PR 13-46

SPECIAL BULLETIN

FOR PROFESSIONAL AND FACILITY PROVIDERS

August 26, 2013

ATTN: ALL PARTICIPATING PROVIDERS

MEDICAL POLICY UPDATES AND NEWS

AUGUST AND SEPTEMBER

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.

NEWS

Attention cardiologists, chiropractors, hematologists/oncologists, neuroscientists, neurosurgeons, orthopedic surgeons, physiatrists, and rheumatologists: accepting candidates for CPMC advisory subcommittees

Highmark Delaware is accepting new members for its four Clinical Policy Management Committee (CPMC) advisory subcommittees.

These specialty subcommittees—cardiology, hematology/oncology, musculoskeletal and the neurosciences (including psychiatry)—serve as an advisory to the CPMC by providing recommendations about the development of new or the modification of, existing medical policies.

Highmark Delaware's CPMC is responsible for medical policy decisions. Each CPMC subcommittee will review the analysis and recommendations of Highmark Delaware's Medical Policy department for existing medical policy criteria/coverage positions as well as the development of policy guidelines for new and evolving technologies that are evidence based and in a discipline directly linked to the subcommittee's designated medical specialty. The subcommittee will make recommendations to the CPMC regarding medical policy criteria and coverage positions based on the Medical Policy department's analysis, either accepting the Medical Policy department's analysis and recommendation, or suggesting a new/revised recommendation.

Subcommittee member qualifications
CPMC subcommittee members must be of Highmark Delaware network participating providers practicing in the community and at academic centers. Subcommittee members must be board certified in their medical specialty.

How to apply
If you would like to apply for appointment to the CPMC subcommittee, please send an e-mail detailing your current medical practice activities and location, along with a resume or curriculum vitae, to **cpmc@highmark.com**. Please respond by September 30, 2013.

You will be notified by December 30, 2013, if you are selected to serve on a CPMC subcommittee.

Selecting patient-specific cardiovascular monitoring services

There are various types of cardiovascular monitoring services available to monitor cardiovascular rhythm (ECG) data. The provider should select the most appropriate monitoring system that is best suited for the patient's condition.

There are three types of diagnostic medical procedures used to remotely assess ECG data.

1. **Holter monitors** (93224-93227) include up to 48 hours of continuous recording.
2. **Mobile cardiac telemetry monitors** (93228 and 93229) have the capability of transmitting a tracing at any time, always have internal ECG analysis algorithms designed to detect major arrhythmias, and transmit to an attended surveillance center.
3. **Event monitors** (93268–93272) record segments of ECGs with recording initiation triggered either by patient activation or by an internal automatic, pre-programmed detection algorithm or both and transmit the recorded electrocardiographic data when requested (but cannot transmit immediately based upon the patient or algorithmic activation rhythm) and require attended surveillance.

The following descriptions are intended to help the provider select the most appropriate type of cardiovascular monitoring. Please consult Medical Policy Bulletins for General Policy Guidelines.

Holter monitor (93224–93227)

- Is continuous ECG recording for up to 48 hours.
- The patient is able to go about his/her usual daily activity.
- With a Holter monitor, the patient has several electrodes (small sticky patches) placed on the chest and wires connect the electrodes to the recorder (Holter monitor). The Holter monitor itself is a small, portable recorder, and typically worn on a strap over the shoulder.
- Possible uses include; detection of abnormal heart rhythms; assess recurring symptoms such as dizziness, fainting, and palpitations; and to evaluate the effectiveness of treatments, such as medications and pacemakers, that helps control abnormal heart rhythms.
- The device records the patient's ECG and the review and analysis occurs after the patient returns the Holter monitor to the provider.
- Upon return of the device, the data is downloaded and printed for a physician or other qualified health care professional to review and interpret.

Mobile cardiology telemetry monitor (93228, 93229)

- Is continuous ECG recording for up to 30 days.
- The patient is able to go about his/her usual daily activity.

