SPECIAL BULLETIN

DECEMBER 31, 2013

ATTN: ALL PARTICIPATING PROFESSIONAL PROVIDERS

MEDICAL POLICY UPDATES AND NEWS

DECEMBER AND JANUARY

Highmark Blue Cross Blue Shield Delaware (Highmark Delaware) is committed to keeping you informed of updates to our medical policies, guidelines and payment policies. This *Special Bulletin* includes information regarding new or updated medical and behavioral health policies, which reflect changes in medical technology, criteria for approving or denying services in various policies, and federal or Delaware medical policy requirements.

Highmark Delaware Medical Policies are available online via the Provider Resource Center, which is accessible through NaviNet® or from the *Providers* tab on our website, **www.highmarkbcbsde.com**. Once there, select *Medical & Claims Payment Guidelines* from the menu on the left-hand side. You can then search our Medical Policies by one (or a combination) of the following options: keywords, code or number.

POLICY

Place of service designation included on additional medical policies

Highmark Delaware is including place of service designation on the following medical policies:

Policy #	Policy Topic	Place of Service	Effective Date
D-5*	Oral Surgical Procedures	Outpatient	03/03/2014
E-28*	High Frequency Chest Wall Oscillation Devices	Outpatient	03/03/2014
E-31*	Negative Pressure Wound Therapy Pumps/Vacuum Assisted Closure of Chronic Wounds	Inpatient/Outpatient (Revised)	12/16/2013
E-39*	Home Uterine Activity Monitor	Outpatient	03/03/2014
G-16*	Chemotherapy Services	Inpatient/Outpatient	01/01/2014 (Revised)
I-12*	Human Growth Hormone	Outpatient	03/03/2014

HIGHMARK. Delaware

Policy #	Policy Topic	Place of Service	Effective Date
I-30*	Denosumab (Prolia, Xgeva)	Outpatient	03/03/2014
I-37*	Ustekinumab (Stelara)	Outpatient	03/03/2014
I-42*	Zoledronic Acid (Reclast, Zometa)	Outpatient	03/03/2014
I-107*	Injectable Collagenase Clostridium Histolyticum	Outpatient	03/03/2014
L-58*	In Vitro Chemoresistance and Chemosensitivity Assays	Outpatient	03/03/2014
L-81*	Laboratory Tests for Heart Transplant Rejection	Outpatient	03/03/2014
L-84*	Laboratory Testing for Novel Influenza A (H1N1)	Inpatient/Outpatient	03/03/2014
M-19*	Pulmonary Function Studies	Outpatient	03/10/2014
M-28*	Electromyography (EMG)	Outpatient	03/03/2014
M-51*	Nerve Conduction Velocity (NCV) Studies	Outpatient	03/03/2014
M-60*	Real Time Cardiac Surveillance (Monitoring)	Outpatient	03/03/2014
M-69*	Dean Ornish Program for Reversing Heart Disease	Outpatient	03/03/2014
O-14*	Gas Permeable Scleral Contact Lens	Outpatient	03/03/2014
S-11*	Pheresis Therapy	Inpatient/Outpatient (Revised)	03/03/2014
S-74*	Suction Assisted Lipectomy (SAL)	Outpatient	03/10/2014
S-76*	Removal of Breast Implants	Outpatient	03/03/2014
S-92*	Treatment of Acne	Outpatient (Revised)	12/16/2013
S-93*	Percutaneous (Transluminal) Balloon Valvuloplasty	Outpatient	03/03/2014
S-128*	Photodynamic Therapy- Outpatient	Outpatient	03/03/2014
S-131*	Sacral Nerve Modulation/Stimulation (SNS) for Pelvic Floor Dysfunction	Inpatient/Outpatient (Revised)	03/03/2014
S-174*	Surgical Interruption of Pelvic Nerve Pathways for Primary and Secondary Dysmenorrhea	Outpatient	03/03/2014
S-178*	Treatment of Hyperhidrosis	Inpatient/Outpatient (Revised)	03/03/2014
S-180*	Platelet-Derived Growth Factors as a Primary Treatment for Wound Healing and Other Miscellaneous Conditions	Outpatient	03/03/2014
S-185	Transplantation for Chondral Defects	Inpatient	03/03/2014

Policy #	Policy Topic	Place of Service	Effective Date
S-196*	Saturation Biopsy for Diagnosis and Staging of Prostate Cancer	Outpatient	03/03/2014
S-204*	Radiofrequency Ablation of the Esophagus	Inpatient/Outpatient	03/03/2014
S-205*	Keratoprosthesis	Outpatient	03/03/2014
S-235*	Bone Morphogenetic Protein	Inpatient/Outpatient	04/28/2014
U-6*	Chorionic Villus Sampling	Outpatient	03/03/2014
V-1*	Cardiac Rehabilitation Programs	Outpatient	03/03/2014
V-37*	Autism Spectrum Disorders	Outpatient	01/01/2014
V-44*	Medical Nutrition Management Services (MNT)	Outpatient	03/03/2014
X-27*	Stereotactic Localization- Outpatient	Outpatient	03/03/2014
X-51*	First Trimester Screening for Fetal Aneuploidy (Title Revised)	Outpatient	01/06/2014
Y-1*	Physical Medicine	Inpatient/Outpatient Revised	01/01/2014
Y-12*	Urinary Incontinence Therapy	Outpatient	03/03/2014
Y-17*	End-Diastolic Pneumatic Compression Therapy	Outpatient (Revised)	01/13/2014

* Typically an outpatient procedure which is only eligible for coverage as an inpatient procedure in special circumstances including, but not limited to the presence of a co-morbid condition that would require monitoring in a more controlled environment such as the inpatient setting.

