SPECIAL BULLETIN

FOR PROFESSIONAL PROVIDERS **OCT. 27, 2014**

MEDICAL POLICY UPDATES AND NEWS

OCTOBER 2014

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 new or updated medical and behavioral health policies for our professional providers, 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, accessible through NaviNet® or under "Helpful Links" 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

Cardiac catheterization changes

Beginning Jan. 1, 2015, some procedures that were previously considered an inherent part of a cardiac catheterization will now be eligible for separate payment.

Some examples are:

- Catheter placements (codes 36215, 36216, 36217, and 36218); and
- Injection procedures (code 36005).

Also, additional procedures will be considered a part of a cardiac catheterization and separate payment will no longer be eligible. Some examples of those procedures are codes 93561, 93562, 93563, 93564, and 93565. These changes are based on code terminology and Medicare correct coding initiative edits.

Arriving in 2015: A new medical policy publication

NEWS FOR ALL PROVIDER TYPES

We know that you're busy, and we want to make staying informed easy for you. So, we are streamlining the way you receive updates and information about Highmark's medical policies.

In January 2015, you will see the very first issue of ***Medical Policy Update***, our new publication for all things medical policy.

HIGHMARK. Delaware

What you need to know about *Medical Policy Update*

- Replaces the Special Bulletins you have received bi-monthly since 2012, but archived bulletins will remain online
- Will be an online publication, accessible on the Provider Resource Center
- Has a clean, updated look and will use the icons you're used to seeing in *Provider News*
- There will be 12 issues instead of six – which will cut down on the time you have to spend reading

You will soon receive a **one-time*** postcard that lists the online publication dates for 2015. We ask that you post it in your office as a friendly reminder.

Keep your eyes open for the new medical policy publication, ***Medical Policy Update***.

*In an effort to be more environmentally friendly and to streamline operations, we will no longer send you regular paper notifications regarding updated medical policies. In late 2015, we will send you a postcard with 2016 ***Medical Policy Update*** *e* publication dates.

REVIEW

Correction to June 2014 Medical Policy Updates: Post-cryptogenic cardiac monitoring considered experimental/investigational

This policy will not be revised at this time and currently remains under review.

Starting Sept. 1, 2014, Highmark Delaware will consider long term implantable cardiac loop monitoring in members with suspected atrial fibrillation post cryptogenic stroke experimental/investigational. Although continuous cardiac monitoring post cryptogenic stroke does look promising, further studies are required to determine patient selection, optimal timing, methods, and duration of monitoring for detection of atrial fibrillation and paroxysmal atrial fibrillation. Other concerns are long-term efficacy and the development of clinical guidelines.

Please refer to Medical Policy **M-50** for more information.

Correction Aug. 2014 Medical Policy Updates: Subcutaneous implantable cardioverter-defibrillator coverage defined

Effective Jan. 1, 2015, Highmark Delaware will consider subcutaneous implantable cardioverter-defibrillator's (S-ICD) experimental/investigational.

While current literature reports the S-ICD is promising for those individuals that cannot receive an implantable cardioverter-defibrillator (ICD) or those individuals waiting for an ICD, the data is not conclusive regarding long-term efficacy. There are no clinical guidelines established as to what patient population the S-ICD would benefit nor has there been any testing or clinical trials comparing the S-ICD to the traditional ICD.

Please refer to Medical Policy **S-59** for more information.

Correction Aug. 2014 Medical Policy Updates: Immune prophylaxis for respiratory syncytial virus (RSV) revised

Effective Oct. 13, 2014, Highmark Delaware coverage criteria for Synagis® (palivizumab) has been updated to reflect the American Academy of Pediatric 2014 guidelines as follows:

Immune prophylaxis with palivizumab (Synagis®)(90378) is eligible for coverage in accordance with the American Academy of Pediatrics guidelines.

Palivizumab, a humanized mouse monoclonal antibody, is licensed for passive immunoprophylaxis against respiratory syncytial virus (RSV) for the following:

- Infants with preterm birth less than 29 weeks 0 days gestation ≤ 12 months of age at the start of the RSV season;
- Certain infants ≤12 months of age, born at less than 32 weeks 0 days with chronic lung disease (CLD) (>21% oxygen requirement for at least the first 28 days after birth);
- Certain infants ≤12 months of age with hemodynamically significant congenital heart disease;
- Certain other instances specifically listed below.

Note: Dosage recommendations for the drugs addressed in this policy are per the FDA label.

RSV seasonality

Because 5 monthly doses of palivizumab at 15 mg/kg per dose will provide more than 6 months (>24 weeks) of serum palivizumab concentrations above the desired level for most children, administration of more than 5 monthly doses is not recommended within the continental United States. For qualifying infants who require 5 doses, a dose beginning in November and continuation for a total of 5 monthly doses will provide protection for most infants through April and is recommended for most areas of the United States. If prophylaxis is initiated in October, the fifth and final dose should be administered in February, which will provide protection for most infants through March. If prophylaxis is initiated in December, the fifth and final dose should be administered in April, which will provide protection for most infants through May.

RSV season varies in different regions of Florida and may affect the timing of palivizumab administration. When determining the appropriate timing for administration of the first dose of palivizumab for qualifying infants, data from the Florida Department of health should be utilized. Despite varying onset and offset dates of the RSV season in different regions of Florida, a maximum of 5 monthly doses of palivizumab should be adequate for qualifying infants for most RSV seasons in Florida.

Eligibility criteria for prophylaxis of high-risk infants and young children

Note: A maximum of five (5) doses of palivizumab within the RSV season which begins during the first year of life for infants with any of the following clinical presentations:

- Infants born before 29 weeks, 0 days of gestation or earlier may benefit from prophylaxis during the RSV season, whenever that occurs during the first 12 months of life.
- Infants and children ≤12 months of age born at gestational age less than 32 weeks 0 days with chronic lung disease (CLD) of prematurity defined as a supplemental oxygen need >21% for the first 28 days after birth.
- Infants and children with hemodynamically significant congenital heart disease.
- Children younger than 12 months of age with congenital heart disease who are most likely to benefit from immunoprophylaxis include:
    - Infants who are receiving medication to control congestive heart failure and will require cardiac surgical procedures
    - Infants with moderate to severe pulmonary hypertension

- Infants with cyanotic heart disease

  Note: Prophylaxis is not recommended in the second year of life on the basis of a history of prematurity alone. Prophylaxis may be considered during the RSV season during the second year of life only for infants who meet the definition of chronic lung disease prematurity and continue to require medical support (chronic corticosteroid therapy, diuretic therapy or supplemental oxygen).

- Infants with congenital abnormalities of the airway or neuromuscular disease - Immunoprophylaxis may be considered for prophylaxis in the first year of life for infants born with congenital abnormalities of the airway or a neuromuscular condition that compromises handling of respiratory secretions.
- Immunocompromised children - A maximum of 5 doses may be medically necessary for children younger than 24 months of age with any of the following clinical presentations during the RSV season:
  - Profoundly immunocompromised (defined as lymphopenia less than 100cells/mm3), or
  - Undergoing cardiac transplantation
  - An additional dose of palivizumab may be considered medically necessary for children in approved course of treatment who undergo cardiopulmonary bypass for surgical procedures if cardiac or pulmonary hemodynamic support remains unchanged after surgery or if any other medically necessary criteria are present (for example, prematurity).
- Patients with cystic fibrosis - Limited studies suggest that some patients with cystic fibrosis may be at increased risk of RSV infection. Whether RSV infection exacerbates the chronic lung disease of cystic fibrosis is not known. In addition, insufficient data exist to determine the effectiveness of palivizumab use in this patient population. Therefore, a recommendation for routine prophylaxis in patients with cystic fibrosis cannot be made. The routine use of palivizumab prophylaxis in patients with cystic fibrosis, including neonates diagnosed with newborn screening is not recommended unless other medical conditions are present.