- The device is automatically activated which requires no patient intervention to either capture or transmit an arrhythmia when it occurs.
- With mobile cardiology telemetry monitors the patient wears a three-lead sensor that constantly communicates with a lightweight monitoring unit carried in a pocket or purse.
- Mobile cardiac telemetry (MCT) is real-time, continuously attended ambulatory cardiac monitoring. Continuously-attended means that there is, at the remote monitoring site or central data center, trained personnel, under the general supervision of a physician, receiving real-time ECG data 24 hours a day. The technician must have immediate, 24-hour access to a physician to review transmitted data and make clinical decisions regarding the patient.
- Coverage is limited to a very select patient population who has demonstrated a need for real-time outpatient cardiac monitoring. This service is not indicated on all patients with arrhythmias and should only be used circumstances in which traditional Holter monitoring or cardiac event recording is not expected to provide adequate information or has been unrevealing. This system is not indicated for use as a screening tool. Please refer to Medical Policy M-60, Real-Time Cardiac Surveillance (Monitoring) for the indications and limitations of coverage and documentation requirements.

Event monitor (93268-93272)

- Can monitor and record events up to 30 days and sometimes longer.
- The patient is able to go about his/her usual daily activity.
- The device is activated by the patient or by an internal automatic, pre-programmed detection algorithm and it records the rhythm strip. The recorded ECG(s) are stored on the device until the information is transmitted via telephone to a receiving station (eg, doctor's office, hospital, or cardiac monitoring service). The receiving station will produce a hard copy of the electrocardiograph for the physician or other qualified health care professional to review and interpret.
- With a cardiac event monitor, the patient has several electrodes (small sticky patches) placed on the chest and wires connect the electrodes to the recorder (Event monitor). The Event monitor itself is a small, portable device, and easily worn during daily activities and sleep.
- Cardiac event detection monitoring involves the recording of arrhythmia in patients where the symptoms may be significant but occur very infrequently. Consequently, the arrhythmia is difficult to identify on a 24 to 48 hour Holter monitor. A cardiac event device is a tape recorder which has a continuous loop and can be worn for up to a month and sometimes longer.
- Possible uses include symptoms such as palpitations, dizziness, syncope and collapse, or other transient symptoms which could be due to an arrhythmia.
- Please refer to Highmark Delaware Medical Policy Bulletin M-31, Cardiac Event Detection Monitoring for the indications and limitations of coverage and documentation requirements.

In closing we offer the following tips:

- Order the most appropriate cardiovascular monitoring system for the patient's condition.
- Assure all documentation requirements are fulfilled.
- Some vendors offer pre-printed order forms for services and equipment. Discretion is highly recommended in using pre-printed order forms from vendors because the order form might limit the physician's choice to a particular model; might not include the service/product ordered; and might not be in alignment with Highmark Delaware Medical Policies and Procedure

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
E-7*	Pneumatic Compression Devices	Outpatient	10/28/2013
E-20*	Positive Airway Pressure (PAP) Devices for the Treatment of Obstructive Sleep Apnea	Outpatient	10/28/2013
E-50*	Continuous Positive Airway Pressure (CPAP) Devices Used in the Treatment of Obstructive Sleep Apnea in Children	Outpatient	10/28/2013
I-2*	Vitamin B-12 Injections	Outpatient	10/28/2013
I-20*	Immune Prophylaxis for Respiratory Syncytial Virus (RSV)	Outpatient	10/28/2013
I-21*	Trastuzumab (Herceptin)	Outpatient	10/28/2013
I-24*	Belatacept (Nulojix)	Inpatient/Outpatient	10/28/2013
I-29*	Pegloticase (Krystexxa)	Outpatient	10/28/2013
I-34*	Ipilimumab (yervoy)	Outpatient	10/28/2013
I-35*	Golimumab (Simponi®)	Outpatient	10/28/2013
I-92*	Naltrexone Extended Release Injection (Vivitrol®)	Outpatient	10/28/2013
I-93*	Idursulfase (Elaprase)	Outpatient	10/28/2013
I-94*	Intravitreal Injections	Outpatient	10/28/2013
I-95*	Ibandronate Sodium (Boniva) Injection	Outpatient	10/28/2013
I-96*	JETREA	Outpatient	10/28/2013
L-83*	RedPath – PathFinderTG	Outpatient	10/28/2013
L-90*	KRAS Mutation Analysis for Non-Small Cell Lung Cancer	Outpatient	10/28/2013
M-15*	Non-invasive Peripheral Arterial Studies	Inpatient/Outpatient	10/28/2013
M-74*	Home Prothrombin Time INR Monitoring for Anticoagulation Management	Outpatient	10/28/2013

