obesity:</b></p> <ul style="list-style-type: none"> <li>Transoral endoscopic surgery</li> </ul>

## Medical Policy Updates

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<b>REVISED</b>			
<a href="#">Bariatric Surgery</a> (continued)	Nov. 1, 2018		<ul style="list-style-type: none"> <li>• Mini-gastric bypass (MGB) or laparoscopic mini-gastric bypass (LMGBP)</li> <li>• Gastric electrical stimulation with an implantable gastric stimulator (IGS)</li> <li>• VBLOC<sup>®</sup> vagal blocking therapy</li> <li>• Intragastric balloon</li> <li>• Laparoscopic greater curvature plication, also known as total gastric vertical plication</li> <li>• Stomach aspiration therapy (AspireAssist<sup>®</sup>)</li> <li>• Bariatric artery embolization (BAE)</li> <li>• Single-Anastomosis Duodenal Switch (also known as duodenal switch with single anastomosis, or stomach intestinal pylorus sparing surgery [SIPS])</li> </ul> <p>Further studies are needed to determine the long-term safety and efficacy of these procedures as a treatment option for obesity.</p> <p><b>Gastrointestinal liners (EndoBarrier<sup>®</sup>) are investigational, unproven and not medically necessary for treating obesity.</b> Gastrointestinal liners have not received U.S. Food and Drug Administration (FDA) approval. Their long-term efficacy has not been demonstrated.</p>
<a href="#">Plagiocephaly and Craniosynostosis Treatment</a>	Oct. 1, 2018	<ul style="list-style-type: none"> <li>• Updated benefit considerations; removed language pertaining to:               <ul style="list-style-type: none"> <li>○ Member specific benefit plan coverage requirements and exclusions</li> <li>○ Out-of-network benefit coverage</li> </ul> </li> <li>• Revised coverage rationale:               <ul style="list-style-type: none"> <li>○ Modified coverage criteria for treatment of craniofacial asymmetry with severe (non-synostotic) positional plagiocephaly:                   <ul style="list-style-type: none"> <li>▪ Replaced criterion requiring:                       <ul style="list-style-type: none"> <li>- "Infant is 18 months of age or younger" with "infant is between 3-18 months of age"</li> </ul> </li> </ul> </li> </ul> </li> </ul>	<p><b>Cranial orthotic devices are reconstructive and medically necessary for treating infants with the following conditions:</b></p> <ul style="list-style-type: none"> <li>• Craniofacial asymmetry with severe (non-synostotic) positional plagiocephaly when all the following criteria are present (1, 2 and 3):           <ol style="list-style-type: none"> <li>1. Infant is between 3-18 months of age</li> <li>2. Severe plagiocephaly* is present with or without torticollis</li> <li>3. There is documentation of a trial of conservative therapy of at least 2 months duration with cranial repositioning, with or without stretching therapy</li> </ol> </li> <li>• Craniosynostosis (i.e., synostotic plagiocephaly) following surgical correction</li> </ul> <p>*Severe plagiocephaly is defined as an asymmetry of 10 mm or more in one of the following anthropometric measures: cranial vault, skull base, or orbitotragial depth; OR a cephalic index at least 2 standard deviations above or below the mean for the appropriate gender/age. Clinical evidence demonstrates improved surgical outcomes with use of the orthotic.</p> <p><b>Note:</b> Please see <i>Description of Services</i> section of the policy for additional information regarding Anthropometric measurements and Cephalic Index</p>

## Medical Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
<b>REVISED</b>			
<a href="#">Plagiocephaly and Craniosynostosis Treatment</a> (continued)	Oct. 1, 2018	<ul style="list-style-type: none"> <li>- “Severe asymmetry is present with or without torticollis” with “severe plagiocephaly is present with or without torticollis”               <ul style="list-style-type: none"> <li>▪ Replaced language indicating “clinical evidence demonstrates improved surgical outcomes with the <i>post-operative</i> use of [a cranial] orthotic” with “clinical evidence demonstrates improved surgical outcomes with use of [a cranial] orthotic”</li> </ul> </li> <li>○ Removed language indicating:               <ul style="list-style-type: none"> <li>▪ Surgical treatment to repair craniosynostosis is reconstructive and medically necessary irrespective of the approach used</li> <li>▪ Less invasive procedures including endoscopic strip craniectomy and spring-mediated cranioplasty are proven and medically necessary as a form of surgical treatment to repair craniosynostosis</li> </ul> </li> <li>• Updated list of applicable CPT codes; removed 61550, 61552, 61556, 61557, 61558, and</li> </ul>	<p>graph. Please see related policies link for detailed information related to repair and replacements of cranial orthotic devices.</p> <p><b>Cranial orthotic devices are cosmetic and not medically necessary for treating infants with mild to moderate plagiocephaly.</b></p> <p>There are no definitive data demonstrating adverse health effects associated with a mild to moderate degree of cranial asymmetry, and, therefore, it is unclear whether treatment of these individuals provides a future health benefit, or merely a cosmetic effect. In general, severe plagiocephaly occurs in utero and is present at birth. Limited clinical evidence suggests that it may be associated with future ocular and/or oral abnormalities. Acquired plagiocephaly occurs following the placement of the infant in a supine sleeping position to prevent sudden infant death syndrome (SIDS), and is ordinarily mild to moderate. Positional plagiocephaly has not been linked to future comorbidities.</p>

## Medical Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
<b>REVISED</b>			
<a href="#">Plagiocephaly and Craniosynostosis Treatment</a> (continued)	Oct. 1, 2018	61559 <ul style="list-style-type: none"> <li>Updated supporting information to reflect the most current description of services, clinical evidence, and references</li> </ul>	
<a href="#">Virtual Upper Gastrointestinal Endoscopy</a>	Oct. 1, 2018	<ul style="list-style-type: none"> <li>Revised coverage rationale; replaced language indicating:               <ul style="list-style-type: none"> <li>“Virtual upper gastrointestinal endoscopy is unproven and not medically necessary for detecting and evaluating upper gastrointestinal lesions” with “virtual upper gastrointestinal endoscopy using 3-D computed tomography (CT) or 3-D magnetic resonance imaging (MRI) is unproven and not medically necessary for detecting and evaluating upper gastrointestinal lesions”</li> <li>“Studies may have overestimated the sensitivity of virtual endoscopy for gastric cancer detection” with “studies may have overestimated the sensitivity of virtual endoscopy for gastric cancer/other GI lesion detection”</li> </ul> </li> <li>Updated supporting information to reflect the most current description of services, clinical evidence, CMS information, and references</li> </ul>	<p><b>Virtual upper gastrointestinal endoscopy using 3-D computed tomography (CT) or 3-D magnetic resonance imaging (MRI) is unproven and not medically necessary for detecting and evaluating upper gastrointestinal lesions due to insufficient clinical data from the peer-reviewed published medical literature to conclude that virtual upper gastrointestinal endoscopy is effective.</b></p> <p>A limited number of studies of virtual upper gastrointestinal endoscopy have been published. Most studies involve a small number of patients and lack definitive patient selection criteria. Many of the studies have a serious shortcoming in that they assessed patients who were known or strongly suspected to have cancer or other upper gastrointestinal (GI) lesions. As a result, these studies may have overestimated the sensitivity of virtual endoscopy for gastric cancer/other GI lesion detection. Randomized controlled studies comparing virtual upper GI endoscopy to conventional upper GI endoscopy are needed.</p>