An infant with cystic fibrosis with clinical evidence of CLD or nutritional compromise in the first year of life may be considered for prophylaxis. The continued use of palivizumab prophylaxis in the second year of life may be considered for infants with symptoms of severe lung disease; e.g., (previous hospitalization for pulmonary exacerbation in the first year of life or an abnormal chest radiograph, computed tomography scan that persist when stable). Or weight or length less than the 10th percentile.

- Other considerations - Hospitalized infants who qualify for prophylaxis during the RSV season should receive the first dose of palivizumab 48 to 72 hours before discharge or promptly after discharge. If an infant or child who is receiving palivizumab immunoprophylaxis experiences a breakthrough RSV infection, monthly prophylaxis should be discontinued because of the extremely low likelihood of a second RSV hospitalization in the same season.
- Children with Down syndrome - Limited data suggest a slight increase in RSV hospitalization rates among children with Down syndrome. However, data are insufficient to justify a recommendation for routine use of prophylaxis in children with Down syndrome unless qualifying heart disease, CLD, airway clearance issues, or prematurity (<29 weeks, 0 days' gestation).
- Recommendations for timing of prophylaxis for Alaska native and American Indian infants - On the basis of the epidemiology of RSV in Alaska, particularly in remote regions where the burden of RSV disease is significantly greater than the general US population, the selection of Alaska Native infants eligible for prophylaxis may differ from the remainder of the United States. Clinicians may wish to use RSV surveillance data generated by the state of Alaska to assist in determining onset and end of the RSV season for qualifying infants. Limited information is available concerning the burden of RSV disease among American Indian populations. However, special consideration may be prudent for Navajo and White Mountain Apache infants in the first year.

- The following groups of infants are not at increased risk of RSV and considered not medically necessary to receive immunoprophylaxis:
    - Infants and children with hemodynamically insignificant heart disease (e.g., secundum atrial septal defect, small ventricular septal defect, pulmonic stenosis, uncomplicated aortic stenosis, mild coarctation of the aorta, and patent ductus arteriosus).
    - Infants with lesions adequately corrected by surgery, unless they continue to require medication for congestive heart failure.
    - Infants with mild cardiomyopathy who are not receiving medical therapy for the condition.
    - Children in second year of life who do not otherwise meet criteria above.
    - Primary asthma or asthma prevention to reduce subsequent episodes of wheezing.
    - Continued RSV prophylaxis children who experience breakthrough RSV hospitalization.
    - For treatment in children or infants with known RSV disease.
    - For all other indications not otherwise addressed as medically necessary, including, but not limited to, individuals with cystic fibrosis or Down syndrome who do not otherwise meet criteria above.

If palivizumab is used for any other indication, it is considered experimental/investigational; and therefore, it is not covered. A participating preferred or network provider may bill the member for the denied palivizumab.

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

Synagis® is available in both a 50 mg and a 100 mg vial. Therefore, procedure code 90378-Respiratory syncytial virus immune globulin (RSV-IgIM) for intramuscular immunizations should be reported per 50 mg.

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

Correction to Aug. 2014 Medical Policy Updates: Hepatorenal syndrome added to indications for liver transplantation—also substance abuse criteria changed

Effective Oct. 27, 2014, Highmark Delaware will add indications for hepatorenal syndrome for liver transplantation. Hepatorenal syndrome may be considered medically necessary for the following:

- Glomerular filtration rate (GFR) < 40ml/min, and
- All other causes for renal failure have been excluded.

Chronic alcoholic liver disease

The following recommendations should be taken into consideration for those individuals diagnosed with “Chronic” alcoholic liver disease and are, most likely, on a liver transplant waiting list before a liver transplant is considered:

- Abstinence of substance abuse for a minimum of six (6) months; and
- Participation in a substance abuse/rehabilitation program, either through the facility transplant program or at a substance abuse clinic; and
- Consistent negative results of random blood or urine drug testing.

Acute alcoholic liver disease

In acute alcoholic liver disease, there will be some patients who will not respond to or will continue to deteriorate despite medical therapy. In these cases, immediate intervention is expected to stabilize the patient, even if that intervention is immediate liver transplantation. It is also expected, that alcohol consumption will be addressed in the post liver transplant care when appropriate.

Please refer to Medical Policy **S-121** for more information.

Correction to Aug. 2014 Medical Policy Updates: Clinical criteria established for Mohs Micrographic Surgery

This policy will not be revised at this time and currently remains under review.

Effective Oct. 27, 2014, Highmark Blue Cross Blue Shield (Highmark Blue Shield) will establish clinical criteria for Mohs Micrographic Surgery (MMS). MMS may be considered medically necessary for the following:

- Primary or recurrent basal cell carcinomas, squamous cell carcinomas, or basalosquamous cell carcinomas in anatomic locations where they are prone to recur:
    - Adenocystic carcinoma of the skin
    - Adenoid type of squamous cell carcinoma
    - Angiosarcoma of the skin
    - Apocrine carcinoma of the skin
    - Atypical fibroxanthoma
    - Bowen's disease (squamous cell carcinoma in situ)
    - Bowenoid papulosis
    - Dermatofibrosarcoma protuberans
    - Erythroplasia of Queryrat
    - Extramammary Paget's disease
    - Keratoacanthoma
    - Leiomyosarcoma or other spindle cell neoplasms of the skin
    - Malignant fibrous histiocytoma
    - Merkel cell carcinoma
    - Microcystic adnexal carcinoma
    - Oral and central facial, paranasal sinus neoplasm
    - Sebaceous gland carcinoma
    - Squamous cell carcinoma, rapid growth
    - Verrucous carcinoma
    - Laryngeal carcinomas

- Aggressive pathology in the following areas:
    - Hands and feet
    - Genitalia
    - Nail unit/periungual
    - Large size (2.0 cm or greater)
    - Positive margins on recent excision
    - Poorly defined borders
    - In the very young (<40 yr. age)
    - Radiation-induced
    - In patients with proven difficulty with skin cancers or who are immunocompromised
    - Basal cell nevus syndrome
    - In an old scar (e.g., a Marjolin's ulcer)
    - Associated with xeroderma pigmentosum
    - Perineural invasion on biopsy or recent resection
    - Deeply infiltrating lesion or difficulty estimating depth of lesion

Mohs micrographic surgery is considered not medically necessary for all other indications because its effectiveness for indications other than those listed above has not been established.

Please refer to Medical Policy **S-46** for more information.

Correction to Aug. 2014 Medical Policy Updates: Medical Policy effective dates revised

The effective dates will be revised for the following medical policies. The policy revisions were announced in the Aug. 2014 **Medical Policy Updates**.

Policy #	Policy Topic	Effective Date
S-31	Arthrocentesis or Needling of a Bursa or Trigger Point Injections	01/01/2015
S-147	Breast Ductal Lavage and Fiberoptic Ductoscopy	01/01/2015

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
G-26*	Electroconvulsive Therapy	Inpatient/Outpatient	11/17/2014
I-40*	Pertuzumab for Treatment of Malignancies	Outpatient	01/01/2015
I-41*	Carfilzomib (Kyprolis®)	Outpatient	01/01/2015
I-112*	Ziv-aflibercept (Zaltrap®)	Outpatient	01/01/2015
I-113*	113 Ado-trastuzumab emtansine (Kadcyla®)	Outpatient	01/01/2015
I-114	Levoleucovorin (Fusilev®)	Outpatient	01/01/2015
I-116*	Ofatumumab (Arzerra®)	Outpatient	01/01/2015
I-117*	Panitumumab (Vectibix®)	Outpatient	01/01/2015
L-84*	Laboratory Testing for Novel Influenza A (H1N1)	Outpatient	01/01/2015
S-31*	Arthrocentesis or Needling of Bursa and Trigger Point Injections	Outpatient	01/01/2015

Policy #	Policy Topic	Place of Service	Effective Date
S-121	Liver Transplantation	Inpatient	10/27/2014
S-147*	Breast Ductal Lavage and Fiberoptic Ductoscopy	Outpatient	01/01/2015
S-178*	Treatment of Hyperhidrosis	Inpatient/Outpatient (Revised)	01/01/2015
U-5*	Assisted Fertilization	Outpatient	01/01/2015
X-71*	Functional Magnetic Resonance Imaging-(fMRI)	Outpatient	01/01/2015
Z-4*	Transcranial Magnetic Stimulation (TMS)	Outpatient	09/22/2014

* 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.