Criteria revised for accessories used with a positive airway pressure device

Highmark Delaware is revising the coverage criteria for Positive Airway Pressure (PAP) Devices for the Treatment of Obstructive Sleep Apnea. Effective March 3, 2014, the following guidelines will be added to the existing criteria for positive airway pressure (PAP) devices for the treatment of obstructive sleep apnea.

A replacement cushion/pillow (A7031) is not billable when supplying an ongoing replacement of the frame with cushion/pillow (A7030). Billing for each individual component is considered unbundling of these supplies. The allowance of a replacement mask interface every month is considered an exception and documentation should support the medical necessity.

A replacement device is not covered due to misuse or abuse.

A7031 Face mask interface, replacement for full face mask, each. One per one month.

Please refer to Medical Policy **E-20** for more information.

Tumor treatment fields also referred to as electric fields considered experimental/investigational

Effective Dec. 30, 2013, Highmark Delaware considers tumor treatment fields as experimental/investigational.

Tumor treatment fields (TTF) or electric fields are created by low-intensity, alternating intermediate frequency (100 – 200 kilohertz [kHz]) electric currents delivered to the malignant tumor site by insulated electrodes placed on skin surface of the tumor site. As a result of the unique shape and electrical characteristics of dividing tumor cells, TTF exposure may damage the dividing cells through anti-microtubule mechanisms and could stop tumor growth while sparing normal tissue.

Please refer to Medical Policy **E-5** for more information.

Fluarix quadrivalent influenza vaccine FDA approved

Effective Aug. 16, 2013, Highmark Delaware began to provide coverage for fluarix quadrivalent influenza subtype A and type B vaccine.

On Aug. 16, 2013, the Food and Drug Administration (FDA) approved fluarix quadrivalent vaccine for prevention of influenza subtype A viruses and type B viruses. It is approved for use in children age three (3) years of age and older.

Procedure code 90688–Influenza virus vaccine, quadrivalent, split virus when administered to individuals three (3) years of age and older, for intramuscular use–is used to report this injection.

For more information on fluarix quadrivalent, refer to Medical Policy **I-8**, Immunizations.

Criteria established for treatment of hyperhidrosis

Effective March 3, 2014, Highmark Delaware may consider Treatment of Hyperhidrosis medically necessary as indicated below:

Treatment for primary focal hyperhidrosis may be considered medically necessary when any ONE of the following criteria have been met:

1. Acrocyanosis of the hands; or
2. History of recurrent skin maceration with bacterial or fungal infections, (including but not limited to cutaneous disorders such as dermatophytosis (ringworm), pitted keratolysis, viral warts at the sites of hyperhidrosis); or
3. History of atopic dermatitis (atopic eczema) in spite of medical treatments with topical dermatological or systemic anticholinergic agents;

In addition to any ONE of the above criteria, BOTH of the following criteria must be met:

- Unresponsive to or unable to tolerate pharmacotherapy modalities prescribed for excessive sweating (including but not limited to anti-cholinergics, beta-blockers, or benzodiazepines); and
- Topical aluminum chloride or other extra strength antiperspirants are ineffective or result in a severe rash.

Focal Regions and corresponding treatments that may be considered medically necessary when the above criteria have been met:

Axillary

- Botulinum toxin A (OnabotulinumtoxinA), for severe primary axillary hyperhidrosis that is inadequately managed with topical agents, in patients 18 years and older; or
- Iontophoresis

- Endoscopic transthoracic sympathectomy (ETS) and surgical excision of axillary sweat glands, if conservative treatment (i.e., aluminum chloride or botulinum toxin, individually and in combination) has failed.

Axillary liposuction and microwave treatment for axillary hyperhidrosis are considered experimental/investigational, and therefore not covered. A participating, preferred, or network provider can bill the member for the denied service.

Palmar

- Botulinum toxin A (OnabotulinumtoxinA), for severe primary palmar hyperhidrosis that is inadequately managed with topical agents, in patients 18 years and older; or
- Iontophoresis
- Endoscopic transthoracic sympathectomy (ETS), if conservative treatment (i.e., aluminum chloride or botulinum toxin type A, individually and in combination) has failed.

Botulimnum toxin B (RimabotulinumtoxinB), microwave treatment and radiofrequency ablation for palmar hyperhidrosis are considered experimental/investigational, and therefore not covered. A participating, preferred, or network provider can bill the member for the denied service.