## Medical Benefit Drug Policy Updates

Policy Title	Effective Date	Coverage Rationale
NEW		
<a href="#">Onpattro™ (Patisiran)</a>	Sep. 1, 2018	<p><b>Onpattro (patisiran) has been added to the Review at Launch program. Some members may not be eligible for coverage of this medication at this time. Please reference the policy titled <a href="#">Review at Launch for New to Market Medications</a> for additional details.</b></p> <p><b>Onpattro (patisiran) is proven for the treatment of the polyneuropathy of hereditary transthyretin-mediated (hATTR) amyloidosis.</b></p> <p><b>Onpattro (patisiran) is medically necessary for the treatment of the polyneuropathy of hATTR amyloidosis in patients who meet ALL of the following criteria:<sup>1,8</sup></b></p> <p><b>I. For initial therapy, all of the following:</b></p> <ul style="list-style-type: none"> <li>A. <b>Both</b> of the following: <ul style="list-style-type: none"> <li>1. Diagnosis of hATTR amyloidosis with polyneuropathy</li> <li>2. Documentation that the patient has a pathogenic TTR mutation (e.g., V30M)</li> </ul> <b>and</b> </li> <li>B. Documentation of <b>one</b> of the following: <ul style="list-style-type: none"> <li>1. Patient has a baseline polyneuropathy disability (PND) score ≤ IIIb</li> <li>2. Patient has a baseline FAP Stage 1 or 2</li> </ul> <b>and</b> </li> <li>C. Presence of clinical signs and symptoms of the disease (e.g., peripheral/autonomic neuropathy, motor disability, cardiovascular dysfunction, renal dysfunction); <b>and</b></li> <li>D. Patient is not receiving patisiran in combination with either of the following: <ul style="list-style-type: none"> <li>3. Oligonucleotide agents (e.g., inotersen)</li> <li>4. Tafamidis meglumine</li> </ul> <b>and</b> </li> <li>E. Patisiran dosing is in accordance with the US Food and Drug Administration prescribing information (0.3 mg/kg up to a maximum of 30mg, every 3 weeks); <b>and</b></li> <li>F. Initial authorization is for no more than 12 months.</li> </ul> <p><b>II. For continuation therapy, all of the following:</b></p> <ul style="list-style-type: none"> <li>A. Patient has previously received treatment with patisiran; <b>and</b></li> <li>B. Documentation of <b>one</b> of the following: <ul style="list-style-type: none"> <li>5. Patient continues to have a polyneuropathy disability (PND) score ≤ IIIb</li> <li>6. Patient continues to have a FAP Stage 1 or 2</li> </ul> <b>and</b> </li> <li>C. Documentation that the patient has experienced a positive clinical response to patisiran (e.g., improved neurologic impairment, motor function, cardiac function, quality of life assessment, serum TTR levels, etc.); <b>and</b></li> <li>D. Patient is not receiving patisiran in combination with either of the following: <ul style="list-style-type: none"> <li>7. Oligonucleotide agents (e.g., inotersen)</li> <li>8. Tafamidis meglumine</li> </ul> </li> </ul>

## Medical Benefit Drug Policy Updates

Policy Title	Effective Date	Coverage Rationale	
<b>NEW</b>			
<a href="#">Onpattro™ (Patisiran)</a> (continued)	Sep. 1, 2018	<p><b>and</b></p> <p>E. Patisiran dosing is in accordance with the US Food and Drug Administration prescribing information (0.3 mg/kg up to a maximum of 30mg, every 3 weeks); <b>and</b></p> <p>F. Authorization is for no more than 12 months.</p> <p><b>Onpattro (patisiran) is unproven and not medically necessary for the treatment of:</b></p> <ul style="list-style-type: none"> <li>• Sensorimotor or autonomic neuropathy not related to hATTR amyloidosis</li> <li>• Primary or leptomenigeal amyloidosis</li> </ul>	
Policy Title	Effective Date	Summary of Changes	
<b>UPDATED</b>			
<a href="#">Botulinum Toxins A and B</a>	Oct. 1, 2018	<ul style="list-style-type: none"> <li>• Updated list of applicable ICD-10 diagnosis codes to reflect annual code edits:               <ul style="list-style-type: none"> <li>○ Added G51.31, G51.32, G51.33, and G51.39</li> <li>○ Removed G51.3</li> </ul> </li> </ul>	
<a href="#">Exondys 51™ (Eteplirsen)</a>	Oct. 1, 2018	<ul style="list-style-type: none"> <li>• Updated list of applicable ICD-10 diagnosis codes to reflect annual code edits:               <ul style="list-style-type: none"> <li>○ Added G71.01</li> <li>○ Removed G71.0</li> </ul> </li> </ul>	
<a href="#">Respiratory Interleukins (Cinqair®, Fasenra®, and Nucala®)</a>	Sep. 1, 2018	<ul style="list-style-type: none"> <li>• Updated supporting information to reflect the most current clinical evidence and references; no change to coverage rationale or lists of applicable codes</li> </ul>	
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
<b>REVISED</b>			
<a href="#">Botulinum Toxins A and B</a>	Sep. 1, 2018	<ul style="list-style-type: none"> <li>• Revised coverage rationale; added language to indicate Xeomin (incobotulinumtoxinA) is proven for the treatment of sialorrhea</li> <li>• Updated supporting information to reflect the most current FDA information and references</li> </ul>	<p>This policy refers to the following Botulinum toxin types A and B drug products:</p> <ul style="list-style-type: none"> <li>• Dysport® (abobotulinumtoxinA)</li> <li>• Xeomin® (incobotulinumtoxinA)</li> <li>• Botox® (onabotulinumtoxinA)</li> <li>• Myobloc® (rimabotulinumtoxinB)</li> </ul> <p>Refer to the policy for complete details on the coverage guidelines for <a href="#">Botulinum Toxins A and B</a>.</p>

## Medical Benefit Drug Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
<b>REVISED</b>			
<a href="#">Crysvita® (Burosumab-Twza)</a>	Sep. 1, 2018	<ul style="list-style-type: none"> <li>• Revised coverage rationale:               <ul style="list-style-type: none"> <li>○ Added language to indicate:                   <ul style="list-style-type: none"> <li>▪ Crysvita (burosumab) has been added to the Review at Launch program; some members may not be eligible for coverage of this medication at this time</li> <li>▪ Refer to the policy titled <a href="#">Review at Launch for New to Market Medications</a> for additional details</li> </ul> </li> <li>○ Modified medical necessity criteria:                   <ul style="list-style-type: none"> <li>▪ Updated criterion requiring diagnosis of X-linked hypophosphatemia (XLH) confirmed by genetic testing; added example of “confirmed <i>PHEX</i> gene mutation in patient or first-degree relative”</li> <li>▪ Added criterion requiring:                       <ul style="list-style-type: none"> <li>- Patient is greater than 1 year of age</li> <li>- One of the following:                           <ul style="list-style-type: none"> <li>• Patient epiphyseal plate has not fused; or</li> <li>• All of the following:                               <ul style="list-style-type: none"> <li>○ Patients’ epiphyseal plate has</li> </ul> </li> </ul> </li> </ul> </li> </ul> </li> </ul> </li> </ul>	<p>Crysvita (burosumab) has been added to the Review at Launch program. Some members may not be eligible for coverage of this medication at this time. Refer to the policy titled <a href="#">Review at Launch for New to Market Medications</a> for additional details.</p> <p><b>Crysvita (burosumab) is proven for the treatment of X-linked hypophosphatemia (XLH).</b></p> <p><b>Crysvita (burosumab) is medically necessary for the treatment of XLH when the following criteria are met:</b></p> <p>I. For <b>initial therapy</b>, <b>all</b> of the following:</p> <p>A. Diagnosis of XLH, confirmed by <b>one</b> of the following:</p> <ol style="list-style-type: none"> <li>1. Genetic testing (e.g., confirmed <i>PHEX</i> gene mutation in patient or first-degree relative)</li> <li>2. Elevated Serum fibroblast growth factor 23 (FGF23) level &gt; 30 pg/mL</li> </ol> <p><b>and</b></p> <p>B. Patient is greater than 1 year of age; <b>and</b></p> <p>C. <b>One</b> of the following:</p> <ol style="list-style-type: none"> <li>1. Patient epiphyseal plate has NOT fused; <b>or</b></li> <li>2. <b>ALL</b> of the following:           <ol style="list-style-type: none"> <li>a. Patients’ epiphyseal plate has fused; <b>and</b></li> <li>b. Patient is experiencing clinical signs and symptoms of the disease (e.g., limited mobility, musculoskeletal pain, bone fractures); <b>and</b></li> <li>c. Failure, contraindication, or intolerance to therapy with calcitriol in combination with an oral phosphate agent (e.g., K-Phos®, K-Phos Neutra®)</li> </ol> </li> </ol> <p><b>and</b></p> <p>D. Prescribed by, or in consultation with, an endocrinologist or specialist experienced in the treatment of metabolic bone disorders; <b>and</b></p> <p>E. Fasting serum phosphorus is below the normal range for age; <b>and</b></p> <p>F. Dosing is in accordance with the United States Food and Drug Administration approved labeling; <b>and</b></p> <p>G. Initial authorization will be for no more than 12 months.</p> <p>II. For <b>continuation therapy</b>, <b>all</b> of the following:</p> <p>A. Patient has previously received treatment with burosumab; <b>and</b></p> <p>B. Prescribed by, or in consultation with, an endocrinologist or specialist experienced in the treatment of metabolic bone disorders; <b>and</b></p>