Changes in criteria for ustekinumab (Stelara®)

Effective Jan. 1, 2015, Highmark Delaware will update the indications and criteria for ustekinumab (Stelara®) as follows:

Ustekinumab (Stelara®) a human interleukin -12 and -23 antagonist, may be considered medically necessary in adult patients (18 years or older) for the following indications and criteria:

1. For the treatment of moderate to severe plaque psoriasis with the following criteria:
    - The member has previously received systemic therapy (e.g., methotrexate, cyclosporine) or phototherapy (e.g., PUVA, UVB).
2. For the treatment of active psoriatic arthritis alone or in combination with methotrexate with the following criteria:
    - The member has failed to respond to, is intolerant of, or has a medical contraindication to one or more non-biologic disease-modifying antirheumatic drugs (DMARDs).

The use of ustekinumab for any other indication is considered experimental/investigational, and therefore, not covered because its effectiveness for these indications has not been established. A participating, preferred, or network provider can bill the member for the denied service.

NOTE:

- Dosage recommendations per the FDA label.
- The member should be under the supervision of a dermatologist
- Stelara should not be used in conjunction with Enbrel, Remicade, Amevive, Humira, or Kineret.

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

New policy for pertuzumab for treatment of malignancy

Effective Jan. 1, 2015, Highmark Delaware is establishing coverage criteria for pertuzumab for treatment of malignancies.

Metastatic breast cancer

Pertuzumab (Perjeta®) may be considered medically necessary for individuals with breast cancer when ALL of the following conditions are met:

- HER2 protein overexpression, verified by one of the following US Food and Drug Administration (FDA)-approved diagnostic tests:
    - An immunohistochemical (IHC) assay with a result of 3+ (positive);
    - A positive fluorescence in situ hybridization (FISH) test (ratio greater than 2.0);
    - A confirmatory (repeat) FISH/ISH test if the IHC assay has a result of 2+ (borderline);
    - A confirmatory FISH/ISH test or additional cell counting and recalculation of the ratio if the original FISH/ISH test is borderline (ratio of 1.8-2.0).
- HER2 protein overexpressing recurrent or metastatic breast cancer with either of the following conditions:
    - Hormone receptor negative or hormone receptor positive, and endocrine therapy refractory;
    - Symptomatic visceral disease.
- First-line treatment of HER2 protein overexpressing recurrent or metastatic breast cancer in individuals who have not received prior anti-HER2 therapy or chemotherapy for metastatic disease;
- Used in combination with trastuzumab (Herceptin®) and docetaxel (Taxotere®) or paclitaxel (Taxol®, Abraxane®, Onxol®);
- Individuals previously treated with chemotherapy in combination with trastuzumab (Herceptin) in the absence of pertuzumab (Perjeta) may be considered for one line of therapy including both trastuzumab (Herceptin) plus pertuzumab (Perjeta) in combination with or without cytotoxic therapy (e.g., vinorelbine, taxane);

Neoadjuvant treatment of breast cancer

Pertuzumab (Perjeta) may be considered medically necessary for neoadjuvant treatment of locally advanced, inflammatory, or early stage breast cancer for a maximum of 6 cycles when ALL of the following conditions are met:

- HER2 protein overexpression:
    - An immunohistochemical (IHC) assay with a result of 3+ (positive);
    - A positive fluorescence in situ hybridization (FISH) test (ratio greater than 2.0);
    - A confirmatory (repeat) FISH/ISH test if the IHC assay has a result of 2+ (borderline);
    - A confirmatory FISH/ISH test or additional cell counting and recalculation of the ratio if the original FISH/ISH test is borderline (ratio of 1.8-2.0);
- Tumors are greater than 2 centimeter in diameter or node positive;
- Used in combination with trastuzumab (Herceptin) and docetaxel (Taxotere®).

The use of pertuzumab is considered experimental/investigational for all other indications, including but not limited to HER2-positive gastric, colorectal, non-small cell lung, and ovarian cancers; HER2-positive cancers of the gastro-esophageal junction; and HER2-negative cancers. A participating, preferred, or network provider can bill the member for this denied service.

Note: Dosage recommendations per the FDA label.

Please refer to Medical Policy **I-40** for more information.

Coverage criteria established for ado-trastuzumab emtansine (Kadcyla®)

Effective Jan. 1, 2015, Highmark Delaware will provide coverage for ado-trastuzumab emtansine (J9354). The following coverage criteria guidelines per the Federal Drug Administration and the National Comprehensive Cancer Network (NCCN) will be established:

Coverage for Ado-trastuzumab emtansine (Kadcyla) is determined according to individual or group customer benefits.

Human epidermal growth factor receptor 2 (HER-2) protein overexpression must be verified by ANY ONE of the following FDA approved diagnostic tests:

- An immunohistochemical (IHC) assay with a result of 3+ (positive); or
- A positive fluorescence in situ hybridization (FISH) test (ratio greater than 2.2); or
- Single-probe in situ hybridization (ISH) test with average HER2 copy number ≥ 6.0 signals/cell or greater or
- Dual-probe ISH test HER2/CEP17 (chromosome enumeration probe 17) ratio 2.0 or greater; or HER2/CEP17 ratio less than 2.0 AND average HER2 copy number ≥6.0 signals/cell or greater.

Ado-trastuzumab emtansine (Kadcyla), also known as trastuzumab-DM1 or T-DM1 may be considered medically necessary as a single agent therapy for adult individuals with metastatic breast cancer when ALL of the following criteria are met:

- The individual has previously received one prior trastuzumab and/or taxane therapy, separately or in combination; and
    - Has developed disease recurrence during or within six months of completing adjuvant therapy**;** and
- Human epidermal growth factor receptor 2 (HER-2) has been verified; and
- Ado-trastuzumab emtansine (Kadcyla) is used as a single agent.

Note: Dosage recommendations are per the FDA label.

Use of ado-trastuzumab emtansine in combination with other targeted biologic agents or chemotherapy agents is considered experimental/investigational and not medically necessary.

The use of ado-trastuzumab emtansine is experimental/investigational in all other situations, including but not limited to, earlier stages of breast cancer, combination treatment with different agents, and treatment of gastric cancer.

Ado-trastuzumab emtansine (Kadcyla) is considered not medically necessary in the adult individual who does not meet the criteria listed above.

Please refer to Medical Policy **I-113** for more information.

Clinical criteria has been established for carfilzomib (Kyprolis®)

As of Jan. 1, 2015, Highmark Delaware clinical criteria established for carfilzomib (Kyprolis®) will become effective. Carfilzomib (Kyprolis) may be considered medically necessary for treatment of the following cancers as long as the patient has received two (2) prior therapies, including bortezomib and an immunomodulatory agent, and has demonstrated disease progression on or within 60 days of completion of the last therapy.

Multiple Myeloma

- Used in combination with leanlidomide and dexamethasone for transplant candidates with progressive solitary plasmacytoma or smoldering myeloma (asymptomatic) that has progressed to active (symptomatic) myeloma as:
    - Primary chemotherapy, or

    - Therapy on or off clinical trials for disease relapse after 6 months following primary chemotherapy with the same regimen.
- Preferred single-agent therapy on or off clinical trials for patients who have received at least two prior therapies including bortezomib, and an immunomodulatory agent, and have demonstrated disease progression on or within 60 days of completion of the last therapy.