Policy #	Policy Topic	Place of Service	Effective Date
O-10*	Dynamic Splinting Devices	Outpatient	10/28/2013
O-23*	Eye Prosthesis	Outpatient	10/28/2013
O-24*	Ankle-Foot/Knee-Ankle-Foot Orthosis	Outpatient	10/28/2013
R-58*	Chronic Wound Management	Inpatient/Outpatient	10/28/2013
S-77*	Endometrial Ablation	Outpatient	10/28/2013
S-114*	Occlusion of Uterine Arteries Using Transcatheter Embolization	Inpatient/Outpatient	10/28/2013
S-141*	Radiofrequency Thermal Ablation of Liver Tumors (RFA)	Inpatient/Outpatient	09/02/2013
S-150*	Radiofrequency Facet Nerve Denervation	Outpatient	10/28/2013
S-187*	Artificial Intervertebral Disc Replacement	Outpatient	10/28/2013 Revised
S-203	Transcatheter Pulmonary Valve Implantation	Inpatient	08/19/2013
V-23*	Temporomandibular Joint (TMJ) Dysfunction	Inpatient/Outpatient	10/28/2013
V-59*	Contraceptive Management	Outpatient	10/28/2013
Y-16*	Radioimmunotherapy for the Evaluation and Treatment of Certain Non-Hodgkin's Lymphoma	Outpatient	10/28/2013
Z-8*	Sleep Disorder Services for Adults	Outpatient	10/28/2013
Z-50*	Determination of Refractive State	Outpatient	10/28/2013
Z-64*	Diagnosis and Treatment of Obstructive Sleep Apnea in Children	Inpatient/Outpatient	10/28/2013

* 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.

Occlusion of uterine arteries using transcatheter embolization criteria revised

Highmark Delaware is updating its coverage criteria for Uterine Artery Embolization for Uterine Fibroids. The medical policy title will be revised to Occlusion of Uterine Arteries Using Transcatheter Embolization.

Effective October 28, 2013, the following criteria will be eligible for occlusion of uterine arteries using transcatheter embolization.

Transcatheter embolization of uterine arteries may be considered medically necessary for ANY ONE of the following:

- treatment of uterine fibroids, or
- treatment of postpartum uterine hemorrhage

Please refer to Highmark Delaware Medical Policy **S-114** for more information.

Frequency limitations revised for transforaminal epidural injections

Effective July 1, 2013, Highmark Delaware revised the frequency limitations for transforaminal epidural injections.

- A maximum of two diagnostic transforaminal epidural injection treatment sessions may be covered at a minimum interval of one week. Blockade in cancer pain treatment may be more frequent.
- In the treatment phase, transforaminal epidural injections in the same spinal level or in different regions of the spine are typically administered no more frequently than once every two (2) months or greater providing there is a 50% pain relief for six (6) weeks and limited to four (4) times per year at the same injection site.

Please refer to Highmark Delaware Medical Policy **S-189** for more information.

Guidelines for radiation therapy following breast conserving surgery

Highmark Delaware has created a new policy with guidelines for Radiation Therapy Following Breast Conserving Surgery. Highmark Delaware Medical Policy R-23 will be published and effective on October 28, 2013.

The following criteria apply:

Whole breast irradiation is covered following breast conserving surgery.

Accelerated partial breast irradiation is covered when all the following indications are met:

- Patient must be at least 50 years old; and
- BRCA 1 or BRCA 2 mutation must not be present; and
- Tumor must be 3cm or less; and
- Pathologically Stage 0,1 or 2; and
- Patient has negative surgical margins of at least 2mm; and
- Node negative confirmed by Sentinel node biopsy or Axillary Lymph Node dissection or pN0 (i-, i+); and
- Patient has not undergone neoadjuvant therapy; and
- The patient has limited or focal lymph-vascular space invasion (LVSI); and
- Tumor must not be multicentric

Electronic brachytherapy for the treatment of breast cancer is considered experimental/investigational.