## Medical Benefit Drug Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
<b>REVISED</b>			
<a href="#">Crysvita® (Burosumab-Twza)</a> <i>(continued)</i>	Sep. 1, 2018	<ul style="list-style-type: none"> <li>o fused</li> <li>o Patient is experiencing clinical signs and symptoms of the disease</li> <li>o Failure, contraindication, or intolerance to therapy with calcitriol in combination with an oral phosphate agent (e.g., K-Phos®, K-Phos Neutra®)</li> <li>▪ Updated list of examples of clinical signs and symptoms of XLH:               <ul style="list-style-type: none"> <li>- Added "limited mobility"</li> <li>- Removed "rickets" and "growth retardation"</li> </ul> </li> <li>▪ Replaced criterion requiring "[drug is] prescribed by, or in consultation with, a specialist experienced in the treatment of metabolic bone disorders" with "[drug is] prescribed by, or in consultation with, an endocrinologist or</li> </ul>	<ul style="list-style-type: none"> <li>C. Patient has experienced normalization of serum phosphate while on therapy; <b>and</b></li> <li>D. Patient has experienced a positive clinical response to burosumab (e.g., enhanced height velocity, improvement in skeletal deformities, reduction of fractures, reduction of generalized bone pain); <b>and</b></li> <li>E. Dosing is in accordance with the United States Food and Drug Administration approved labeling; <b>and</b></li> <li>F. Reauthorization will be for no more than 12 months.</li> </ul>

## Medical Benefit Drug Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
<b>REVISED</b>			
<a href="#">Crysvita® (Burosumab-Twza)</a> (continued)	Sep. 1, 2018	<p>specialist experienced in the treatment of metabolic bone disorders”</p> <ul style="list-style-type: none"> <li>▪ Replaced reference to “serum phosphorus” with “fasting serum phosphorus”</li> <li>• Updated list of applicable HCPCS codes; added C9399</li> <li>• Updated supporting information to reflect the most current background information, clinical evidence, and references</li> </ul>	
<a href="#">Intravenous Enzyme Replacement Therapy (ERT) for Gaucher Disease</a>	Sep. 1, 2018	<ul style="list-style-type: none"> <li>• Revised coverage rationale: <ul style="list-style-type: none"> <li>○ Replaced language indicating “Cerezyme, Elelyso and VPRIV are proven <i>and medically necessary</i> for the treatment of Type 1 Gaucher disease when all of the [listed] criteria are met” with “Cerezyme, Elelyso and VPRIV are proven for the treatment of Type 1 Gaucher disease when all of the [listed] criteria are met; enzyme replacement therapy with Elelyso or Cerezyme is medically necessary for the treatment of Gaucher disease when [the listed] criteria are met”</li> </ul> </li> <li>• Updated supporting information to reflect the most current CMS information and references; replaced references to “MCG™ Care Guidelines, Ambulatory</li> </ul>	<p>This policy refers to the following drug products, all of which are intravenous enzyme replacement therapies used in the treatment of Gaucher disease:</p> <ul style="list-style-type: none"> <li>• Cerezyme® (imiglucerase)</li> <li>• Elelyso® (taliglucerase)</li> <li>• VPRIV® (velaglucerase)</li> </ul> <p><b>I. Cerezyme, Elelyso and VPRIV* are proven for the treatment of Type 1 Gaucher disease when all of the following criteria are met:</b></p> <ol style="list-style-type: none"> <li>A. Diagnosis of Type 1 Gaucher disease; <b>and</b></li> <li>B. Symptomatic disease (e.g., moderate to severe anemia, thrombocytopenia, bone disease, hepatomegaly, splenomegaly); <b>and</b></li> <li>C. Dose does not exceed 60 units/kg every 2 weeks.</li> </ol> <p>*<b>VPRIV</b> is the preferred enzyme replacement therapy.</p> <p><b>II. Enzyme replacement therapy with Elelyso is medically necessary for the treatment of Gaucher disease when both of the following criteria are met:</b></p> <ol style="list-style-type: none"> <li>A. Diagnosis of <b>Type 1</b> Gaucher disease; <b>and</b></li> <li>B. <b>One</b> of the following: <ol style="list-style-type: none"> <li>1. History of failure of VPRIV due to failure to meet clinical goals (e.g., persistent anemia, thrombocytopenia, bone disease, hepatomegaly, or splenomegaly) despite VPRIV therapy.</li> <li>2. History of failure of VPRIV due to hypersensitivity to VPRIV</li> </ol> </li> </ol>

## Medical Benefit Drug Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
<b>REVISED</b>			
<a href="#">Intravenous Enzyme Replacement Therapy (ERT) for Gaucher Disease</a> (continued)	Sep. 1, 2018	Care 21 <sup>st</sup> Edition" with "MCG™ Care Guidelines, Ambulatory Care 22 <sup>nd</sup> Edition"	therapy.  <b>III. Enzyme replacement therapy with Cerezyme is medically necessary for the treatment of Gaucher disease when one of the following criteria is met:</b> A. <b>Both</b> of the following: <ol style="list-style-type: none"> <li>1. Diagnosis of <b>Type 1</b> Gaucher disease; <b>and</b></li> <li>2. <b>One</b> of the following:               <ol style="list-style-type: none"> <li>a. History of failure of VPRIV due to failure to meet clinical goals (e.g., persistent anemia, thrombocytopenia, bone disease, hepatomegaly, or splenomegaly) despite VPRIV therapy.</li> <li>b. History of failure of VPRIV due to hypersensitivity to VPRIV therapy.</li> <li>c. Patient is pregnant or breastfeeding.</li> <li>d. Patient is attempting to become pregnant.</li> </ol> </li> </ol> <b>or</b> B. Diagnosis of <b>Type 3</b> Gaucher disease.  <b>IV. Cerezyme is proven and medically necessary for the treatment of Type 3 Gaucher disease when all of the following criteria are met:</b> A. Diagnosis of Type 3 Gaucher disease; <b>and</b> B. Symptomatic disease (e.g., moderate to severe anemia, thrombocytopenia, bone disease, hepatomegaly, splenomegaly); <b>and</b> C. Dose does not exceed 60 units/kg every 2 weeks.
<a href="#">Ophthalmologic Policy: Vascular Endothelial Growth Factor (VEGF) Inhibitors</a>	Sep. 1, 2018	<ul style="list-style-type: none"> <li>• Revised coverage rationale; removed language indicating Eylea (aflibercept), Avastin (bevacizumab), Macugen (pegaptanib), and Lucentis (ranibizumab) are unproven and not medically necessary for the treatment of retinopathy of prematurity</li> <li>• Updated supporting information to reflect the most current clinical evidence, FDA and CMS information, and references</li> </ul>	This policy provides information about the use of certain specialty pharmacy medications administered by the intravitreal route for ophthalmologic conditions.  This policy refers to the following drug products, all of which are vascular endothelial growth factor (VEGF) inhibitors: <ul style="list-style-type: none"> <li>• Eylea™ (aflibercept)</li> <li>• Avastin® (bevacizumab)</li> <li>• Macugen® (pegaptanib)</li> <li>• Lucentis® (ranibizumab)</li> </ul> <b>Proven</b> <b>I. Eylea (aflibercept) is proven and medically necessary for the treatment of:</b>

## Medical Benefit Drug Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
<b>REVISED</b>			
<a href="#">Ophthalmologic Policy: Vascular Endothelial Growth Factor (VEGF) Inhibitors</a> (continued)	Sep. 1, 2018		<ul style="list-style-type: none"> <li>A. Neovascular age-related macular degeneration (AMD)</li> <li>B. Diabetic macular edema (DME)</li> <li>C. Macular edema secondary to branch retinal vein occlusion (BRVO) or central retinal vein occlusion (CRVO)</li> <li>D. Diabetic retinopathy in patients with diabetic macular edema (DME)</li> </ul> <p><b>II. Avastin (bevacizumab) is proven and medically necessary for the treatment of:</b></p> <ul style="list-style-type: none"> <li>A. Neovascular age-related macular degeneration (AMD)</li> <li>B. Diabetic macular edema</li> <li>C. Macular edema secondary to branch retinal vein occlusion (BRVO) or central retinal vein occlusion (CRVO)</li> <li>D. Proliferative diabetic retinopathy</li> <li>E. Neovascular glaucoma</li> <li>F. Choroidal neovascularization secondary to pathologic myopia, angioid streaks/pseudoxanthoma elasticum, or ocular histoplasmosis syndrome (OHS)</li> </ul> <p><b>III. Macugen (pegaptanib) is proven and medically necessary for the treatment of:</b></p> <ul style="list-style-type: none"> <li>A. Neovascular age-related macular degeneration (AMD)</li> <li>B. Diabetic macular edema</li> </ul> <p><b>IV. Lucentis (ranibizumab) is proven and medically necessary for the treatment of:</b></p> <ul style="list-style-type: none"> <li>A. Neovascular age-related macular degeneration (AMD)</li> <li>B. Diabetic macular edema (DME)</li> <li>C. Macular edema secondary to branch retinal vein occlusion (BRVO) or central retinal vein occlusion (CRVO)</li> <li>D. Choroidal neovascularization secondary to pathologic myopia, angioid streaks/pseudoxanthoma elasticum, or ocular histoplasmosis syndrome (OHS)</li> <li>E. Diabetic retinopathy</li> </ul> <p><b>Additional Information</b>            Avastin (bevacizumab) is supplied in sterile vials containing a solution of 25 mg/mL. Doses utilized in ophthalmic conditions generally range from 6.2 mcg to 2.5 mg. Therefore, bevacizumab in vials is often divided into single-dose, prefilled syringes for intravitreal use by compounding pharmacies. Compounding pharmacies must comply with United States Pharmacopeia</p>