Waldenström's Macroglobulinemia/Lympholasmacytic Lymphoma

- Used as a component of CaRD (carfilzomib, rituximab, and dexamethasone) regimen:
    - As a primary therapy, or
    - For relapse ≥ 12 months if used as a primary therapy.

Note: Dosage recommendations per the FDA label.

Please refer to Medical Policy **I-47** for more information.

Ozurdex® considered medically necessary for diabetic macular edema

Effective Sept. 1, 2014, Highmark Delaware will consider Ozurdex® medical necessary for the treatment of diabetic macular edema in patients who are pseudophakic or are phakic and scheduled for cataract surgery.

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

Please refer to Medical Policy **I-78** for more information.

Contraindications expanded for the use of negative pressure wound therapy

Effective Jan. 1, 2015, Highmark Delaware will expand contraindications for the use of Negative Pressure Wound Therapy (NPWT).

The following are contraindicated for the use of a NPWT. Any use of NPWT will be denied as not medically necessary, if one or more of the following are present:

- The presence in the wound of necrotic tissue with eschar or thick slough in wound bed;
- Untreated osteomyelitis within the vicinity of the wound;
- Cancer present in the wound;
- The presence of a fistula to an organ or body cavity within the vicinity of the wound;
- Non-enteric and unexplored fistulae;
- Exposed vasculature, nerves, anastomotic sites or organs;
- Compromised micro-vascular blood flow to wound;
- Wounds including open joint capsules;
- Untreated coagulopathy;
- Ongoing infection;
- Fragile skin-due to age, chronic corticosteroid use, or collagen vascular disorder;
- Adhesive allergy-NPWT requires an adequate seal to maintain suction. This seal is accomplished with the use of adhesive material.

Please refer to Medical Policy **E-31** for more information.

Eylea® now FDA approved for diabetic macular edema

Effective Sept. 15, 2014, Highmark Delaware considers aflibercept (Eylea®) medically necessary for treatment of individuals with diabetic macular edema (DME). The use of aflibercept (Eylea) for any other indication is

considered experimental/investigational. A participating, preferred, or network provider can bill the member for the denied service.

Please refer to Medical Policy **I-94** for more information.

New coverage position for ziv-aflibercept (Zaltrap®)

Effective Jan. 1, 2015, Highmark Delaware is establishing coverage criteria for Ziv-aflibercept (Zaltrap®).

Ziv-aflibercept (Zaltrap) may be considered medically necessary for the treatment of metastatic colorectal cancer (mCRC) when ALL the following conditions are met:

- metastatic colorectal cancer (mCRC) has progressed during or within 12 months of receiving oxaliplatin-based combination chemotherapy; and
- is given in combination with 5-fluorouracil, leucovorin, irinotecan-(FOLFIRI)

Ziv-aflibercept (Zaltrap) is considered experimental/investigational. More clinical studies are needed to determine efficacy and safety of Ziv-aflibercept (Zaltrap) for all other indications. A participating, preferred, or network provider can bill the member for this denied service.

Note: Dosage per FDA recommended guidelines.

Please refer to Medical Policy **I-112** for more information.

Clinical criteria for AlloMap® molecular testing updated

Effective Jan. 1, 2015, Highmark Delaware will have the following updated clinical criterial for AlloMap® Molecular Testing:

Gene expression profiling using AlloMap Molecular Expression Test may be considered medically necessary when ALL of the following criteria are met:

- Age 15 years or older, and
- Six (6) months to five (5) years post-heart transplantation, and
- Result will be used to determine the need for subsequent endomyocardial biopsy (EMB) to clarify rejection status, and
- Heart allograft function is stable as demonstrated by ALL of the following:
    - absence of signs or symptoms of congestive heart failure, and
    - current echocardiogram with left ventricular ejection fraction (LVEF) ≥ 45%, and
    - absence of severe cardiac allograft vasculopathy (CAV), and
    - within the first six (6) months transplant window there has been no evidence of Grade 2R or Grade 3R graft rejection detected by EMB and the individual has not deteriorated since the prior clinical assessment, and
- Low probability of moderate or severe acute cellular rejection as demonstrated by BOTH of the following:
    - International Society for Heart and Lung Transplantation [ISHLT] rejection status Grade 0R or 1R on all previous endomyocardial biopsies, and
    - no history or evidence of antibody mediated rejection, and
- No history of elevated genetic expression profile (i.e., AlloMap) that prompted subsequent endomyocardial biopsy to clarify rejection status .

AlloMap Molecular Expression Test is considered experimental/investigational if above criteria is not met and for all other uses.

A participating, preferred, or network provider can bill the member for the non-covered service.

Please refer to Medical Policy **L-81** for more information.

PET and PET/CT criteria have been revised and expanded

Effective Jan. 1, 2015, Highmark Delaware will revise and expand criteria for the use of PET and PET/CT scanning as follows:

Initial anti-tumor treatment strategy

PET imaging using the radiopharmaceutical diagnostic imaging agent fluorodeoxyglucose F-18 (FDG)(procedure code A9552) is covered to determine the appropriate initial anti-tumor treatment strategy for patients with brain, breast, colorectal, esophagus, head and neck (excluding Central Nervous System), lung, lymphoma, melanoma, myeloma, ovarian, pancreas, soft tissue sarcoma, and testicular cancers, and certain situations involving cervical cancer as provided below. For these applications, PET imaging improves physician decision making in determining initial anti-tumor treatment strategy in patients and promotes improved health outcomes.

One PET study is covered for patients with solid tumors that are biopsy proven or strongly suspected based on other diagnostic testing, and the patient's treating physician determines that a PET study is needed to determine the location and/or extent of the tumor for therapeutic purposes related to the initial treatment strategy, such as determining:

- Whether the patient is a candidate for an invasive diagnostic or therapeutic procedure and the optimal anatomic location for that procedure; or
- The anatomic extent of the tumor when the anti-tumor treatment chosen depends on the extent of the tumor.

Note:

1. All policy statements apply to both positron emission tomography (PET) scans and PET/computed tomography (CT) scans, i.e., PET scans with or without PET/CT fusion.
2. For the clinical situations indicated that may be considered medically necessary, this is with the assumption that the results of the PET scan will influence treatment decisions. If the results will not influence treatment decisions, these situations would be considered not medically necessary.

There are several exceptions to the above initial anti-tumor treatment strategy guidelines. These are listed below by anatomic areas.

Bone cancer and metastases

PET scanning may be considered medically necessary in the staging of Ewing sarcoma and osteosarcoma.

PET scanning is considered experimental/investigational in the staging of chondrosarcoma. A participating, preferred, or network provider can bill the member for the denied service.

Breast

PET scanning may be considered medically necessary in the staging and restaging of breast cancer for the following application:

- Detecting locoregional or distant recurrence or metastasis (except axillary lymph nodes) when suspicion of disease is high and other imaging is inconclusive.

PET scanning is considered experimental/investigational in the evaluation of breast cancer for all other applications, including but not limited to the following:

- Differential diagnosis in patients with suspicious breast lesions or an indeterminate/low suspicion finding on mammography;
- Staging axillary lymph nodes;

- Predicting pathologic response to neoadjuvant therapy for locally advanced disease.

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

Cervix
PET scans are covered in the initial staging of patients with locally advanced cervical cancer.

PET scans are covered in the evaluation of known or suspected recurrence.

Colorectal cancer
PET scanning may be considered medically necessary as a technique for:
- Staging and restaging to detect and assess resectability of hepatic or extrahepatic metastases of colorectal cancer; and
- To evaluate a rising and persistently elevated carcinoembryonic antigen (CEA) level when standard imaging, including CT scan, is negative.

PET scanning is considered experimental/investigational as:
- A technique to assess the presence of scarring versus local bowel recurrence in patients with previously resected colorectal cancer;
- A technique contributing to radiotherapy treatment planning.

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

Esophageal cancer
PET scanning may be considered medically necessary in the:
- Staging of esophageal cancer; and
- Determining response to preoperative induction therapy.