Non-invasive brachytherapy (eg, AccuBoost®) for the treatment of breast cancer is considered experimental/investigational.

Intra-operative accelerated partial breast irradiation is considered experimental/investigational.

For additional information, please refer to Highmark Delaware Medical Policy **R-23**.

Further defined criteria for ibandronate sodium (Boniva) injection

Effective October 28, 2013, Highmark Delaware has further defined the criteria for ibandronate sodium (Boniva) injection.

Ibandronate Sodium is being used to prevent fractures in men and postmenopausal women with a low bone mass (T-score between -1 and -2.5) AND a history of a previous osteoporotic fracture;

AND

1. The member has had an adequate trial and failure of at least one oral bisphosphonate. Trial and failure will be defined as a decrease in Bone Mineral Density (BMD) despite at least 12 months of oral bisphosphonate therapy; or
2. The member has a contraindication to at least one oral bisphosphonate. Contraindications to oral bisphosphonate therapy include hypocalcemia, esophageal ulcerations, esophageal stricture, Barrett's esophagitis, active ulcers, and an inability to stand or sit upright for 30 minutes.

Ibandronate Sodium is being used to prevent fractures in men and postmenopausal women who are found to have a ten-year risk of major osteoporotic fracture greater than or equal to 20% or a risk of hip fracture greater than or equal 3% using the FRAX calculator; AND

1. The member has had an adequate trial and failure of at least one oral bisphosphonate. Trial and failure will be defined as a decrease in BMD despite at least 12 months of oral bisphosphonate therapy; or
2. The member has a contraindication to at least one oral bisphosphonate. Contraindications to oral bisphosphonate therapy include hypocalcemia, esophageal ulcerations, esophageal stricture, Barrett's esophagitis, active ulcers, and an inability to stand or sit upright for 30 minutes.

NOTE: Dosage recommendations per the FDA label.

Please reference Highmark Delaware Medical Policy **I-95** for further information.

Minimally invasive lumbar decompression and iO-Flex® procedures are considered experimental/investigational

Effective October 28, 2013, Highmark Delaware will consider minimally invasive lumbar decompress (MILD) and iO-Flex experimental/investigation. There is lack of evidence in medical literature and scientific conclusions regarding their role. A participating, preferred, or network provider can bill the member for the denied service.

For more information, refer to Highmark Delaware Medical Policy **S-229**.

Conservative management for lumbar spine fusion surgery redefined

Effective July 22, 2013, Highmark Delaware has redefined the definition for conservative management for lumbar spine fusion surgery. Conservative management for lumbar spine fusion surgery has been revised as follows.

Conservative management typically includes any or all of the following:

- Use of prescription strength analgesics (including anti-inflammatory medications if not contraindicated),
- Participation in physical therapy (including active exercise),
- Bracing (especially in scoliosis, adjacent segment instability, and spondylolistheses, Wiltse types),
- Evaluation and appropriate management of associated cognitive, behavioral or addiction issues when present.

Please refer to Highmark Delaware Medical Policy **S-230** for more information on lumbar spine fusion surgery.

Coverage for JETREA

Highmark Delaware considers JETREA medically necessary for treatment of an eye* with symptomatic vitreomacular adhesion (VMA) when ALL of the following criteria are met:

1. Individual's age is equal to or greater than 18 years; and

2. Optical coherence tomography (OCT) demonstrates ALL of the following:
    a. there is vitreous adhesion within 6-mm of the fovea (center of macula); and
    b. there is elevation of the posterior vitreous cortex (outer layer of the vitreous).
3. Individual has best-corrected visual acuity of 20/25 or less in the eye to be treated with ocriplasmin; and
4. Individual does not have ANY of the following:
    a. proliferative diabetic retinopathy;
    b. neovascular age-related macular degeneration;
    c. retinal vascular occlusion;
    d. aphakia;
    e. high myopia (more than -8diopters);
    f. uncontrolled glaucoma;
    g. macular hole greater than 400 µm in diameter;
    h. vitreous opacification;
    i. lenticular or zonular instability;
    j. history of retinal detachment in either eye;
    k. prior vitrectomy in the affected eye;
    l. prior laser photocoagulation of the macula in the affected eye;
    m. prior treatment with ocular surgery, intravitreal injection or retinal laser photocoagulation in the previous 3 months.