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
<b>REVISED</b>			
<a href="#">Ophthalmologic Policy: Vascular Endothelial Growth Factor (VEGF) Inhibitors</a> <i>(continued)</i>	Sep. 1, 2018		<p>(USP) Chapter 797, which sets standards for the compounding, transportation, and storage of compounded sterile products (CSP). The Pharmacy Compounding Accreditation Board can verify that the pharmacy is adhering to these standards.</p> <p>The American Society of Retinal Specialists (ASRS) is committed to ensuring that retina specialists have access to compounded drugs (such as Avastin) that are prepared with high-quality material following good quality controls and sound engineering design by appropriately trained personnel. Please refer to their information page at <a href="https://www.asrs.org/advocacy-practice/access-to-safe-compounded-agents">https://www.asrs.org/advocacy-practice/access-to-safe-compounded-agents</a> for resources pertaining to access of safe compounded agents.</p> <p>Please refer to the <i>US Food and Drug Administration (FDA)</i> section of the policy for information related to contamination of compounded bevacizumab. In an effort to guard against contamination during the compounding process, the United States Veterans Health Administration (USVHA) requires that only USVHA pharmacies may dispense bevacizumab for intravitreal administration to Veterans Administration beneficiaries. The medication must be dispensed directly to the VA ophthalmologist, who will then be responsible for preparing and administering the bevacizumab dose for each patient. In addition to strict labeling and storage requirements, the ophthalmologist is required to prepare only one dose of medication from each vial; if both eyes are to be treated, a separate vial and syringe must be utilized.</p>
<a href="#">Somatostatin Analogs</a>	Sep. 1, 2018	<ul style="list-style-type: none"> <li>• Revised coverage rationale:               <ul style="list-style-type: none"> <li>○ Added language to indicate Signifor LAR is proven and medically necessary for the treatment of <b>Cushing’s disease</b> when criteria listed in the policy are met</li> <li>○ Replaced language pertaining to the treatment of <b>acromegaly</b> indicating “[the listed drug products] are proven <i>and medically necessary</i> for the treatment of acromegaly when the</li> </ul> </li> </ul>	<p>Please refer to the <a href="#">Oncology Medication Clinical Coverage Policy</a> for updated information based on the National Comprehensive Cancer Network (NCCN) Drugs &amp; Biologics Compendium for oncology indications.</p> <p><b>I. Sandostatin (octreotide acetate) and Sandostatin LAR (octreotide acetate LAR) are proven for the treatment of ONE of the following:</b></p> <p>A. Bleeding gastroesophageal varices associated with liver disease  <b>Octreotide acetate is medically necessary for the treatment of bleeding esophageal varices when both of the following criteria are met:</b></p> <ol style="list-style-type: none"> <li>1. Diagnosis of bleeding esophageal varices associated with liver disease; <b>and</b></li> <li>2. Octreotide acetate will be used as an adjunct to endoscopic</li> </ol>

## Medical Benefit Drug Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
<b>REVISED</b>			
<a href="#">Somatostatin Analogs</a> (continued)	Sep. 1, 2018	<p>[listed] criteria are met” with “[the listed drug products] are proven for the treatment of acromegaly; [the listed drug products] are medically necessary when the [listed] criteria are met”</p> <ul style="list-style-type: none"> <li>Updated list of applicable ICD-10 diagnosis codes; added E34.0</li> <li>Updated supporting information to reflect the most current FDA information, CMS information, and references</li> </ul>	<p>therapy.</p> <ul style="list-style-type: none"> <li>B. Diarrhea, chemotherapy and/or radiation-induced</li> <li>C. Diarrhea, refractory HIV/AIDS-related</li> </ul> <p><b>Octreotide acetate is medically necessary for the treatment of refractory HIV/AIDS-related diarrhea when both of the following criteria are met:</b></p> <ol style="list-style-type: none"> <li>Diagnosis of HIV/AIDS-related diarrhea; <b>and</b></li> <li>History of failure, contraindication, or intolerance to standard therapy (e.g., loperamide, diphenoxylate/atropine).</li> </ol> <ul style="list-style-type: none"> <li>D. Malignant bowel disease</li> </ul> <p><b>II. Sandostatin immediate release (IR) is proven for the treatment of acromegaly.</b></p> <p><b>Sandostatin immediate release (IR) is medically necessary when BOTH of the following criteria are met:</b></p> <p>A. Diagnosis of acromegaly by <b>one</b> of the following:</p> <ol style="list-style-type: none"> <li>Serum GH level &gt; 1 ng/mL after a 2 hour oral glucose tolerance test (OGTT) at time of diagnosis;</li> <li>Elevated serum IGF-1 levels (above the age and gender adjusted normal range as provided by the physician’s lab) at time of diagnosis;</li> </ol> <p><b>and</b></p> <p>B. <b>One</b> of the following:</p> <ol style="list-style-type: none"> <li>Inadequate response to <b>one</b> of the following:           <ol style="list-style-type: none"> <li>Surgery</li> <li>Radiotherapy</li> <li>Dopamine agonist (e.g., bromocriptine, cabergoline) therapy</li> </ol> </li> <li>Not a candidate for <b>any</b> of the following:           <ol style="list-style-type: none"> <li>Surgery</li> <li>Radiotherapy</li> <li>Dopamine agonist (e.g., bromocriptine, cabergoline) therapy</li> </ol> </li> </ol> <p><b>III. Sandostatin LAR is proven for the treatment of acromegaly.</b></p> <p><b>Sandostatin LAR is medically necessary when ALL of the following criteria are met:</b></p> <p>A. Diagnosis of acromegaly by <b>one</b> of the following:</p> <ol style="list-style-type: none"> <li>Serum GH level &gt; 1 ng/mL after a 2 hour oral glucose tolerance test (OGTT) at time of diagnosis;</li> </ol>

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<a href="#">Somatostatin Analogs</a> (continued)	Sep. 1, 2018		<p>2. Elevated serum IGF-1 levels (above the age and gender adjusted normal range as provided by the physician's lab) at time of diagnosis;</p> <p><b>and</b></p> <p>B. <b>One</b> of the following:</p> <ol style="list-style-type: none"> <li>1. Inadequate response to one of the following:               <ol style="list-style-type: none"> <li>a. Surgery</li> <li>b. Radiotherapy</li> <li>c. Dopamine agonist (e.g., bromocriptine, cabergoline) therapy</li> </ol> </li> <li>2. Not a candidate for <b>any</b> of the following:               <ol style="list-style-type: none"> <li>a. Surgery</li> <li>b. Radiotherapy</li> <li>c. Dopamine agonist (e.g., bromocriptine, cabergoline) therapy</li> </ol> </li> </ol> <p><b>and</b></p> <p>C. Initial treatment with octreotide immediate release (IR) has been shown to be effective and tolerated.</p> <p><b>IV. Signifor and Signifor LAR (pasireotide diaspertate) are proven and medically necessary for the treatment of Cushing's disease when BOTH of the following criteria are met:</b></p> <ol style="list-style-type: none"> <li>A. Diagnosis of Cushing's disease; <b>and</b></li> <li>B. <b>One</b> of the following:               <ol style="list-style-type: none"> <li>1. Inadequate response to pituitary surgery; <b>or</b></li> <li>2. Not a candidate for pituitary surgery.</li> </ol> </li> </ol> <p><b>V. Signifor LAR (pasireotide) is proven for the treatment of acromegaly.</b></p> <p><b>Signifor LAR is medically necessary when BOTH of the following criteria are met:</b></p> <ol style="list-style-type: none"> <li>A. Diagnosis of acromegaly by <b>one</b> of the following:               <ol style="list-style-type: none"> <li>1. Serum GH level &gt; 1 ng/mL after a 2 hour oral glucose tolerance test (OGTT) at time of diagnosis;</li> <li>2. Elevated serum IGF- 1 levels (above the age and gender adjusted normal range as provided by the physician's lab) at time of diagnosis;</li> </ol> </li> </ol> <p><b>and</b></p> <p>B. <b>One</b> of the following:</p> <ol style="list-style-type: none"> <li>1. Inadequate response to <b>one</b> of the following:               <ol style="list-style-type: none"> <li>a. Surgery</li> </ol> </li> </ol>