Plantar

- Iontophoresis

Botulinum toxin, lumbar sympathectomy and •microwave treatment for plantar hyperhidrosis are considered experimental/investigational, and therefore not covered. A participating, preferred, or network provider can bill the member for the denied service.

Craniofacial

- Endoscopic transthoracic sympathectomy (ETS), if conservative treatment (e.g., aluminum chloride) has failed

Botulinum toxin, iontophoresis, and microwave treatment for craniofacial hyperhidrosis are considered experimental/investigational, and therefore not covered. A participating, preferred, or network provider can bill the member for the denied service.

Secondary hyperhidrosis: secondary gustatory hyperhidrosis

The following treatments may be considered medically necessary for the treatment of severe gustatory hyperhidrosis when the above general criteria have been met:

- Surgical options (e.g., tympanic neurectomy), if conservative treatment has failed.

Botulinum toxin and iontophoresis for severe gustatory hyperhidrosis are considered experimental/investigational and therefore not covered. A participating, preferred, or network provider can bill the member for the denied service.

Treatment of hyperhidrosis is considered not medically necessary in the absence of functional impairment or medical complications and therefore, non-covered. A participating, preferred, or network provider can bill the member for the denied service.

Please refer to Medical Policy **S-178** for more information.

Changes in criteria for ustekinumab

Effective March 3, 2014, Highmark Delaware will cover Ustekinumab for patients who meet the following criteria:

1. Used for the treatment of moderate to severe plaque psoriasis in adult patients (>18 years) who have previously received systemic therapy (e.g., methotrexate, cyclosporine) or phototherapy (e.g., PUVA, UVB); and
2. Member has had an adequate trial or has experienced an intolerance to both preferred biologic products, Enbrel and Humira, indicated for the treatment of psoriasis.

The use of ustekinumab for any other indication is considered experimental/investigational, and therefore, not covered. A participating, preferred, or network provider can bill the member for the non-covered service.

Please refer to Medical Policy **I-37** for more information.

Nerve conduction velocity not medically necessary for polyneuropathy

Effective March 3, 2014, Highmark Delaware will consider nerve conduction velocity not medically necessary for screening, testing, monitoring disease intensity, or monitoring of treatment effectiveness for ANY ONE of the following:

- polyneuropathy of diabetes; or
- polyneuropathy of end stage renal disease (ESRD).

Please refer to Medical Policy **M-51** for more information.

Additional criteria added for prophylactic mastectomy

Highmark Delaware is updating its coverage criteria for prophylactic mastectomy. The new guidelines will become effective on March 3, 2014.

Risk Factors added:

- Li-Fraumeni syndrome or Cowden syndrome or Bannayan-Riley-Ruvalcaba syndrome or a first-degree relative with one of these syndromes

Prophylactic mastectomy may be considered medically necessary in patients with lobular carcinoma in situ.

Please refer to Medical Policy **S-163** for more information.

Sacral nerve stimulation now covered for overactive bladder

Highmark Delaware is updating its coverage criteria for Sacral Nerve Modulation/Stimulation (SNS) for Pelvic Floor Dysfunction. The new guidelines will become effective on March 3, 2014.

Sacral nerve modulation/stimulation (SNS), e.g., InterStim Continence Control Therapy System, is recognized as safe and effective for treatment of urinary urge incontinence, urgency-frequency, non-obstructive urinary retention, or overactive bladder not resulting from a neurologic condition.

As of March 3, 2014, the following criteria will be eligible for overactive bladder.

Sacral nerve modulation/stimulation may be considered medically necessary when documentation is submitted indicating the patient meets all the following criteria:

- The patient has a diagnosis of urinary urge incontinence, urgency-frequency, or non-obstructive urinary retention or overactive bladder that is not due to a neurologic condition.
- Symptoms of urinary urge incontinence, urgency-frequency, or non-obstructive urinary retention, or overactive bladder have been present for at least one (1) year's duration and have resulted in significant disability (e.g., the urgency-frequency and/or severity of leakages, or urinary retention are limiting the patient's ability to work or participate in activities outside the home).
- The patient has tried and failed the following conservative treatments:
    - *Pharmacological* - e.g., two different anticholinergic drugs (such as oxybutynin and hyoscyamine) or a combination of an anticholinergic and a tricyclic antidepressant (such as imipramine);
    - *Behavioral* - e.g., pelvic muscle exercises, biofeedback, timed voids, fluid management.
- The patient has had a successful screening peripheral nerve evaluation test.
- A test stimulation of the device has provided at least a 50% reduction in incontinence symptoms or a 50% reduction in residual urine volume

Please refer to Medical Policy **S-131** for more information.