PET scanning is considered experimental/investigational in other aspects of the evaluation of esophageal cancer, including but not limited to the following applications:
- Detection of primary esophageal cancer.

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

Gastric cancer
PET scanning may be considered medically necessary in the
- The initial diagnosis and staging of gastric cancer;
- Evaluation for recurrent gastric cancer following surgical resection, when other imaging modalities are inconclusive.

Head and neck cancer
PET scanning may be considered medically necessary in the evaluation of head and neck cancer in the diagnosis of suspected cancer, initial staging of disease, and restaging of residual or recurrent disease during follow up.

Lung
PET scanning may be considered medically necessary for any of the following applications:
- Patients with a solitary pulmonary nodule as a single scan technique (not dual-time) to distinguish between benign and malignant disease when prior CT scan and chest x-ray findings are inconclusive or discordant;
- As staging or restaging technique in those with known non-small lung cancer;
- To determine resectability for patients with a presumed solitary metastatic lesion from lung cancer.

PET scanning is considered experimental/investigational in staging of small cell lung cancer. A participating, preferred, or network provider can bill the member for the denied service.

Lymphoma, including Hodgkin's disease
PET scanning may be considered medically necessary as a technique for staging lymphoma either during initial staging or for restaging at follow-up.

Melanoma
PET scanning may be considered medically necessary as a technique for assessing extranodal spread of malignant melanoma at initial staging or at restaging during follow-up treatment.

PET is covered to determine the initial treatment strategy for melanoma. However, the evaluation of regional lymph nodes in melanoma (code G0219) is considered not medically necessary.

Ovarian cancer
PET scanning may be considered medically necessary in the evaluation of patients with signs and/or symptoms of suspected ovarian cancer recurrence (restaging) when standard imaging, including CT scan, is inconclusive.

PET scanning is considered experimental/investigational in the initial evaluation of known or suspected ovarian cancer in all situations. A participating, preferred, or network provider can bill the member for the denied service.

Pancreas
PET may be considered medically necessary in patients with suspected pancreatic adenocarcinoma when the results of other imaging modalities (for example, CT, endoscopic retrograde cholangiopancreatography (ERCP), ultrasonography) are in doubt, inconclusive of equivocal.

PET scanning is considered experimental/investigational as a technique to evaluate other aspects of pancreatic cancer. A participating, preferred, or network provider can bill the member for the denied service.

Sarcomas
PET scans for Ewing's sarcoma and osteogenic sarcoma for both initial and subsequent anti-tumor treatment strategy. Ewing's sarcoma or osteogenic sarcoma may be considered medically necessary:

- Prior to resection of an apparently solitary metastasis;
- For grading unresectable lesions when the grade of the histopathological specimen is in doubt. It is eligible for both initial and subsequent anti-tumor treatment strategy;
- When predictive information (e.g., tumor recurrence, response to chemotherapy) is needed to determine clinical management.

Testicular
PET is only covered for stage IIB and III seminomas in patients with a CT documented residual mass after chemotherapy treatment. (The PET scan should be completed not sooner than 6 weeks following chemotherapy.)

Except as noted above for above for seminoma, PET scanning is considered experimental/investigational in evaluation of testicular cancer, including but not limited to the following applications:

- Initial staging of testicular cancer;
- Distinguishing between viable tumor and necrosis/fibrosis after treatment of testicular cancer;
- Detection of recurrent disease after treatment of testicular cancer.

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

Thyroid
PET is covered for subsequent treatment strategy of recurrent or residual thyroid cancer of follicular cell origin previously treated by thyroidectomy and radioiodine ablation and have a serum thyroglobulin >10ng/ml and have a negative I-131 whole body scan.

PET scanning is considered experimental/investigational in the evaluation of known or suspected differentiated or poorly differentiated thyroid cancer in all other situations. A participating, preferred, or network provider can bill the member for the denied service.

Unknown primary
PET scanning may be considered medically necessary in patients with an unknown primary who meet ALL of the following criteria:

- In patients with a single site of disease outside the cervical lymph nodes; and
- Patient is considering local or regional treatment for a single site of metastatic disease; and
- After a negative workup for an occult primary tumor; and
- PET scan will be used to rule out or detect additional sites of disease that would eliminate the rationale for local or regional treatment.

PET scanning is considered experimental/investigational for other indications in patients with an unknown primary, including, but not limited to the following:

- As part of the initial workup of an unknown primary;
- As part of the workup of patients with multiple sites of disease.

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

Other oncologic applications
Other oncologic applications of PET scanning, including but not limited to the following, are considered experimental/investigational:

- Diagnosis and management of known or suspected prostate cancer;
- Diagnosis of brain tumors;
- Staging of multiple myeloma;
- Evaluation of neuroendocrine tumors;
- Staging inguinal lymph nodes in patients with squamous cell carcinoma of the penis.

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

Subsequent Anti-tumor Treatment Strategy

PET imaging also improves physician decision making in determining subsequent treatment strategy in patients with brain, breast, colorectal, esophagus, head and neck (excluding Central Nervous System), lung, lymphoma, melanoma, myeloma, ovarian, pancreas, soft tissue sarcoma, testicular and thyroid cancers, and certain situations involving cervical cancer.

Tumors in anatomic areas, other than those listed above, are considered not medically necessary and will be denied. The available scientific evidence is not adequate to determine whether PET imaging improves physician decision making in the determination of subsequent anti-tumor treatment strategy or improves health outcomes in patients.

However, a subsequent PET study may be covered for tumor types other than those listed above, when the patient's treating physician determines that the PET study is needed to determine the need and develop a treatment plan for subsequent anti-tumor treatment. It will be necessary for the provider to submit medical records

and/or additional documentation to determine coverage in this situation. For example, the documentation should indication whether the prospective PET scan will lead to:

- A change in patient management to more appropriate palliative care;
- A change in patient management to more appropriate curative care;
- Improved quality of life;
- Improved survival.

PET imaging using the radiopharmaceutical diagnostic imaging agent sodium fluoride-18 (NaF-18) is recognized as useful for imaging areas of altered osteogenic activity in bone. Imaging to detect bone metastases can also be performed when a patient, following completion of initial treatment, is symptomatic with bone pain suspicious for metastases from a known primary tumor.

As such, PET imaging with NaF-18 (procedure code A9580) is covered for suspected or biopsy-proven bone metastases when the patient's treating physician determines that the NaF-18 PET study is needed to determine the initial antitumor treatment strategy, or to guide subsequent antitumor treatment strategy after the completion of initial treatment. In these situations, it will be necessary for the provider to submit medical records and/or additional documentation to determine coverage in this situation as described above.

PET and PET/CT scans performed for oncologic indications not listed in this policy as covered will be denied as not medically necessary.

Surveillance

Surveillance PET scanning is a study performed after the completion of treatment, in the absence of signs or symptoms of cancer recurrence or progression, for the purpose of detecting recurrence or progression or predicting outcome. The principles of surveillance are similar to those of traditional screening tests used for the early detection of disease. Surveillance has also been called "tertiary prevention." Tertiary preventive services are those that are provided to persons who have or have had a disease in order to prevent further complications.

PET performed for surveillance is considered not medically necessary for the following reasons:

- There are no clinical trials evaluating PET as a method of cancer surveillance to improve patient outcomes.
- The sensitivity and specificity of PET scans in the surveillance setting is questionable given the possibility of false positives in these situations.
- There is little published literature from clinical trials and studies that address PET for surveillance. As such, there is inadequate direct or indirect scientific evidence supporting the efficacy of PET scanning for the purpose of surveillance.
- Because of the lack of outcome studies supporting the use of PET for surveillance in oncology, there are no standardized selection criteria.
- It is unknown how frequently and for which cancers PET is used for surveillance. Registries of PET utilization and analyses of claims data (such as the National Oncologic PET Registry or NOPR), do not report or appear to be capable of counting PET scans used for surveillance.
- CMS did not collect information on surveillance PET. Surveillance has not been identified by CMS as one of the possible indications for a PET scan.
- The length of time after the completion of the cancer treatment is not adequately defined to determine with certainty whether or not a PET study is performed for surveillance purposes.