***NOTE:** For treatment of bilateral VMA, a waiting period of at least 7 days is recommended before treatment of the contralateral eye.

Repeat intravitreal injection of ocriplasmin in the affected eye is considered experimental/investigational and not medically necessary.

NOTE: Dosage recommendations per the FDA label.

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

Please refer to Highmark Delaware Medical Policy **I-96** for more information.

Coverage criteria revised for Golimumab (Simponi®)

Effective October 28, 2013, Highmark Delaware will revise the medical necessity coverage criteria for Golimumab (Simponi®) for treatment of adults 18 years and older with moderately to severely active rheumatoid arthritis, active psoriatic arthritis and active ankylosing spondylitis as follows:

Golimumab (Simponi) may be considered medically necessary for the treatment of adults, 18 years of age or older, when ALL of the following are met.

ANY ONE of the following:

- moderately to severely active rheumatoid arthritis in adults, in combination with methotrexate; or
- active psoriatic arthritis in adults, alone or in combination with methotrexate; or
- active ankylosing spondylitis in adults.

AND

- The member has had an adequate trial or experienced intolerance to both preferred biologic products of Humira® and Enbrel®.

Golimumab (Simponi) may be considered medically necessary for the treatment of ulcerative colitis in adults, 18 years of age or older, when ANY ONE of the following are met:

- who have not responded to treatment with at least two immunosuppressants such as corticosteroids, azathioprine or 6-mercaptopurine; or
- patients who require continuous steroid therapy AND have trialed or experienced intolerance to the preferred biologic product, Humira.

The use of golimumab for all other indications is considered experimental/investigational, and therefore, non-covered. Peer reviewed literature does not support the use of golimumab for any indications other than those listed on this medical policy. A participating preferred, or network provider can bill the member for the non-covered service.

Coverage for golimumab is determined according to individual or group customer benefits.

Please refer to Highmark Delaware Medical Policy **I-35** for more information.

Multiple sleep latency testing considered medically necessary

Highmark Delaware is updating its coverage criteria for multiple sleep latency testing. The new guidelines will become effective October 28, 2013.

Multiple sleep latency testing (MSLT)
Multiple sleep latency testing (MSLT) may be considered medically necessary in children and adolescents younger than 18 years of age for the evaluation of ANY ONE of the following after obstructive sleep apnea (OSA) has been ruled out by polysomnography:

- Narcolepsy; or
- Suspected idiopathic hypersomnia.

MSLT is not medically necessary in children and adolescents younger than 18 years of age unless performed for ANY ONE of the following:

- The first test was invalid or uninterpretable; or
- The response to treatment needs to be determined; or
- The member is suspected of having more than one sleep disorder (eg, diagnosis of OSA and member continues to have excessive daytime sleepiness despite treatment); or
- The most recent prior MSLT test was conducted two (2) or more years ago.

MSLT is not medically necessary in children and adolescents younger than 18 years of age in ANY ONE of the following:

- When performed for routine diagnosis of OSA; or
- For routine follow-up after treatment of sleep related disorder; or
- Portable MSLT performed in the home setting.

See Highmark Delaware Medical Policy Bulletin **Z-8** for guidelines on sleep disorder services for adults.

Please refer to Highmark Delaware Medical Policy **Z-64** for more information.

Hemophilia clotting factors criteria revised

Effective October 28, 2013, Highmark Delaware will revise the medical necessity criteria for Hemophilia Clotting Factors as follows:

Blood clotting factors

A yearly consultation with a Hemophilia Treatment Center or Hematologist is strongly recommended for any patient receiving blood clotting factors.

Clotting factors includes the following products:

- antihemophilic factor/von Willebrand factor complex (Humate-P® J7187)(Alphanate J7186)
- Factor VIII (J7185, J7190, J7191, J7192)
- Factor VIII Concentrate (Corifact®)(J7180)
- von Willebrand factor/coagulation factor VIII complex (Wilate®)(J7183)
- anti-inhibitor coagulant complex vapor heated (Feiba® VH)(J7198)
- Factor VIIa (NovoSeven RT®)(J7189)
- Factor IX (J7193, J7194, J7195)

Episodic/prophylactic treatment

Episodic therapy is medically necessary in adults and children when ALL of the following criteria are met:

- Diagnosis of hemophilia A, hemophilia B, or von Willebrand's disease; and
- Member is hemorrhaging or physical trauma such as surgery is anticipated (secondary short-term prophylaxis); and
- Dosing is required until bleeding stops or up to 14 days after surgery.