Changes in coverage for denosumab (prolia, xgeva)

Effective March 3, 2014, Highmark Delaware will cover Denosumab (Prolia, Xgene) for the following indications:

1. Denosumab is being used to increase bone mass in men at high risk for fracture (T score <-1.0 and multiple risk factors for fracture *OR* a previous osteoporotic fracture) who are receiving androgen deprivation therapy for non-metastatic prostate cancer.
2. Denosumab is being used to increase bone mass in women at high risk for fracture (T score <-1.0 and multiple risk factors for fracture *OR* a previous osteoporotic fracture) who are receiving adjuvant aromatase therapy for breast cancer.
3. Denosumab is being used to treat osteoporosis and to prevent fractures in men and postmenopausal women who have a documented bone mineral density (BMD) T-score <2.5 establishing the diagnosis of osteoporosis; and
    - The member has had an adequate trial and failure of at least one bisphosphonate. Trial and failure will be defined as a decrease in BMD despite at least 12 months of bisphosphonate therapy; or
    - The member has a contraindication to at least one bisphosphonate. Contraindications to bisphosphonate therapy include hypocalcemia, esophageal ulcerations, esophageal stricture, Barrett's esophagitis, active ulcers, and an inability to stand or sit upright for 30 minutes.
4. Denosumab is being used to prevent fractures in men and postmenopausal women with a low bone mass (T-score between -1 and -2.5) *AND* history of a previous osteoporotic fracture; and
    - The member has had an adequate trial and failure of at least one bisphosphonate. Trial and failure will be defined as a decrease in BMD despite at least 12 months of bisphosphonate therapy; or
    - The member has a contraindication to at least one bisphosphonate. Contraindications to Barrett's esophagitis, active ulcers, and an inability to stand or sit upright for 30 minutes.
5. Denosumab is being used to prevent fractures in men and postmenopausal women who are found to have a 10-year risk of major osteoporotic fracture greater than or equal to 20% or a risk of hip fracture greater than or equal to 3% using the FRAX calculator; and
    - The member has had an adequate trial and failure of at least one bisphosphonate. Trial and failure will be defined as a decrease in BMD despite at least 12 months of bisphosphonate therapy; or
    - The member has a contraindication to at least one bisphosphonate. Contraindications to bisphosphonate therapy include hypocalcemia, esophageal ulcerations, esophageal stricture, Barrett's esophagitis, active ulcers, and an inability to stand or sit upright for 30 minutes.

Limitations of coverage

- It is recommended that the member is taking calcium and vitamin D supplements on a daily basis.
- The member does not have an underlying cause for secondary osteoporosis such as hyperthyroidism or hyperparathyroidism, hypogonadism, chronic estrogen deficiency state (e.g., menopause before age 45, bilateral oophorectomy), vitamin D deficiency, chronic liver disease, or chronic kidney disease.

The use of denosumab (Prolia) for any other indication is considered experimental/investigational, and therefore, not covered. A participating, preferred, or network provider can bill the member for the non-covered service.

NOTE: Dosage recommendations per the FDA label.

Please refer to Medical Policy **I-30** for more information.

Additional criteria added for human growth hormone

Effective March 3, 2014, Highmark Delaware will cover a non-preferred growth hormone product only after the member has had an adequate therapeutic trial and has experienced an intolerance to both of the preferred products, Humatrope and Norditropin, in the growth hormone category.

Also, all claims for growth hormone therapy should be referred for review on a yearly basis for ongoing approval.

Use of this drug for any condition other than those listed above should be denied as not medically necessary and, therefore, not covered.

Please refer to Medical Policy **I-12** for more information.

Plugs for anal fistula repair considered experimental/investigational

Effective March 3, 2014, Highmark Delaware will consider anal fistula plug(s) experimental/investigational. There is limited data available to support the use of anal fistula plugs.

A participating, preferred, or network provider can bill the member for the denied service.

Please refer to Medical Policy **Z-24** for more information.

Criteria revised for real-time cardiac surveillance monitoring

Real-time cardiac surveillance (monitoring) is a form of external ambulatory monitors developed to combine the benefits and overcome the limitations of Holter and standard external loop monitors (ERLs). Real-time cardiac surveillance (monitoring), also known as ambulatory electrocardiography (AECG) is limited to a very select patient population. Effective March 3, 2014, Highmark Delaware will consider real-time cardiac surveillance monitoring medically necessary when the following criteria are met:

1. When traditional Holter monitoring or cardiac event recording is not expected to provide adequate information or has been unrevealing; and
2. There is low likelihood of a malignant cardiac event; and
3. Patients who experience infrequent symptoms (less frequently than every 24-48 hours) suggestive of cardiac arrhythmias (i.e., palpitations, dizziness, pre-syncope, or syncope); and
4. It is anticipated that the results of this service would provide diagnostic and treatment information; AND

5. ONE of the following :
    - Patients who require monitoring for known, non- life-threatening arrhythmias, such as atrial fibrillation, other supra-ventricular arrhythmias, evaluation of various bradyarrhythmias, and intermittent bundle branch block; or
    - Patients recovering from cardiac surgery who have had documented atrial arrhythmias; or
    - Patients with symptomatic underlying structural disease; or
    - Patients with no structural heart disease but who have recurrent severe symptoms (i.e., recurrent syncope) in who all testing is negative and an implantable event recorder is contemplated; or
    - Patients with unexplained syncope, near syncope, or episodic dizziness; or
    - Patients with unexplained recurrent palpitations; or
    - Patients who require evaluation of antiarrhythmic drug therapy.