Note: A scan is considered surveillance if performed more than 6 months after completion of cancer therapy (12 months for lymphoma) in patients without objective signs or symptoms suggestive of cancer recurrence.

Additional studies are needed to determine the usefulness of PET in the surveillance setting compared to the results obtained using other diagnostic and imaging techniques.

PET scans using a coincidence detection system

A non-dedicated PET scanner, also called a coincidence detection system, uses a modified SPECT gamma camera that has been adapted to produce PET-like images. PET or PET/CT studies performed on a non-dedicated PET scanner or coincidence detection system (procedure code S8085) are not eligible for reimbursement. The equipment used to perform these studies does not provide images that meet accepted standards of quality achieved when these scans are performed on a dedicated PET or PET/CT scanner. As such, claims reporting code S8085 will be denied because it was performed on equipment that does not provide images that meet clinically accepted standards of quality. Therefore, no payment can be made. A participating, preferred, or network provider cannot bill the member for the denied service.

Modifiers PI and PS

Modifiers – PI and PS are used to identify those PET studies performed for initial (PI) or subsequent (PS) anti-tumor treatment strategy.

PI – Positron Emission Tomography (PET) or PET/Computed Tomography (CT) to indicate the initial treatment strategy of tumors that are biopsy proven or strongly suspected of being cancerous based on other diagnostic testing.

PS – Positron Emission Tomography (PET) or PET/Computed Tomography (CT) to indicate the subsequent treatment strategy of cancerous tumors when the patient's treating physician determines that the PET study is needed to plan subsequent anti-tumor strategy.

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

Revised coverage for stereotactic radiosurgery

Effective Jan. 1, 2015, Highmark Delaware has added criteria for stereotactic radiosurgery (SRS) for solitary or multiple brain metastases. The additional criteria include:

- Good Karnofsky performance status of 70 or greater;
- No lesion is greater than 3 cm;
- Systemic disease is under control;
- All lesions can be encompassed in a single treatment plan.

Additionally, patients with 1-3 recurrent brain lesions who have not received whole brain radiotherapy and additional SRS may be considered medically necessary if 6 months has lapsed since previous radiotherapy.

Please refer to Medical Policy **R-21** for more information.

Hybrid cochlear implants considered experimental/investigational

Effective Jan. 1, 2015, Highmark Delaware will consider cochlear implantation with a hybrid cochlear implant/hearing aid device (L8699) that includes the hearing aid integrated into the external sound processor of the cochlear implant, including but not limited to the Nucleus® Hybrid™ L24 Cochlear Implant System, experimental/investigational and therefore not covered. The available evidence does not demonstrate that hybrid devices improve outcomes compared with standard cochlear implants. A participating, preferred, or network provider can bill the member for the denied service.

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

Changes made to heart transplantation criteria

Effective Jan. 1, 2015, Highmark Delaware will change criteria for heart transplant as follows:

Adult clinical indications

Heart transplantation may be considered medically necessary for selected adults and children with end-stage heart failure when patient selection criteria are met:

- Terminal cardiac disease (New York Heart Classification III and IV [see Note below] with an estimated life expectancy of less than 12 months);
- Age - Ideally up to 65 years of age;
- Normal, expectantly reversible renal and hepatic function;
- Absence of infection;
- A pulmonary vascular resistance less than 6 Wood Units and a transpulmonary gradient less than 15 mm Hg which is not responsive to a prostaglandin E infusion;
- Absence of pulmonary infarction in the preceding four (4) weeks;
- Blood type compatibility;
- Lymphocyte cross match compatibility in cases where panel reactive antibody level indicates its necessity;
- Absence of coexisting systemic illness which may limit life expectancy or compromise recovery.

Note: New York Heart Classification Class III and Class IV for heart failure are defined as follows:

Class III: Persons with cardiac disease resulting in marked limitation of physical activity. They are comfortable at rest. Less than ordinary activity (i.e., mild exertion) causes fatigue, palpitation, dyspnea, or anginal pain.

Class IV: Persons with cardiac disease resulting in inability to carry on any physical activity without discomfort. Symptoms of cardiac insufficiency or of the anginal syndrome may be present even at rest. If any physical activity is undertaken, discomfort is increased.

Other accepted indications for transplantation:

1. Hemodynamic compromise due to heart failure demonstrated by ANY of the following three (3) bulleted items, or:
    - Maximal VO2 (oxygen consumption) <10 mL/kg/min with achievement of anaerobic metabolism;
    - Refractory cardiogenic shock;
    - Documented dependence on intravenous inotropic support to maintain adequate organ perfusion.
2. Severe ischemia consistently limiting routine activity not amenable to bypass surgery or angioplasty, or
3. Recurrent symptomatic ventricular arrhythmias refractory to ALL accepted therapeutic modalities.

Probable indications for cardiac transplantation:

1. Maximal VO2 <14 mL/kg/min and major limitation of the patient's activities, or
2. Recurrent unstable ischemia not amenable to bypass surgery or angioplasty, or
3. Instability of fluid balance/renal function not due to patient noncompliance with regimen of weight monitoring, flexible use of diuretic drugs, and salt restriction

The following conditions are inadequate indications for transplantation unless other factors listed above are present, and without meeting other adult indications above, would be considered not medically necessary.

1. Ejection fraction <20%
2. History of functional class III or IV symptoms of heart failure
3. Previous ventricular arrhythmias
4. Maximal VO2 >15 mL/kg/min

Pediatric clinical indications

Heart transplantation may be considered medically necessary for the following indications:

1. Patients with heart failure with persistent symptoms at rest who require one or more of the following:
    - Continuous infusion of intravenous inotropic agents; or

- Mechanical ventilator support; or
- Mechanical circulatory support.

2. Patients with pediatric heart disease with symptoms of heart failure who do not meet the above criteria but who have:
    - Severe limitation of exercise and activity (if measurable, such patients would have a peak maximum oxygen consumption < 50% predicted for age and sex); or
    - Cardiomyopathies or previously repaired or palliated congenital heart disease and significant growth failure attributable to the heart disease; or
    - Near sudden death and/or life-threatening arrhythmias untreatable with medications or an implantable defibrillator; or
    - Restrictive cardiomyopathy with reactive pulmonary hypertension; or
    - Reactive pulmonary hypertension and potential risk of developing fixed, irreversible elevation of pulmonary vascular resistance that could preclude orthotopic heart transplantation in the future; or
    - Anatomical and physiological conditions likely to worsen the natural history of congenital heart disease in infants with a functional single ventricle;, or
    - Anatomical and physiological conditions that may lead to consideration for heart transplantation without systemic ventricular dysfunction.

Absolute contraindications

Absolute contraindications for transplant recipients include, but are not limited to, the following:

1. Metastatic cancer;
2. Ongoing or recurring infections that are not effectively treated;
3. Serious ongoing insufficiencies that create an inability to tolerate transplant surgery;
4. Serious conditions that are unlikely to be improved by transplantation as life expectancy can be finitely measured;
5. Demonstrated patient noncompliance, which places the organ at risk by not adhering to medical recommendations;
6. Potential complications from immunosuppressive medications are unacceptable to the patient;
7. AIDS (diagnosis based on CDC definition of CD4 count, 200cells/mm3) unless the following are noted:
    - CD4 count greater than 200 cells/mm3 for greater than six (6) months;
    - HIV-1 RNA undetectable;
    - On stable anti-retroviral therapy greater than three (3) months;
    - No other complications from AIDS (e.g., opportunistic infection, including aspergillus, tuberculosis, coccidioidomycosis, resistant fungal infections, Kaposi's sarcoma or other neoplasm);
    - Meeting all other criteria for heart transplantation.