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<a href="#">Somatostatin Analogs</a> (continued)	Sep. 1, 2018		<p>b. Radiotherapy            c. Dopamine agonist (e.g., bromocriptine, cabergoline) therapy</p> <p>2. Not a candidate for <b>any</b> of the following:            a. Surgery            b. Radiotherapy            c. Dopamine agonist (e.g., bromocriptine, cabergoline) therapy</p> <p><b>VI. Somatuline Depot (lanreotide) is proven for the treatment of acromegaly. Somatuline Depot is medically necessary when BOTH of the following criteria are met:</b></p> <p>A. Diagnosis of acromegaly by <b>one</b> of the following:            1. Serum GH level &gt; 1 ng/mL after a 2 hour oral glucose tolerance test (OGTT) at time of diagnosis;            2. Elevated serum IGF- 1 levels (above the age and gender adjusted normal range as provided by the physician's lab) at time of diagnosis;</p> <p><b>and</b></p> <p>B. <b>One</b> of the following:            1. Inadequate response to <b>one</b> of the following:            a. Surgery            b. Radiotherapy            c. Dopamine agonist (e.g., bromocriptine, cabergoline) therapy            2. Not a candidate for <b>any</b> of the following:            a. Surgery            b. Radiotherapy            c. Dopamine agonist (e.g., bromocriptine, cabergoline) therapy</p> <p><b>Somatostatin analogs are unproven and not medically necessary for treating the following conditions:</b></p> <ul style="list-style-type: none"> <li>• Chylothorax</li> <li>• Dumping syndrome</li> <li>• Pancreatitis</li> <li>• Persistent hyperinsulinemic hypoglycemia of infancy</li> <li>• Prevention of postoperative complications following pancreatic surgery</li> <li>• Short bowel syndrome</li> </ul> <p>Somatostatin analogs are unproven for treating other conditions not listed above as proven due to the lack of published clinical evidence of safety and/or efficacy in published peer-reviewed medical literature.</p>



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<a href="#">White Blood Cell Colony Stimulating Factors</a>	Sep. 1, 2018	<ul style="list-style-type: none"> <li>• Revised coverage rationale:               <ul style="list-style-type: none"> <li>○ Added “Fulphila” and “Nivestym” to the list of white blood cell colony stimulating factors (CSFs) addressed in the policy                   <ul style="list-style-type: none"> <li>▪ Criteria applies to Fulphila for the following indications only:                       <ul style="list-style-type: none"> <li>- Neutropenia associated with cancer chemotherapy – dose dense chemotherapy</li> <li>- Primary prophylaxis of chemotherapy-induced febrile neutropenia (FN)</li> <li>- Secondary prophylaxis of febrile neutropenia (FN)</li> <li>- Treatment of febrile neutropenia</li> </ul> </li> <li>▪ Criteria applies to Nivestym for all indications listed in the policy</li> </ul> </li> <li>○ Added language to indicate Zarxio is proven for hepatitis-C treatment related neutropenia and medically necessary when the criteria listed in the policy are met</li> <li>○ Replaced language indicating “[the listed drug products] are <i>proven and</i> medically necessary when all of the [listed] criteria are met” with</li> </ul> </li> </ul>	<p>The policy refers to the following white blood cell colony stimulating factors:</p> <ul style="list-style-type: none"> <li>• Fulphila</li> <li>• Granix</li> <li>• Leukine</li> <li>• Neulasta</li> <li>• Neupogen</li> <li>• Nivestym</li> <li>• Zarxio</li> </ul> <p>For the coverage criteria below, in absence of specified drug products, the term “colony stimulating factors” or “CSFs” will be used in this policy where the coverage criteria apply to all products listed above.</p> <p><b>White blood cell colony stimulating factors are proven for the following indications:</b></p> <p><b>I. Bone marrow/stem cell transplant (Leukine, Neupogen, Nivestym, Zarxio)</b>  <b>Leukine, Neupogen, Nivestym, and Zarxio are medically necessary when all of the following criteria are met:</b></p> <p>A. <b>One</b> of the following:</p> <ol style="list-style-type: none"> <li>1. Patient has non-myeloid malignancies and is undergoing myeloablative chemotherapy followed by autologous or allogeneic bone marrow transplant (BMT); <b>or</b></li> <li>2. Used for mobilization of hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis; <b>or</b></li> <li>3. Patient has had a peripheral stem cell transplant (PSCT) and have received myeloablative chemotherapy;</li> </ol> <p><b>and</b></p> <p>B. Medication is dosed in accordance with the United States Food and Drug Administration approved labeling; <b>and</b></p> <p>C. Prescribed by or in consultation with a hematologist or oncologist.</p> <p><b>II. Acute myeloid leukemia (AML) induction or consolidation therapy (Leukine, Neupogen, Nivestym, Zarxio)</b>  <b>Leukine, Neupogen, Nivestym, and Zarxio are medically necessary when all of the following criteria are met:</b></p> <p>A. Diagnosis of AML; <b>and</b></p> <p>B. Patient has completed either induction or consolidation chemotherapy; <b>and</b></p>

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<a href="#">White Blood Cell Colony Stimulating Factors</a> (continued)	Sep. 1, 2018	<p><i>“white blood cell colony stimulating factors are proven for [indications listed in the policy]; [the listed drug products] are medically necessary when all of the [listed] criteria are met”</i></p> <ul style="list-style-type: none"> <li>Updated list of applicable HCPCS codes; added Q5108</li> <li>Updated supporting information to reflect the most current background information, FDA information, and references</li> </ul>	<p>C. Medication is dosed in accordance with the United States Food and Drug Administration approved labeling; <b>and</b></p> <p>D. Prescribed by or in consultation with a hematologist or oncologist.</p> <p><b>III. Neutropenia associated with cancer chemotherapy – dose dense chemotherapy (Fulphila, Leukine, Neulasta, Neupogen, Nivestym, Zarxio)</b>  <b>Fulphila, Leukine, Neulasta, Neupogen, Nivestym, and Zarxio are medically necessary when all of the following criteria are met:</b></p> <p>A. <b>One</b> of the following:</p> <ol style="list-style-type: none"> <li>Patient is receiving National Cancer Institute’s Breast Intergroup, INT C9741 dose dense chemotherapy protocol for primary breast cancer; <b>or</b></li> <li>Patient is receiving a dose-dense chemotherapy regimen for which the incidence of febrile neutropenia (FN) is unknown;</li> </ol> <p><b>and</b></p> <p>B. Medication is dosed in accordance with the United States Food and Drug Administration approved labeling; <b>and</b></p> <p>C. Prescribed by or in consultation with a hematologist or oncologist.</p> <p><b>IV. Primary prophylaxis of chemotherapy-induced febrile neutropenia (FN) (Fulphila, Granix, Leukine, Neulasta, Neupogen, Nivestym, Zarxio)</b>  <b>White blood cell colony stimulating factors are medically necessary when all of the following criteria are met:</b></p> <p>A. <b>One</b> of the following:</p> <ol style="list-style-type: none"> <li>Patient is receiving chemotherapy regimen(s) associated with &gt; 20% incidence of FN; <b>or</b></li> <li>Both of the following:           <ol style="list-style-type: none"> <li>Patient is receiving chemotherapy regimen(s) associated with 10-20% incidence of FN; <b>and</b></li> <li>Patient has one or more risk factors associated with chemotherapy-induced infection, FN, or neutropenia (see the list of risk factors in the <i>Clinical Evidence</i> section of the policy);</li> </ol> </li> </ol> <p><b>and</b></p> <p>B. Medication is dosed in accordance with the United States Food and Drug Administration approved labeling; <b>and</b></p> <p>C. Prescribed by or in consultation with a hematologist or oncologist.</p>