Please refer to Medical Policy **M-60** for more information.

Myocardial sympathetic innervation imaging in patients with heart failure considered experimental/investigational

Effective March 3, 2014, Highmark Delaware will consider myocardial sympathetic innervation imaging experimental/investigational. There is insufficient or inconclusive scientific evidence to determine the efficacy of this imaging. A participating, preferred, or network provider can bill the member for this procedure.

For more information on myocardial sympathetic innervation imaging, refer to Medical Policy **R-8**, Non-Malignant Applications of PET and PET/CT.

Criteria revised for cochlear implant

Effective March 3, 2014 Highmark Delaware may consider unilateral or bilateral cochlear implantation of a Food and Drug Administration (FDA) approved cochlear implant device(s) medically necessary when ALL of the following criteria have been met:

1. Patients age 12 months and older with bilateral severe to profound pre- or post-lingual (sensorineural) hearing loss defined as a hearing threshold of pure-tone average of 70 dB (decibels) hearing loss or greater at 500 Hz (hertz), 1,000 Hz, and 2,000 Hz, and have shown limited or no benefit from hearing aids; and
2. Cognitive ability to use auditory clues and a willingness to undergo an extended program of rehabilitation; and
3. Freedom from middle ear infection, an accessible cochlear lumen that is structurally suited to implantation, and freedom from lesions in the auditory nerve and acoustic areas of the central nervous system; and
4. No medical contraindications to cochlear implantation (including but not limited to active middle ear infection, deafness due to lesions of the eighth cranial nerve or brainstem, absence of cochlear development).

Bilateral cochlear implantation may be considered medically necessary when it has been determined that the alternative of unilateral cochlear implant plus hearing aid in the contralateral ear will not result in a binaural benefit; (i.e., in those patients with hearing loss of a magnitude where a hearing aid will not produce the required amplification.)

Cochlear implantation as a treatment for patients with unilateral hearing loss with or without tinnitus is considered experimental/investigational, and therefore non-covered. A participating, preferred, or network provider can bill the member for the denied service.

In addition, auditory training and basic guidance (e.g., fitting external parts, programming the processor, etc.) performed during the postoperative period may be eligible for separate payment when coverage for the cochlear implantation has been established.

Cochlear implantation provided for any diagnosis other than the conditions referenced above may be considered not medically necessary.

Please refer to Medical Policy **S-67** for more information.

New criteria added for intra-articular hyaluronan injections for osteoarthritis of the knee

Highmark Delaware is revising the coverage criteria for Intra-articular hyaluronan injections for osteoarthritis of the knee.

Effective March 3, 2014, the following criteria will be added for intra-articular hyaluronan injections.

- The patient has documentation of diagnosis and symptomatic osteoarthritis of the knee and there is no evidence of inflammatory arthritis (e.g., rheumatoid arthritis)

- There is documentation of failure to respond adequately to at least three (3) months of conservative therapy which includes activity modification, home exercise, protective weight bearing, and analgesics (e.g., acetaminophen or non-steroidal anti-inflammatory drugs [NSAIDs]) or the individual is unable to tolerate conservative therapy because of adverse side effects

- There is documentation that the pain interferes with functional activities (e.g., ambulation, prolonged standing)

Please refer to Medical Policy **G-25** for more information.

Changes to criteria for transcatheter closure devices for congenital heart defects

The criteria changes for transcatheter closure devices for congenital heart defects will be effective March 3, 2014.

All transcatheter closure devices for congenital heart defects, when approved by the Food and Drug Administration (FDA) for their intended indication may be considered medically necessary for the following criteria:

Transcatheter closure of cardiac septal defects using an FDA approved closure device, according to the labeled indications, is considered medically necessary and, therefore, covered for the following:

- Closure of ostium secundum atrial septal defects (ASDs) in individuals with echocardiographic evidence of right ventricular volume overload; or
- Closure of the fenestration in individuals who have undergone a fenestrated Fontan procedure; or
- Closure of patent ductus arteriosus (PDA); or
- Treatment of complex ventricular septal defects (VSDs) of significant size to warrant closure in individuals who are at high risk for standard transatrial or transarterial surgical closure due to anatomic conditions or overall medical condition (e.g., the need for a left ventriculotomy, a failed previous VSD closure, multiple apical and/or anterior muscular VSDs [Swiss cheese septum], posterior apical VSDs covered by trabeculae).

Transcatheter closure of ostium secundum atrial septal defects and closure of the fenestration should be reported under procedure code 93580.

Transcatheter closure of patent ductus arteriosus should be reported under procedure code 93582.

Transcatheter closure of single ventricular septal defects should be reported under code 93581.