Prophylactic therapy (continuous or long-term) is medically necessary to prevent hemorrhagic complications in adults and children with hemophilia A, hemophilia B or von Willebrand's disease when ANY ONE of the following criteria is met:

- Primary prophylactic therapy – Member has severe hemophilia A or hemophilia B (less than 1% of normal factor (less than 0.01 IU/ml)); or
- Secondary prophylactic therapy – Member has hemophilia A or hemophilia B (regardless of normal factor levels) and has documented history of two (2) or more episodes of spontaneous bleeding into joints.

It is strongly recommended that individuals on prophylaxis have regular follow-up visits with a hematologist or Hemophilia Treatment Center to evaluate joint status, to document any complications, and to record any bleeding episodes that occur during prophylaxis.

Recombinant factor VIIa (rFVIIa) is medically necessary when ANY ONE of the following criteria is met:

- Treatment of bleeding episodes in congenital Factor VII deficiency; or
- Treatment of bleeding episodes in hemophilia A or B patients with inhibitors to ANY ONE of the following:
    - Factor VIII; or
    - Factor IX; or
    - Other acquired hemophilia.

OR

- Prevention of bleeding in surgical interventions or invasive procedures in congenital Factor VII deficiency; or
- Prevention of bleeding in surgical or invasive procedures in hemophilia A or B patients with inhibitors to ANY ONE of the following:
    - Factor VIII; or
    - Factor IX; or
    - Other acquired hemophilia.

Factor eight inhibitor bypassing activity (FEIBA) anti-inhibitor coagulant complex is medically necessary when ANY ONE of the following criteria is met:

- Treatment of spontaneous bleeding episodes in members with an inhibitor; or
- Use during surgery in persons with hemophilia A and hemophilia B with inhibitors; or
- In non-hemophiliac persons with acquired inhibitors to factor VIII, XI, and XII.

Immune tolerance induction

High-dose immune tolerance induction is medically necessary when ALL of the following criteria are met:

- Member has a diagnosis of hemophilia A or hemophilia B; and
- Member has inhibitors (anti-factor VIII:c or IX:c antibodies); and
- Anti-hemophilic factor or factor IX survival and recovery of anti-hemophilic factor levels after infusion are abnormal; and
- Attempts to lower antibody levels with either immunosuppressant or corticosteroids have been unsuccessful; and
- Dosing continues beyond 14 days.

Limits applicable to immune tolerance induction:

- Continued immune tolerance induction is no longer considered medically necessary when ALL of the following criteria are met:
    - Anti-hemophilic factor or factor IX survival after infusion is normal (6-hr level at least 46 % of 10-min level); and
    - Inhibitor levels become undetectable; and
    - Recovery of anti-hemophilic factor or factor IX levels after infusion are normal (defined as at least 85 % of the expected for individuals without inhibitors);
- Cases in which members are on immune tolerance induction for six (6) months or more may be referred for review of medical necessity to determine whether continued immune tolerance therapy is medically necessary.

Services that do not meet the criteria of this policy will not be considered medically necessary. A Delaware participating, preferred or network provider cannot bill the member for the denied service unless: (a) the provider has given advance written notice, informing the member that the service may be deemed not medically necessary; (b) the member is provided with an estimate of the cost; and (c) the member agrees in writing to assume financial responsibility in advance of receiving the service. The signed agreement must be maintained in the provider's records. Out of Network/Non-participating providers and providers located outside of Delaware may be able to bill members if the service is denied.

Procedure codes J7180, J7183, J7185, J7186, J7187, J7189, J7190, J7191, J7192, J7193, J7194, J7195, and J7198 are managed by the Medical Injectable Drug Program.

Please refer to Highmark Delaware Medical Policy **I-4** for more information on Hemophilia Clotting Factors.