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<a href="#">White Blood Cell Colony Stimulating Factors</a> (continued)	Sep. 1, 2018		<p><b>V. Secondary prophylaxis of febrile neutropenia (FN) (Fulphila, Granix, Leukine, Neulasta, Neupogen, Nivestym, Zarxio)</b>  <b>White blood cell colony stimulating factors are medically necessary when all of the following criteria are met:</b></p> <ul style="list-style-type: none"> <li>A. Patient is receiving myelosuppressive anticancer drugs associated with neutropenia (ANC <math>\leq</math> 500 cells/mm<sup>3</sup>); <b>and</b></li> <li>B. Patient has a history of FN during a previous course of chemotherapy; <b>and</b></li> <li>C. Medication is dosed in accordance with the United States Food and Drug Administration approved labeling; <b>and</b></li> <li>D. Prescribed by or in consultation with a hematologist or oncologist.</li> </ul> <p><b>VI. Treatment of Febrile Neutropenia (Fulphila, Leukine, Neulasta, Neupogen, Nivestym, Zarxio) [off-label]</b>  <b>Fulphila, Leukine, Neulasta, Neupogen, Nivestym, and Zarxio are medically necessary when all of the following criteria are met:</b></p> <ul style="list-style-type: none"> <li>A. Patient is receiving myelosuppressive anticancer drugs associated with neutropenia (ANC <math>\leq</math> 500 cells/mm<sup>3</sup>); <b>and</b></li> <li>B. Diagnosis of FN and patient is considered high risk for infection-associated complications; <b>and</b></li> <li>C. Medication is dosed in accordance with the United States Food and Drug Administration approved labeling; <b>and</b></li> <li>D. Prescribed by or in consultation with a hematologist or oncologist.</li> </ul> <p><b>VII. Severe Chronic Neutropenia (SCN) (Neupogen, Nivestym, Zarxio)</b>  <b>Neupogen, Nivestym, and Zarxio are medically necessary when all of the following criteria are met:</b></p> <ul style="list-style-type: none"> <li>A. Diagnosis of SCN (i.e., congenital, cyclic, and idiopathic neutropenias with chronic ANC <math>\leq</math> 500 cells/mm<sup>3</sup>); <b>and</b></li> <li>B. Medication is dosed in accordance with the United States Food and Drug Administration approved labeling; <b>and</b></li> <li>C. Prescribed by or in consultation with a hematologist or oncologist.</li> </ul> <p><b>VIII. HIV-related neutropenia (Leukine, Neupogen, Nivestym, Zarxio) [off-label]</b>  <b>Leukine, Neupogen, Nivestym, and Zarxio are medically necessary when all of the following criteria are met:</b></p> <ul style="list-style-type: none"> <li>A. Diagnosis of HIV infection; <b>and</b></li> <li>B. Patient has an ANC <math>\leq</math> 1,000 (cells/mm<sup>3</sup>); <b>and</b></li> </ul>

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<a href="#">White Blood Cell Colony Stimulating Factors</a> (continued)	Sep. 1, 2018		<p>C. Medication is dosed in accordance with the United States Food and Drug Administration approved labeling; <b>and</b></p> <p>D. Prescribed by or in consultation with a hematologist, oncologist or infectious disease specialist.</p> <p><b>IX. Hepatitis-C treatment related neutropenia (Neupogen, Nivestym, Zarxio) [off-label]</b>  <b>Neupogen, Nivestym, and Zarxio are medically necessary when all of the following criteria are met:</b></p> <p>A. <b>One</b> of the following:</p> <ol style="list-style-type: none"> <li>1. <b>All</b> of the following:               <ol style="list-style-type: none"> <li>a. Diagnosis of Hepatitis C virus; <b>and</b></li> <li>b. Patient is undergoing treatment with Peg-Intron (peginterferon alfa-2b) or Pegasys (peginterferon alfa-2a); <b>and</b></li> <li>c. Documentation of neutropenia (ANC <math>\leq</math> 500 cells/mm<sup>3</sup>) after dose reduction of Peg-Intron or Pegasys;</li> </ol> </li> <li><b>or</b></li> <li>2. <b>Both</b> of the following:               <ol style="list-style-type: none"> <li>a. Documentation of interferon-induced neutropenia (ANC <math>\leq</math> 500 cells/mm<sup>3</sup>) due to treatment with Peg-Intron (peginterferon alfa-2b) or Pegasys (peginterferon alfa-2a); <b>and</b></li> <li>b. <b>One</b> of the following:                   <ol style="list-style-type: none"> <li>i. Diagnosis of HIV co-infection; <b>or</b></li> <li>ii. Status post liver transplant; <b>or</b></li> <li>iii. Diagnosis of established cirrhosis</li> </ol> </li> </ol> </li> </ol> <p><b>and</b></p> <p>B. Medication is dosed in accordance with the United States Food and Drug Administration approved labeling; <b>and</b></p> <p>C. Prescribed by or in consultation with a hematologist, oncologist, infectious disease specialist, hepatologist, or gastroenterologist.</p>
<a href="#">Xolair® (Omalizumab)</a>	Sep. 1, 2018	<ul style="list-style-type: none"> <li>• Revised coverage rationale/ medical necessity criteria for patients with:               <ul style="list-style-type: none"> <li>○ Moderate to severe persistent asthma; added "Fasenra (benralizumab)" to the list of drug products the patient cannot receive in</li> </ul> </li> </ul>	<p><b>Xolair (omalizumab) for subcutaneous use is proven for:</b></p> <p><b>I. Patients with moderate to severe persistent asthma who meet all of the following criteria:</b></p> <ol style="list-style-type: none"> <li>A. Have a positive skin test or in vitro reactivity to a perennial aeroallergen.</li> <li>B. Symptoms inadequately controlled with inhaled corticosteroids.</li> <li>C. Have a baseline plasma immunoglobulin E (IgE) level greater than or</li> </ol>

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<a href="#">Xolair® (Omalizumab)</a> (continued)	Sep. 1, 2018	<ul style="list-style-type: none"> <li>○ combination with Xolair</li> <li>○ Chronic urticaria who continue to remain symptomatic despite H1 antihistamine treatment; removed duplicative language pertaining to medical necessity review</li> <li>• Updated list of applicable ICD-10 diagnosis codes; removed J45.20, J45.21, J45.30, and J45.31</li> <li>• Updated supporting information to reflect the most current clinical evidence and references</li> </ul>	<p>equal to 30 IU/mL and less than or equal to 1500 IU/mL.</p> <p><b>Xolair is medically necessary when all of the following criteria are met:</b></p> <p>A. Diagnosis of moderate or severe asthma; <b>and</b></p> <p>B. Classification of asthma as uncontrolled or inadequately controlled as defined by <b>at least one</b> of the following:</p> <ol style="list-style-type: none"> <li>1. Poor symptom control (e.g., Asthma Control Questionnaire [ACQ] score consistently greater than 1.5 or Asthma Control Test [ACT] score consistently less than 20); <b>or</b></li> <li>2. Two or more bursts of systemic corticosteroids for at least 3 days each in the previous 12 months; <b>or</b></li> <li>3. Asthma-related emergency treatment (e.g., emergency room visit, hospital admission, or unscheduled physician's office visit for nebulizer or other urgent treatment); <b>or</b></li> <li>4. Airflow limitation (e.g., after appropriate bronchodilator withhold forced expiratory volume in 1 second [FEV1] less than 80% predicted [in the face of reduced FEV1/forced vital capacity [FVC] defined as less than the lower limit of normal])</li> </ol> <p><b>and</b></p> <p>C. Baseline (pre-omalizumab treatment) serum total IgE level greater than or equal to 30 IU/mL and less than or equal to 1500 IU/mL; <b>and</b></p> <p>D. Positive skin test or in vitro reactivity to a perennial aeroallergen; <b>and</b></p> <p>E. Used in combination with <b>one</b> of the following:</p> <ol style="list-style-type: none"> <li>1. One maximally-dosed (appropriately adjusted for age) combination inhaled corticosteroid (ICS)/long-acting beta2-agonist (LABA) product [e.g., fluticasone propionate/salmeterol (Advair®), budesonide/formoterol (Symbicort®)]; <b>or</b></li> <li>2. Combination therapy including <b>both</b> of the following:             <ol style="list-style-type: none"> <li>a. One high-dose (appropriately adjusted for age) ICS product [e.g., ciclesonide (Alvesco®), mometasone furoate (Asmanex®), beclomethasone dipropionate (QVAR®)]; <b>and</b></li> <li>b. One additional asthma controller medication [e.g., LABA - olodaterol (Striverdi®) or indacaterol (Arcapta®); leukotriene receptor antagonist - montelukast (Singulair®); theophylline]</li> </ol> </li> </ol> <p><b>and</b></p> <p>F. Patient is not receiving Xolair in combination with <b>any</b> of the following:</p> <ol style="list-style-type: none"> <li>1. Nucala (mepolizumab)</li> </ol>