Percutaneous transcatheter devices for the closure of secundum atrial septal defects are contraindicated and considered not medically necessary for the following:

- Any patient known to have extensive congenital cardiac anomaly which can only be adequately repaired by way of cardiac surgery; or
- Any patient known to have local or generalized sepsis, or any systemic infection that cannot be successfully treated prior to device placement; or
- Any patient known to have a bleeding disorder, untreated ulcer, or any other contraindications to aspirin therapy, unless another anti-platelet agent can be administered for six (6) months; or
- Any patient known to have a demonstrated intracardiac thrombi on echocardiography (especially left atrial or left atrial appendage thrombi); or
- Any patient whose size or condition would cause the patient to be a poor candidate for cardiac catheterization; or
- Any patient where the margins of the defect are <5mm to the coronary sinus, AV valves and right upper lobe pulmonary vein.

The following are contraindications for the use of FDA approved transcatheter devices for the closure of patent ductus arteriosus and considered not medically necessary:

- Patients weighing less than six (6) kg; or
- Patients less than six (6) months of age; or
- Presence of thrombus at the intended site of implant, or documented evidence of venous thrombus in the vessels through which access to the defect is gained; or
- Active endocarditis or other infections producing bacteremia; or
- Patients whose vasculature, through which access to the defect is gained, is inadequate to accommodate the appropriate sheath size; or
- Patients with pulmonary hypertension with pulmonary vascular resistance of >8 Woods units or Rp/Rs of >0.4.

All other uses of transcatheter closure devices are considered experimental/investigational and, therefore, not covered because the safety and/or effectiveness of these devices for other purposes has not been established by review of the available published literature. A participating, preferred, or network provider can bill the member for the non-covered service.

The use of any transcatheter closure device, that has not been approved by the FDA, for cardiac septal defects, including the use in the closure of patent foramen ovale is considered experimental/ investigational and, therefore, not covered. A participating, preferred, or network provider can bill the member for the non-covered service.

Please refer to Medical Policy S-152 for more information.

Clinical criteria revised for pheresis therapy

Highmark Delaware has revised the clinical criteria for pheresis therapy. Effective March 3, 2014, pheresis therapy is eligible for payment when performed for the following indications:

Plasma exchange for autoimmune conditions:

- Severe multiple manifestations of mixed cryoglobulinemia (MC) such as cryoglobulinemic nephropathy, skin ulcers, sensory motor neuropathy, and widespread vasculitis in combination with immunosuppressive treatment, or
- Catastrophic antiphospholipid syndrome (CAPS), or

Plasma exchange for hematologic condition:

- ABO incompatible hematopoietic progenitor cell transplantation, or
- Hyperviscosity syndromes associated with multiple myeloma or Waldenstrom's macroglobulinemia, or
- Idiopathic thrombocytopenic purpura in emergency situations, or
- Thrombotic thrombocytopenic purpura (TTP), or
- Atypical hemolytic-uremic syndrome, or
- Post-transfusion purpura, or
- HELLP syndrome of pregnancy (a severe form of preeclampsia, characterized by hemolysis [H], elevated liver enzymes [EL], and low platelet [LP] counts), or
- Myeloma with acute renal failure, or

Plasma exchange for neurological conditions:

- Guillain-Barré syndrome, or
- Chronic inflammatory demyelinating polyradiculoneuropathy (CIDP), or
- Multiple sclerosis (MS); acute fulminant central nervous system (CNS) demyelination, or
- Myasthenia gravis in crisis or as part of preoperative preparation, or
- Paraproteinemia polyneuropathy; IgA, IgG, or

Plasma exchange for renal conditions:

- Anti-glomerular basement membrane disease (Goodpasture's syndrome), or
- ANCA [antineutrophil cytoplasmic antibody]-associated vasculitis [e.g., Wegener's granulomatosis [also known as granulomatosis with polyangitis (GPA)] with associated renal failure, or
- Dense deposit disease with factor H deficiency and/or elevated C3 Nephritic factor, or

Plasma exchange for transplantation conditions:

- Prior to solid organ transplant, treatment of patients at high risk of antibody-mediated rejection, including highly sensitized patients, and those receiving an ABO incompatible organ.
    - Kidney, or
    - Heart (infants), or
- Renal transplantation: antibody mediated rejection; HLA [human leukocyte antigen] desensitization, or
- Focal segmental glomerulosclerosis after renal transplant.

Apheresis therapy for the following conditions:

- Apheresis in the treatment of chronic relapsing polyneuropathy for patients with severe or life-threatening symptoms who have failed to respond to conventional therapy, or
- Apheresis in the treatment of life-threatening scleroderma and polymyositis, when the patient is unresponsive to conventional therapy.

Plasmapheresis therapy for the following conditions:

- Plasmapheresis in the treatment of pure red cell aplasia unresponsive to steroid and immunosuppressive therapy, or

- Plasmapheresis or plasma exchange in the last resort treatment of life threatening rheumatoid vasculitis when all other conventional therapies have failed.

Pheresis therapy for other conditions

- Familial homozygous hypercholesterolemia.
- Leukapheresis in the treatment of leukemia, or
- Systemic lupus erythematosus (SLE), life threatening, as a treatment of last resort, or
- Chronic myelogenous leukemia, or
- Advanced prostate cancer only when used in the development of sipuleucel-T (Provenge). Refer to Medical Policy Bulletin I-26 on Cellular Immunotherapy for Prostate Cancer.