Coverage criteria revised for sleep disorder service

Highmark Delaware is updating its coverage criteria for sleep disorder. The new guidelines will become effective on October 28, 2013.

As of October 28, 2013, the following criteria will be eligible for sleep disorder.

Unattended home sleep studies may be considered medically necessary when ALL of the following are met:

ANY ONE of the following:

- Sleep monitoring using a Type II device; or
- Sleep monitoring using a Type III device; or
- Sleep monitoring using a Type IV(A) device, measuring airflow and at least 2 other channels and providing measurement of apnea-hypopnea index (AHI); or
- Sleep monitoring using a device that measures 3 or more channels that include pulse oximetry, actigraphy, and peripheral arterial tone (eg, Watch-PAT device)

AND

ANY ONE of the following:

- Confirmation of diagnosis of obstructive sleep apnea (OSA) when suspected on clinical grounds associated with high pretest probability and at least 2 of the following signs or symptoms are present:
    - disruptive snoring when other evidence of sleep-disordered breathing is present (eg, rapid, shallow breathing);
    - disturbed or restless sleep;
    - non-restorative sleep;
    - excessive daytime sleepiness (EDS) as evidenced by an Epworth Sleepiness Scale > 10 (ESS);
    - witnessed apnea events during sleep;
    - choking during sleep;
    - gasping during sleep;
    - BMI > 35;
    - frequent unexplained arousals from sleep;
    - restless legs syndrome; or
- Positive airway pressure (CPAP or BiPAP) titration in patients with sleep related breathing disorders with the following proven option for titration:
    - auto-titrating continuous positive airway pressure (APAP) devices when used in the self-adjusting mode for unattended treatment or in an unattended way to determine a fixed CPAP treatment pressure for patients with moderate to severe obstructive sleep apnea without significant comorbidities (eg, CHF, COPD, central sleep apnea syndromes, or hypoventilation syndromes); or
- Evaluation for the presence of obstructive sleep apnea in patients before they undergo upper airway surgery for snoring or obstructive sleep apnea; or

- Assessment of treatment results to evaluate response to oral appliance treatment, surgical treatment for OSA, or resolution of OSA after significant weight loss such as that associated with bariatric surgery; or
- Assessment of patients with heart failure if they have nocturnal symptoms suggestive of sleep related breathing disorders (eg, disturbed sleep, nocturnal dyspnea, snoring) or if they remain symptomatic despite optimal medical management of congestive heart failure.

Unattended home sleep studies are considered not medically necessary for ANY ONE of the following:

- Devices that do not meet the minimum requirement (heart rate, oxygen saturation, and respiratory analysis); or
- Suspicion of complex sleep disorders (eg, narcolepsy, circadian rhythm disorder, parasomnias, periodic limb movement disorder, restless leg syndrome); or
- Co-morbid conditions that could impact the accuracy of the study (eg, moderate to severe pulmonary disease, neuromuscular disease, congestive heart failure, chronic lung disease, circadian rhythm disorders, and depression with or without insomnia, insomnia associated with psychiatric disorders, seizures in the absence of symptoms of sleep disorder, transient or chronic insomnia).
- Positive airway pressure (CPAP or BiPAP) evaluation in patients whose symptoms continue to resolve with CPAP or BiPAP treatment.

Facility/Laboratory sleep studies

Attended polysomnogram/sleep studies performed in a healthcare facility may be considered medically necessary when ALL of the following are met:

- Sleep monitoring using a Type I device

AND

ANY ONE of the following:

- Previous home study was technically inadequate; or
- Confirmation of diagnosis of obstructive sleep apnea (OSA) when suspected on clinical grounds associated with high pretest probability and at least two of the following signs or symptoms are present:
    - disruptive snoring when other evidence of sleep-disordered breathing is present (eg., rapid, shallow breathing);
    - disturbed or restless sleep;
    - non-restorative sleep;
    - excessive daytime sleepiness (EDS) as evidenced by an Epworth Sleepiness Scale > 10 (ESS);
    - witnessed apnea events during sleep;
    - choking during sleep;
    - gasping during sleep;
    - BMI > 35;
    - frequent unexplained arousals from sleep;
    - restless legs syndrome; or
- Positive airway pressure (CPAP or BiPAP) titration in patients with sleep related breathing disorders with the following proven option for titration:
    - full night study in a laboratory based facility; or