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<a href="#">Xolair®</a> <a href="#">(Omalizumab)</a> (continued)	Sep. 1, 2018		<ol style="list-style-type: none"> <li>2. Cinqair (reslizumab)</li> <li>3. Fasentra (benralizumab)</li> </ol> <p><b>and</b></p> <p>G. Xolair dosing for moderate to severe persistent asthma is in accordance with the United States Food and Drug Administration approved labeling; <b>and</b></p> <p>H. Prescribed by or in consultation with an allergist/immunologist or pulmonologist; <b>and</b></p> <p>I. Initial authorization will be for no more than 6 months.</p> <p><b>Reauthorization/Continuation of Care Criteria</b>            For patients currently on Xolair for the treatment of moderate to severe persistent asthma, authorization for continued use will be approved based on <b>all</b> of the following criteria:</p> <p>A. Documentation of positive clinical response as demonstrated by <b>at least one</b> of the following:</p> <ol style="list-style-type: none"> <li>1. Reduction in the frequency of exacerbations</li> <li>2. Decreased utilization of rescue medications</li> <li>3. Increase in percent predicted FEV1 from pretreatment baseline</li> <li>4. Reduction in severity or frequency of asthma-related symptoms (e.g., wheezing, shortness of breath, coughing, etc.)</li> </ol> <p><b>and</b></p> <p>B. Used in combination with an ICS-containing controller medication; <b>and</b></p> <p>C. Patient is not receiving Xolair in combination with <b>any</b> of the following:</p> <ol style="list-style-type: none"> <li>1. Nucala (mepolizumab)</li> <li>2. Cinqair (reslizumab)</li> <li>3. Fasentra (benralizumab)</li> </ol> <p><b>and</b></p> <p>D. Xolair dosing for moderate to severe persistent asthma is in accordance with the United States Food and Drug Administration approved labeling; <b>and</b></p> <p>E. Prescribed by or in consultation with allergist/immunologist or pulmonologist; <b>and</b></p> <p>F. Reauthorization will be for no more than 12 months.</p> <p><b>II. Patients with chronic urticaria who continue to remain symptomatic despite H1 antihistamine [e.g., cetirizine (Zyrtec), fexofenadine (Allegra)] treatment</b></p>

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<a href="#">Xolair® (Omalizumab)</a> (continued)	Sep. 1, 2018		<p><b>Xolair is medically necessary when all of the following criteria are met:</b></p> <p>A. Diagnosis of chronic urticaria; <b>and</b></p> <p>B. <b>One</b> of the following:</p> <ol style="list-style-type: none"> <li>1. Patient remains symptomatic despite at least a 2-week trial of, or history of contraindication or intolerance to, <b>two</b> H1-antihistamines [e.g., Allegra (fexofenadine), Benadryl (diphenhydramine), Claritin (loratadine)]*; <b>or</b></li> <li>2. Patient remains symptomatic despite at least a 2-week trial of, or history of contraindication or intolerance to <b>both</b> of the following taken in combination:               <ol style="list-style-type: none"> <li>a. A second generation H1-antihistamine [e.g., Allegra (fexofenadine), Claritin (loratadine), Zyrtec (cetirizine)]; <b>and</b></li> <li>b. <b>One</b> of the following:                   <ol style="list-style-type: none"> <li>i. Different second generation H1-antihistamine [e.g., Allegra (fexofenadine), Claritin (loratadine), Zyrtec (cetirizine)]</li> <li>ii. First generation H1-antihistamine [e.g., Benadryl (diphenhydramine), Chlor-Trimeton (chlorpheniramine), Vistaril (hydroxyzine)]*</li> <li>iii. H2-antihistamine [e.g., Pepcid (famotidine), Tagamet HB (cimetidine), Zantac (ranitidine)]</li> <li>iv. Leukotriene modifier [e.g., Singulair (montelukast)]</li> </ol> </li> </ol> </li> </ol> <p><b>and</b></p> <p>C. Xolair dosing for chronic urticaria is in accordance with the United States Food and Drug Administration approved labeling; <b>and</b></p> <p>D. Prescribed by or in consultation with an allergist/immunologist or dermatologist; <b>and</b></p> <p>E. Initial authorization will be for no more than 6 months.</p> <p><b>Reauthorization/Continuation of Care Criteria</b></p> <p>For patients currently on Xolair for the treatment of chronic urticaria, authorization for continued use will be approved based on all of the following criteria:</p> <ol style="list-style-type: none"> <li>A. Documentation of positive clinical response (e.g., reduction in exacerbations, itch severity, hives); <b>and</b></li> <li>B. Xolair dosing for chronic urticaria is in accordance with the United States Food and Drug Administration approved labeling; <b>and</b></li> <li>C. Prescribed by or in consultation with allergist/immunologist or</li> </ol>

## Medical Benefit Drug Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
<b>REVISED</b>			
<a href="#">Xolair® (Omalizumab)</a> (continued)	Sep. 1, 2018		<p>dermatologist; <b>and</b></p> <p>D. Reauthorization will be for no more than 12 months.</p> <p><b>*Note:</b> Patients 65 years of age and older in whom first generation H1-antihistamines are considered high risk medications to be avoided (e.g., Beers criteria, HEDIS) should be directed to try alternatives that are not considered high risk.</p> <p><b>Xolair is unproven and not medically necessary in the following:</b></p> <ul style="list-style-type: none"> <li>• Seasonal allergic rhinitis</li> <li>• Perennial allergic rhinitis</li> <li>• Atopic dermatitis</li> <li>• Peanut allergy</li> <li>• Acute bronchospasm or status asthmaticus</li> </ul>



## Coverage Determination Guideline (CDG) Updates

Policy Title	Effective Date	Summary of Changes	
<b>UPDATED</b>			
<a href="#">Breast Reduction Surgery</a>	Sep. 1, 2018	<ul style="list-style-type: none"> <li>Updated coverage rationale/appendix; added instruction to clarify the Du Bois formula is used to calculate body surface area (BSA)</li> <li>Updated supporting information to reflect the most current references</li> </ul>	
<a href="#">Emergency Health Care Services and Urgent Care Center Services</a>	Sep. 1, 2018	<ul style="list-style-type: none"> <li>Updated coverage rationale; removed duplicative language pertaining to Essential Health Benefits for Individual and Small Group plans (addressed in the <i>Benefit Considerations</i> section of the policy)</li> </ul>	
<a href="#">Habilitative Services for Essential Health Groups</a>	Oct. 1, 2018	<ul style="list-style-type: none"> <li>Updated list of applicable ICD-10 diagnosis codes:               <ul style="list-style-type: none"> <li>Added E72.81*, E72.89*, E75.26*, G51.31*, G51.32*, G51.33*, G51.39*, P04.11*, P04.12*, P04.13*, P04.14*, P04.15*, P04.16*, P04.17*, P04.18*, P04.19*, P04.1A*, P04.40*, P04.42*, P04.81*, P04.89*, P35.4*, Q93.51*, Q93.59*, and Q93.82*</li> <li>Removed E67.1, E72.53, E72.8*, G51.3*, and Q93.5* (*annual code edit)</li> </ul> </li> </ul>	
<a href="#">Panniculectomy and Body Contouring Procedures</a>	Sep. 1, 2018	<ul style="list-style-type: none"> <li>Updated definition of:               <ul style="list-style-type: none"> <li>Functional or Physical or Physiological Impairment</li> <li>Reconstructive Procedures</li> <li>Reconstructive Procedures (California only)</li> <li>Sickness</li> </ul> </li> </ul>	
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
<b>REVISED</b>			
<a href="#">Preventive Care Services</a>	Oct. 1, 2018	<ul style="list-style-type: none"> <li>Reformatted and revised lists of applicable procedure and diagnosis codes:               <ul style="list-style-type: none"> <li>Replaced references to "ICD-10 diagnosis codes" with "diagnosis codes"</li> <li>Clarified preventive benefit instructions; replaced language indicating "[service is] payable or preventive [when listed guidelines are met]" with "[service] requires [listed guidelines to be met]"</li> </ul> </li> </ul>	Refer to the policy for complete details on the coverage guidelines for <a href="#">Preventive Care Services</a> .