Relative contraindications

Relative contraindications to heart transplantation include, but are not limited to, the following:

- Pulmonary hypertension that is fixed as evidenced by pulmonary vascular resistance (PVR) greater than five (5) Woods units, or trans-pulmonary gradient (TPG) greater than or equal to 16 mm/Hg;
- Severe pulmonary disease despite optimal medical therapy, not expected to improve with heart transplantation;
- History of cancer with a moderate risk of recurrence;
- Systemic disease that could be exacerbated by immunosuppression;
- Psychosocial or dependence affecting ability to adhere to therapy conditions;
- Active sepsis or multi-organ failure, (patients may be considered for transplantation after line sepsis has been treated successfully for one week with intravenous antibiotics);
- Active ulcer disease;

- Drug or alcohol addiction;
- Morbid obesity;
- Severe diabetes mellitus with end-organ damage;
- Severe peripheral vascular disease;
- Pulmonary function (FEV, FVC) <60% or history of chronic bronchitis;
- Creatinine clearance <40-50 ml/min;
- Bilirubin >2.5 mg/dl. transaminases >2X normal;
- Pulmonary artery systolic pressure >60 mmHg;
- Mean transpulmonary gradient >15mmHg;
- Pulmonary disease of a chronic, restrictive, or obstructive nature requiring either prednisone or frequent bronchodilator therapy;
- Ongoing tobacco use (less than six (6) months since quitting);
- Current or recent diverticulitis.

Heart transplantation for patients presenting with a relative contraindication will be reviewed on a case-by-case basis.

Heart transplantation for all other indications or for patients presenting with an absolute contraindication will be considered not medically necessary.

Retransplantation

Retransplantation in individuals with graft failure of an initial heart transplant, due to hyperacute reaction, chronic rejection, rejection refractory to immunosuppressive therapy, moderate graft vasculopathy and graft coronary artery disease with severe ischemia of heart graft may be considered medically necessary. Heart transplantation for all other indications or for patients presenting with an absolute contraindication will be considered not medically necessary.

For additional information on patients that may be candidates for combined heart-lung transplantation, refer to Medical Policy Bulletin **S-125**.

Please refer to Medical Policy **S-122** for more information.

Criteria revised for treatment of hyperhidrosis

Effective Jan. 1, 2015, Highmark Delaware the criteria for treating hyperhidrosis will be revised.

Treatment for primary focal hyperhidrosis may be considered medically necessary when ANY ONE of the following general 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.

AND

In addition to ANY ONE of the above criteria, BOTH of the following criteria must be met to be considered medically necessary:

- 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 20% 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:

A. Axillary Region

- Botulinum toxin A (OnabotulinumtoxinA)(J0585),for severe primary axillary hyperhidrosis that is inadequately managed with topical agents, in patients 18 years and older; or
- Iontophoresis (97033); or
- Endoscopic transthoracic sympathectomy (ETS)(32644) and surgical excision of axillary sweat glands, if conservative treatment (i.e., aluminum chloride or botulinum toxin, individually and in combination) has failed.

Note: Sympathectomy for hyperhidrosis treatment of axillary and palmar regions requires an inpatient stay.

Initial authorization for botulinum toxin A (OnabotulinumtoxinA)(J0585) for axillary hyperhidrosis will expire in 3 months from the original authorization date for any diagnosis. Additional authorization may be given if documentation of an objective measurable effect is provided indicating clinical improvement of the condition. Absence of clinical improvement of axillary hyperhidrosis will be considered not medically necessary for further injections of botulinum toxin A (OnabotulinumtoxinA)(J0585).

Dosage recommendations per the FDA label.

Axillary liposuction (17999, 15877, 15878) and microwave treatment for axillary hyperhidrosis are considered experimental/investigational, and therefore non-covered. A participating, preferred, or network provider can bill the member for the denied service.

B. Palmar Region

- Botulinum toxin A (OnabotulinumtoxinA)(J0585), for severe primary palmar hyperhidrosis that is inadequately managed with topical agents, in patients 18 years and older;

  Note: Injections should occur no sooner than 6 months apart.

  or
- Iontophoresis (97033), or
- Endoscopic transthoracic sympathectomy (ETS), if conservative treatment (i.e., aluminum chloride or botulinum toxin type A, individually and in combination) has failed.

Botulinum toxin B (RimabotulinumtoxinB)(J0587), 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.

C. Plantar Region

- Iontophoresis (97033)

Botulinum toxin (J0585, J0587), lumbar sympathectomy (64818) and microwave treatment for plantar hyperhidrosis are considered experimental/investigational, and therefore non-covered. A participating, preferred, or network provider can bill the member for the denied service.

D. Craniofacial Region

- Endoscopic transthoracic sympathectomy (ETS) (32664), if conservative treatment (e.g., aluminum chloride) has failed.

Botulinum toxin (J0585, J0587), iontophoresis (97033), 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)(69676), if conservative treatment has failed.

Botulinum toxin (J0585, J0587), and iontophoresis (97033) 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 cannot bill the member for the denied service.

Axillary liposuction (17999, 15877, 15878) as treatment for primary hyperhidrosis is considered experimental/investigational, and therefore not covered. A participating, preferred, or network provider can bill the member for these denied procedures.

See Medical Policy Bulletin **I-11** for information regarding botulinum toxin.

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

Additional criteria added to prophylactic mastectomy

Effective Jan. 1, 2015 Highmark Delaware will add additional criteria for prophylactic bilateral mastectomy:

Prophylactic mastectomy may be considered medically necessary in patients with increased risk of breast cancer. One or more of the following risk factors constitutes an increased risk of breast cancer:

Risk factors

- Two or more first-degree relatives with breast cancer; or
- One first-degree relative and two or more second-degree or third-degree relatives with breast cancer; or
- One first-degree relative with breast cancer before the age of 45 years and one other relative with breast cancer; or
- One first-degree relative with breast cancer and one or more relatives with ovarian cancer; or
- Two second-degree or third-degree relatives with breast cancer and one or more with ovarian cancer; or
- One second-degree or third-degree relative with breast cancer and two or more with ovarian cancer; or
- Three or more second-degree or third-degree relatives with breast cancer; or
- One first-degree relative with bilateral breast cancer; or
- Presence of a BRCA1 or BRCA2 mutation in the patient consistent with a BRCA 1 or 2 mutation in a family member with breast or ovarian cancer; or
- Family history with or without breast lesions associated with an increased risk, including but not limited to atypical hyperplasia or breast cancer diagnosed in the opposite breast; or

- Patients with such extensive mammographic abnormalities (i.e., calcifications) that adequate biopsy is impossible; or
- Patients with a personal history of breast cancer in the contralateral breast. (There is no time limit imposed on the prophylactic mastectomy.); or
- Li-Fraumeni syndrome or Cowden syndrome or Bannayan-Riley-Ruvalcaba syndrome or a first-degree relative with one of these syndromes; or
- Received radiation therapy to the chest between 10 and 30 years of age. (e.g., mantle radiation to treat Hodgkin's disease).

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

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

Clinical criteria revised for lumbar spinal fusion and the addition of axial lumbosacral interbody fusion

Effective Jan. 1, 2015 Highmark Delaware Lumbar Spinal Fusion's clinical criteria will be revised as follows. Axial lumbosacral interbody fusion will be added to this policy.