- Evaluation for the presence of obstructive sleep apnea in patients before they undergo upper airway surgery for snoring or obstructive sleep apnea; or
- Assessment of treatment results to evaluate response to oral appliance treatment, surgical treatment for OSA, or resolution of OSA after significant weight loss such as that associated with bariatric surgery; or
- Assessment of patients with heart failure if they have nocturnal symptoms suggestive of sleep related breathing disorders (eg, disturbed sleep, nocturnal dyspnea, snoring) or if they remain symptomatic despite optimal medical management of congestive heart failure.

Multiple sleep latency test (MSLT)

Multiple sleep latency testing (MSLT) may be considered medically necessary for the evaluation of ANY ONE of the following after OSA has been ruled out by polysomnography:

- Narcolepsy; or
- Suspected idiopathic hypersomnia

MSLT is not medically necessary unless performed for ANY ONE of the following:

- The first test was invalid or uninterpretable; or
- The response to treatment needs to be determined; or
- The member is suspected of having more than one sleep disorder (eg, diagnosis of OSA and member continues to have excessive daytime sleepiness despite treatment); or
- The most recent prior MSLT test was conducted 2 or more years ago.

MSLT is not medically necessary for ANY ONE of the following:

- When performed for routine diagnosis of obstructive sleep apnea; or
- For routine follow-up after treatment of sleep related disorder; or
- Portable MSLT performed in the home setting.

See Highmark Delaware Medical Policy E-50 for guidelines on continuous positive airway pressure (CPAP) devices used in the treatment of obstructive sleep apnea in children.

Please refer to Highmark Delaware Medical Policy **Z-8** for more information.

Additional criteria for repeat or revised bariatric surgical procedures

Effective October 28, 2013, Highmark Delaware will consider surgical repair following gastric bypass and gastric restrictive procedure medically necessary when there is documentation of a surgical complication related to the original surgery, such as a fistula, obstruction, erosion, disruption/leakage of a suture/staple line, bad herniation, or pouch enlargement due to vomiting.

Repeat surgical procedures for revision or conversion to another surgical procedure (that is also considered medically necessary within this document) for inadequate weight loss (unrelated to a surgical complication of a prior procedure) are considered medically necessary when ALL the following criteria are met:

- The individual continues to meet all the medical necessity criteria for bariatric surgery; and
- There is documentation of compliance with the previously prescribed post-operative dietary, and exercise program; and
- Two (2) years following the original surgery, weight loss is less than 50% of pre-operative excess body weight and weight remains at least 30% over ideal body weight (taken from standard tables for adult

weight ranges based on height, body frame, gender and age; an example is available from the National Heart Lung and Blood Institute [NHLBI] at: http://www.nhlbi.nih.gov/guidelines/obesity/bmi_tbl.htm).

Repeat procedures for repair, revision, or conversion to another surgical procedure following a gastric bypass or gastric restrictive procedure are considered experimental/investigational and not medically necessary when the criteria listed above are not met.

Revision of a sleeve gastrectomy is medically necessary for the following:

- Intractable gastroesophageal reflux disease (GERD) or reflux may require revision of a sleeve into a gastric bypass, by dividing the sleeve proximally, then constructing a Roux limb, then a gastrojejunostomy.
- Persistent narrowing or stricture at a portion of the sleeve may make resection of that segment necessary or revision into a gastric bypass.
- A chronic leak may mandate resection or revision.
- Inadequate weight loss, or weight regain due to dilation of the sleeve.
- Revision to a gastric bypass or to a duodenal switch for inadequate weight loss.

Please refer to Highmark Delaware Medical Policy **G-24** for more information.

Handling and/or conveyance of specimen for transfer from the patient considered overhead expenses

Effective October 28, 2013, Highmark Delaware will consider the following procedure code (99001) as provider overhead expenses.

99001–Handling and/or conveyance of specimen for transfer from the patient in other than an office to a laboratory (distance may be indicated)

Please refer to Highmark Delaware Medical Policy **Z-39** for additional information.