## Coverage Determination Guideline (CDG) Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
<b>REVISED</b>			
<a href="#">Preventive Care Services</a> (continued)	Oct. 1, 2018	<p><b>Preventive Care Services</b></p> <p><i>Cervical Cancer Screening, Pap Smear</i></p> <ul style="list-style-type: none"> <li>○ Updated preventive benefit instructions; added language to clarify <i>Code Group 2 Procedure Codes</i> require one of the <i>Code Group 2 Diagnosis Codes</i></li> </ul> <p><i>Cholesterol Screening (Lipid Disorders Screening)</i></p> <ul style="list-style-type: none"> <li>○ Updated preventive benefit instructions; modified list of diagnosis codes for lipid disorders to which the preventive benefit does not apply to reflect annual code edits:               <ul style="list-style-type: none"> <li>▪ Added E78.41 and E78.49</li> <li>▪ Removed E78.4</li> </ul> </li> </ul> <p><i>Osteoporosis Screening</i></p> <ul style="list-style-type: none"> <li>○ Removed January 2011 USPSTF 'B' rating</li> <li>○ Added June 2018 USPSTF 'B' rating to indicate:               <ul style="list-style-type: none"> <li>▪ The USPSTF recommends screening for osteoporosis with bone measurement testing to prevent osteoporotic fractures in women 65 years and older</li> <li>▪ The USPSTF recommends screening for osteoporosis with bone measurement testing to prevent</li> </ul> </li> </ul>	

## Coverage Determination Guideline (CDG) Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
<b>REVISED</b>			
<a href="#">Preventive Care Services</a> (continued)	Oct. 1, 2018	<p>osteoporotic fractures in postmenopausal women younger than 65 years who are at increased risk of osteoporosis, as determined by a formal clinical risk assessment tool</p> <p><i>Screening for Depression in Adults and Depression in Children and Adolescents (Screening)</i></p> <ul style="list-style-type: none"> <li>○ Updated list of applicable ICD-10 diagnosis codes required for 96127 only:               <ul style="list-style-type: none"> <li>▪ Added Z13.31* and Z13.32*</li> <li>▪ Removed Z13.89</li> </ul>               (*annual code edit)             </li> </ul> <p><i>Behavioral Counseling in Primary Care to Promote a Healthful Diet and Physical Activity for Cardiovascular Disease Prevention in Adults with Cardiovascular Risk Factors</i></p> <ul style="list-style-type: none"> <li>○ Updated list of diagnosis codes for hyperlipidemia/dyslipidemia to reflect annual code edits:               <ul style="list-style-type: none"> <li>▪ Added E78.41 and E78.49</li> <li>▪ Removed E78.4</li> </ul> </li> </ul> <p><i>Prevention of Falls in Community-Dwelling Older Adults</i></p> <ul style="list-style-type: none"> <li>○ Removed May 2012 USPSTF 'B' rating</li> <li>○ Added April 2018 USPSTF 'B' rating to indicate the USPSTF</li> </ul>	

## Coverage Determination Guideline (CDG) Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
<b>REVISED</b>			
<a href="#">Preventive Care Services</a> <i>(continued)</i>	Oct. 1, 2018	<p>recommends exercise interventions to prevent falls in community-dwelling adults 65 years or older who are at increased risk for falls</p> <p><i>Formal Developmental/Autism Screening (Bright Futures)</i></p> <ul style="list-style-type: none"> <li>○ Updated list of applicable ICD-10 diagnosis codes to reflect annual code edits: <ul style="list-style-type: none"> <li>▪ Added Z13.40, Z13.41, Z13.42, and Z13.49</li> <li>▪ Removed Z13.4</li> </ul> </li> </ul> <p><b>Preventive Immunizations</b></p> <ul style="list-style-type: none"> <li>○ Removed age range descriptions from "Age Group" column heading <i>(duplicative to language provided in notation above code table)</i></li> </ul> <p><i>Rotavirus (RV1, RV5)</i></p> <ul style="list-style-type: none"> <li>○ Added benefit limit/age guideline of 0-8 months for CPT codes 90680 and 90681</li> </ul> <p><b>Expanded Women's Preventive Health</b></p> <p><i>Well-Woman Visits</i></p> <ul style="list-style-type: none"> <li>○ Updated preventive benefit instructions; modified language to clarify prenatal care visits and global obstetrical codes do not have diagnosis code requirements for the preventive benefit to apply</li> </ul> <p><i>Screening for Diabetes Mellitus After Pregnancy</i></p> <ul style="list-style-type: none"> <li>○ Modified preventive benefit</li> </ul>	

## Coverage Determination Guideline (CDG) Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
<b>REVISED</b>			
<a href="#">Preventive Care Services</a> (continued)	Oct. 1, 2018	<p>instructions for diabetes screening and blood draw; added language to clarify Z86.32 is required in addition to one of the <i>Required Screening</i> diagnosis codes</p> <p><b>Diagnosis Codes</b></p> <p><i>Hepatitis C Virus Infection Screening Diagnosis Code List</i></p> <ul style="list-style-type: none"> <li>○ Updated attachment file to reflect annual code edits; added F12.23, F12.93, Z04.81, and Z62.813</li> </ul> <p><i>Pregnancy Diagnosis Code List</i></p> <ul style="list-style-type: none"> <li>○ Updated attachment file to reflect annual code edits; added O30.131, O30.132, O30.133, O30.139, O30.231, O30.232, O30.233, O30.239, O30.831, O30.832, O30.833, O30.839, O86.00, O86.01, O86.02, O86.03, O86.04, and O86.09</li> <li>• Updated supporting information to reflect the most current references</li> </ul>	

## Utilization Review Guideline (URG) Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
<b>REVISED</b>			
<a href="#">Specialty Medication Administration – Site of Care Review Guidelines</a>	Oct. 1, 2018	<ul style="list-style-type: none"> <li>Revised coverage rationale; added Crysvida® (Burosumab-Twza) to the list of applicable specialty medications that require healthcare provider administration</li> </ul>	<p>This guideline addresses the criteria for consideration of allowing hospital outpatient facility specialty medication infusion services. This includes claim submission for hospital based services with the following CMS/AMA Place of Service codes:</p> <ul style="list-style-type: none"> <li>19 Off Campus-Outpatient Hospital; and</li> <li>22 On Campus-Outpatient Hospital.</li> </ul> <p>Alternative sites of care, such as non-hospital outpatient infusion, physician office, ambulatory infusion or home infusion services are well accepted places of service for medication infusion therapy. If a patient does not meet criteria for outpatient hospital facility infusion, alternative sites of care may be used.</p> <p><b>Outpatient hospital facility-based intravenous medication infusion is medically necessary for persons who meet any of the following criteria (submission of medical records is required, detailing at least ONE of the following):</b></p> <ul style="list-style-type: none"> <li>Medically unstable based upon submitted clinical history; or</li> <li>Initial medication infusion of or re-initiation after more than 6 months following discontinuation of therapy; or</li> <li>Previous experience of a severe adverse event following infusion. Examples include but are not limited to anaphylaxis, seizure, thromboembolism, myocardial infarction, renal failure; or</li> <li>Continuing experience of adverse events that cannot be mitigated by pre-medications or infusion rate adjustments; or</li> <li>Physically and/or cognitively impaired <b>and</b> no home caregiver available; or</li> <li>Difficulty establishing and maintaining patent vascular access; or</li> <li>Homecare or infusion provider has deemed that the patient, home caregiver, or home environment is not suitable for home infusion therapy.</li> </ul> <p>This policy applies to these specialty medications that require healthcare provider administration:</p> <ul style="list-style-type: none"> <li>Actemra® (Tocilizumab)</li> <li>Adagen® (Pegademase bovine)</li> <li>Aldurazyme® (Laronidase)</li> <li>Aralast NP™ (A1-PI)</li> <li>Benlysta® (Belimumab)</li> </ul>

## Utilization Review Guideline (URG) Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
<b>REVISED</b>			
<a href="#">Specialty Medication Administration – Site of Care Review Guidelines</a> (continued)	Oct. 1, 2018		<ul style="list-style-type: none"> <li>• Cerezyme® (Imiglucerase)</li> <li>• Crysvisa® (Burosumab)</li> <li>• Elaprase® (Idursulfase)</li> <li>• Elelyso® (Taliglucerase)</li> <li>• Entyvio® (Vedolizumab)</li> <li>• Exondys 51™ (Eteplirsen)</li> <li>• Fabrazyme® (Agalsidase beta)</li> <li>• Glassia™ (A1-PI)</li> <li>• Ilaris® (Canakinumab)</li> <li>• Inflectra™ (Infliximab-dyyb)</li> <li>• Kanuma® (Sebelipase alfa)</li> <li>• Lumizyme® (Alglucosidase alfa)</li> <li>• Mepsevii™ (Vestronidase alfa-vjvk)</li> <li>• Naglazyme® (Galsulfase)</li> <li>• Ocrevus™ (Ocrelizumab)</li> <li>• Orenzia® (Abatacept)</li> <li>• Prolastin®-C™ (A1-PI)</li> <li>• Radicava™ (edaravone)</li> <li>• Remicade® (Infliximab)</li> <li>• Renflexis™ (Infliximab-abda)</li> <li>• Simponi Aria® (Golimumab)</li> <li>• Soliris® (Eculizumab)</li> <li>• Trogarzo™ (Ibalizumab)</li> <li>• Vimizim® (Elosulfase alfa)</li> <li>• VPRIV® (Velaglucerase)</li> <li>• Zemaira® (A1-PI)</li> </ul> <p>Medical necessity criteria for administration of intravenous infusion therapy at home are addressed in MCG™ Care Guidelines, 22nd edition, 2018, Home Infusion Therapy, CMT: CMT-0009(SR).</p>