NOTE: It will be necessary for the provider to submit medical records and/or additional documentation to determine coverage for the following indications:

- Prior to solid organ transplant, treatment of patients at high risk of antibody-mediated rejection, including highly sensitized patients, and those receiving an ABO incompatible organ.
- Plasmapheresis or plasma exchange in the last resort treatment of life threatening rheumatoid vasculitis when all other conventional therapies have failed.

Low-density lipid (LDL) apheresis

Low-Density Lipid (LDL) apheresis may be considered medically necessary for the following indications:

- Patients with homozygous familial hypercholesterolemia as an alternative to plasmapheresis; and,
- Patients with heterozygous familial hypercholesterolemia who have failed a 6 month trial of diet therapy, and maximum tolerated combination drug therapy(*), and who meet the following FDA-approved indications:
  - Functional hypercholesterolemic heterozygotes with LDL cholesterol > 300 mg/dl; without coronary artery disease, or
  - Functional hypercholesterolemic heterozygotes with LDL cholesterol > 200 mg/dl and documented coronary artery disease.

* Maximum tolerated drug therapy is defined as a trial of drugs from at least 2 separate classes of hypolipidemic agents such as bile acid sequestrants, HMG-CoA reductase inhibitors, fibric acid derivatives, or Niacin/Nicotinic acids.

Documented coronary artery disease includes a history of myocardial infarction, coronary artery bypass surgery, percutaneous transluminal coronary angioplasty or alternative revascularization procedure, or progressive angina documented by exercise or non-exercise stress test.

LDL apheresis provided for any other indication is considered not medically necessary.

Please refer to Medical Policy **S-11** for more information.

Patient selection criteria added for cryosurgery of the liver

Highmark Delaware is revising the coverage criteria for Cryosurgery of the Liver. Effective March 3, 2014, the following guideline will be added to the existing patient selection criteria for cryosurgery of the liver.

- Lesion measures no more than 4 cm in diameter

Please refer to Medical Policy **S-130** for more information.

Clinical criteria revised for kyphoplasty

Highmark Delaware has revised the clinical criteria for kyphoplasty. Kyphoplasty may be considered medically necessary for ANY of the following criteria:

- symptomatic osteoporotic vertebral fractures that have failed to respond to conservative treatment (e.g., analgesics, physical therapy, and rest) for at least 6 weeks, or
- osteoporotic vertebral compression fractures in the cervical, thoracic, and lumbar spine causing moderate to severe pain and unresponsive to conservative therapy (if the osteoporotic vertebral compression fracture is > 8 weeks old, additional clinical and diagnostic criteria are needed [i.e. MRI and evidence of a detailed physical exam] to determine that the fracture is the source of the pain); or
- severe pain due to osteolytic lesions of the spine related to multiple myeloma or metastatic malignancies, or
- painful metastasis and multiple lymphoma or myelomas with or without adjuvant radiation or surgical therapy; or
- painful vertebral hemangiomas; or
- vertebral osteonecrosis; or
- reinforcement of a pathologically weak vertebral body before a surgical stabilization procedure; or; or
- kyphosis

Please refer to Medical Policy **S-148** for more information.

New policy for Corus CAD® diagnostic test

Highmark Delaware is adding coverage criteria for Corus CAD®. The new guidelines will become effective on January 6, 2014.

Corus CAD® is considered experimental/investigational for any indication, and therefore, not covered because the safety and/or effectiveness cannot be established by review of the published peer-reviewed literature. A participating, preferred, or network provider can bill the member for the non-covered service.

Please refer to Medical Policy **L-9** for more information.

Biomarkers in risk assessment and management of cardiovascular disease considered experimental/investigational

Effective March 3, 2014 Highmark Delaware will consider measurement of novel lipid and non-lipid risk factors (i.e., apolipoprotein B, apolipoprotein A-I, apolipoprotein E, B-type natriuretic peptide, cystatin C, leptin, LDL subclass, HDL subclass, lipoprotein[a]) experimental/investigational as an adjunct to LDL cholesterol in the risk assessment and management of cardiovascular disease.

The available scientific evidence does not provide adequate data to establish that the use of panels that include lipid and non-lipid cardiovascular risk markers improve outcomes when used in clinical care.

A participating, preferred, or network provider can bill the member for the denied service.

Please refer to Medical Policy Bulletin **L-96** for more information.

Macro electromyography (EMG) considered experimental/investigational

Effective March 3, 2014, Highmark Delaware considers macro electromyography (EMG) experimental/investigational and is not eligible for payment. Scientific evidence does not demonstrate the

efficacy of the surface EMG. A participating, preferred, or network provider can bill the member for the denied service.

Please refer to Medical Policy **M-28** for more information.

Criteria revision for cranial orthosis for plagiocephaly

Effective March 3, 2014, medical necessity criteria is revised for cranial orthosis for plagiocephaly and moderate to severe plagiocephaly is defined.

Non-synostotic plagiocephaly

Cranial orthotic devices (L0112, L0113, S1040) used in the treatment of non-synostotic plagiocephaly are eligible for reimbursement when ALL of the following criteria are met:

1. The infant must have tried and failed conservative therapy (i.e., repositioning) for a minimum of two months; and
2. The infant must be 3 - 18 months of age; and
3. Cranial asymmetry is documented by either of the following:
   a. Moderate to severe plagiocephaly in one of the following anthropometric dimensions (Table 1):
      Cranial vault; or
      Cranial base; or
      Orbitotragial depth

      OR

   b. Cephalic index measurement is two standard deviations above or below the mean (Table 2)

Cranial orthosis is considered cosmetic when used in the treatment of non-synostotic plagiocephaly with mild deformity and/or when a minimum trial period of two (2) months of conservative therapy has not been tried. Therefore, these services are not covered. A participating, preferred, or network provider can bill the member for the non-covered service.

Synostotic plagiocephaly

Cranial orthotic devices (L0112, L0113, S1040) used in the post-operative treatment of synostotic plagiocephaly are eligible for reimbursement for infants with moderate to severe residual plagiocephaly after surgical correction when cranial asymmetry is documented by ANY of the following:

a. Moderate to severe plagiocephaly in ONE of the following anthropometric dimensions (Table 1):
   Cranial vault; or
   Cranial base; or
   Orbitotragial depth

   OR

b. Cephalic index measurement is two standard deviations above or below the mean (Table 2)

Determination of severity of plagiocephaly

Determination of the severity of plagiocephaly requires precise measurements of the skull using either the cephalic index or anthropomorphic measurements.

Table 1
Specifications for Taking Anthropometric Measurements

	Comparative Cranial Landmarks
Cranial Vault	Left frontozygomatic point (fz) to right euryon (eu) minus right frontozygomatic point (fz) to left euryon (eu)
Cranial Base	Subnasal point (sn) to left tragus (t) minus subnasal point (sn) to right tragus (t)
Orbitotragial Depth	Left exocanthion point (ex) to left tragus (t) minus right exocanthion point (ex) to right tragus (t)

Moderate to severe plagiocephaly is defined as one of the following:

- Cranial base (sn – t): >= 6 mm difference between left and right measurements
- Cranial vault (fz – contralateral eu): >= 8 mm difference between left and right measurements
- Obitotragial depth (ex – t): >= 4 mm difference between left and right measurements

Please refer to the following link for diagrams of the cranial landmarks and their definitions: http://www.plagiocephaly.info/faqs/anthropometry.htm#Kelly.

Table 2
Cephalic Index:

$$\frac{\text{Head width (eu - eu)} \times 100}{\text{Head length (g - op)}}$$

Moderate to severe plagiocephaly is defined as a cephalic index two standard deviations above or below the mean. Infants with deformational scaphocephaly will have a lower cephalic index due to a very long and narrow skull deformity. Infants with deformational brachycephaly will have an increased cephalic index due to a very wide and short skull deformity.

Gender	Age	-2SD	-1SD	Mean	+1SD	+2SD
Male	16 days-6 months	63.7	68.7	73.7	7	83.7
	6-12 months	64.8	71.4	78.0	84.6	91.2
Female	16 days-6 months	63.9	68.6	73.3	78.0	82.7
	6-12 months	69.5	74.0	78.5	83.0	87.5

Please refer to Medical Policy **O-13** for more information.

Telehealth medical consultations

Teladoc is a nationwide network of licensed, board certified physicians, providing telehealth visits. Teladoc physicians can remotely diagnose and treat minor, no-emergency medical problems. All teladoc physicians are carefully credentialed and covered by medical malpractice insurance. Members who have the benefit for Telehealth Medical Consultations have access to locally-licensed physicians 24 hours-a day, 365 days a year. Teladoc physicians can diagnose over 100 conditions and can prescribe certain medications (they do NOT prescribe DEA controlled substances or lifestyle drugs, such as Viagra). Telehealth consultations include video, telephone, and in the future mobile phone applications. Teladoc's platforms are secure and HIPAA compliant.

Teladoc does visits by both web and phone. It does not replace the member's PCP. Teladoc provides members with another access point of care.

Teladoc is the premier vendor/approved provider for Plan members to receive telehealth medical consultations. Only teladoc physicians are eligible to report this service.

Effective January 1, 2014, coverage for Telehealth Medical Consultations (Telemedicine Services) will be determined according to individual or group customer benefits. When a telemedicine service benefit, a member can call teladoc or visit them on the web to request a visit. This should be done via the web for the first time, as the member will need to fill out a Medical History Disclosure form before being able to have a visit. The form will only need to be completed one time. Once the member requests a visit, they will then wait for the physician to call them back. Teladoc will provide the member with a physician who is licensed in the state in which the member is located.

Teladoc visits are reported with codes 99441, 99442 and 99443.

Please refer to Medical Policy **Z-68** for more information.