Lumbar spinal fusion/arthrodesis surgery may be considered medically necessary when ANY ONE of the following conditions is met:

- Spinal tuberculosis; or
- Spinal stenosis with any one of the following:
    - Associated spondylolisthesis demonstrated on plain x-rays; or
    - Spinal instability demonstrated on imaging studies; or
    - Spinal instability is anticipated due to need for bilateral or wide decompression with facetectomy or resection of pars interarticularis; and
    - Any one of the following:
        - Neurogenic claudication or radicular pain that results in significant functional impairment in a patient who has failed at least 3 months of conservative management* and has documentation of central/lateral recess/or foraminal stenosis on MRI or other imaging; or
        - Severe or rapidly progressive symptoms of motor loss, neurogenic claudication or cauda equina syndrome.
- Severe, progressive idiopathic scoliosis with either of the following:
    - Cobb angle greater than 40°; or
    - Spinal cord compression with neurogenic claudication or radicular pain that results in significant functional impairment in a patient who has failed at least 3 months of conservative treatment.
- Severe degenerative scoliosis (i.e., lumbar or thoracolumbar) with a minimum Cobb angle of 30°, or significant sagittal imbalance (e.g., Sagittal vertical axis >5 cm) ANY ONE of the following:
    - Documented progression of deformity with persistent axial (non-radiating) pain and impairment or loss of function unresponsive to at least 1 year of conservative management*; or
    - Persistent and significant neurogenic symptoms (claudication or radicular pain) with impairment or loss of function, unresponsive to at least 1 year of conservative management*;
    - Severe or rapidly progressive symptoms of motor loss, neurogenic claudication or cauda equine syndrome.
- Isthmic spondylolisthesis when ALL of the following are present:
    - Congenital (Wiltse type I) or acquired pars defect (Wiltse II), documented on x-ray, and
    - Persistent back pain (with or without neurogenic symptoms), with impairment or loss of function, and

    - Either unresponsive to at least 3 months of conservative nonsurgical care or with severe or rapidly progressive symptoms of motor loss, neurogenic claudication, or cauda equina syndrome.
- Recurrent, same level, disk herniation, at least 3 months after previous disk surgery, when ALL of the following are present:
    - Recurrent neurogenic symptoms (radicular pain or claudication) or evidence of nerve-root irritation, as demonstrated by a positive nerve-root tension sign or positive femoral tension sign or a corresponding neurologic deficit, and
    - Impairment or loss of function; and
    - Unresponsive to at least 3 months of conservative nonsurgical care or with severe or rapidly progressive symptoms of motor loss, neurogenic claudication, or cauda equina syndrome; and
    - Neural structure compression and instability documented by imaging at a level and side corresponding to the clinical symptoms;
    - Adjacent level disease when ALL of the following are present:
        - Persistent back pain (with or without neurogenic symptoms) with impairment or loss of function that is unresponsive to at least 3 months of conservative therapy; and
        - Eccentric disc space collapse, spondylolisthesis, acute single level scoliosis, or lateral listhesis on imaging; and
        - Symptoms and functional measures correlate with imaging findings; and
        - The previous fusion resulted in significant relief for at least 6 months.
- Pseudarthrosis, documented radiographically when ALL of the following are present:
    - No less than 6 months after initial fusion;
    - With persistent axial back pain, with or without neurogenic symptoms, or with severe or rapidly progressive symptoms of motor loss, neurogenic claudication, or cauda equina syndrome;
    - Impairment or loss of function, in a patient who had experienced significant interval relief of prior symptoms;
- Iatrogenic or degenerative flatback syndrome with significant sagittal imbalance; when fusion is performed with spinal osteotomy or interbody spacers;
- Instability due to fracture, dislocation, infection, abscess, or tumor when extensive surgery is required that could create an unstable spine.

*Conservative management typically includes any or ALL of the following:

- Use of prescription strength analgesics (including anti-inflammatory medications if not contraindicated);
- Participation in 6 weeks of physical therapy (including active exercise) or documentation of why the patient could not tolerate physical therapy;
- Bracing (especially in scoliosis, adjacent segment instability, and spondylolistheses, Wiltse types);
- Evaluation and appropriate management of associated cognitive, behavioral or addiction issues when present;
- Documentation of patient compliance with the preceding criteria.

Smoking within the previous 3 months is a contraindication for lumbar spinal fusion.

Significant functional impairment or loss of function should generally include documentation of the following: Inability or significantly decreased ability to perform normal daily activities of work, school or at home duties.

Persistent debilitating pain is defined as:

a. Significant level of pain on a daily basis defined on a Visual Analog Scale (VAS) as greater than 4; and
b. Pain on a daily basis that has a documented impact on activities of daily living in spite of optimal conservative management* as outlined above and appropriate for the patient.

Lumbar spine fusion/arthrodesis surgery is considered experimental/investigational if the sole indication is ANY ONE of the following conditions:

- Disk herniation;
- Chronic nonspecific low back pain without radiculopathy;
- Degenerative disk disease;
- Initial discectomy/laminectomy for neural structure decompression;
- Facet syndrome.

Lumbar spinal fusion performed for any other indication will be considered not medically necessary.

Multiple level lumbar spinal fusions are considered not medically necessary when the criteria listed above are not met for all levels.

Axial lumbosacral interbody fusion

Axial lumbosacral interbody fusion (axial LIF) is considered experimental/investigational as there is insufficient evidence to evaluate whether axial lumbosacral interbody fusion is as effective or as safe as other surgical approaches. Axial lumbosacral interbody fusion is not covered and not eligible for reimbursement or payment. A participating, preferred, or network provider can bill the member for this denied service.

Sacroiliac joint fusion, including minimally invasive and percutaneous sacroiliac joint fusion for the treatment of mechanical back pain is considered experimental/investigational. The peer-reviewed medical literature includes small case series, retrospective studies, and review articles reporting limited safety and efficacy data for sacroiliac joint fusion procedures for the treatment of pain-related sacroiliac conditions from all causes. Sacroiliac joint fusion is not covered and not eligible for reimbursement or payment. A participating, preferred, or network provider can bill the member for the denied service.

Please refer to Medical Policy **S-230** for more information.

Additional criteria added to photodynamic therapy

Effective Jan. 1, 2015, Highmark Delaware, the following criteria will be added to photodynamic therapy.

Photodynamic therapy may be considered medically necessary for the treatment of the following indications:

- Palliation of obstructing esophageal cancer; that cannot be satisfactorily treated with Nd.YAG laser therapy; or
- Barrett's esophagus with high-grade dysplasia; or
- Partially obstructing and endobronchial non-small cell lung cancer

Although PDT has been investigated in a wide variety of cancers, (e.g., prostate, bladder, brain, head and neck cancer) all other applications of PDT are considered experimental/investigational and, therefore, not covered. A participating, preferred, or network provider can bill the member for the denied service.

Please refer to Medical Policy **S-128** for more information.

Additional criteria for treatment of twin-twin transfusion syndrome

Effective Jan. 1, 2015, Highmark Delaware is revising coverage criteria for Treatment of Twin-Twin Transfusion Syndrome with Amnioreduction and/or Fetoscopic Laser Therapy. The following guidelines will be added to the existing criteria.

Amnioreduction in combination with laser coagulation therapy may be considered medically necessary as a treatment of twin-twin transfusion syndrome.

Please refer to Medical Policy **U-8** for more information.

New policy on functional magnetic resonance imaging (fMRI)

Effective Jan. 1, 2015, Highmark Delaware will create a new policy X-71, Functional Magnetic Resonance Imaging-fMRI. fMRI may be considered medically necessary for the preoperative assessment of refractory epilepsy and/or for brain tumors which lie in close proximity to an eloquent area of the brain.

All other indications are considered not medically necessary.

For more information on Functional MRI, please refer to Medical Policy **X-71**.

Transcranial magnetic stimulation considered medically necessary

Effective Sept. 22, 2014, Highmark Delaware may consider repetitive transcranial magnetic stimulation (rTMS) of the brain medically necessary as a treatment of major depressive disorder when ALL of the following conditions have been met:

- Confirmed diagnosis of severe major depressive disorder (single or recurrent) documented by standardized rating scales that reliably measure depressive symptoms; **and**
- **ANY ONE** of the following:
    - Failure of 4 trials of psychopharmacologic agents including 2 different agent classes and 2 augmentation trials; **or**
    - Inability to tolerate a therapeutic dose of medications as evidenced by 4 trials of psychopharmacologic agents with distinct side effects; **or**
    - History of response to rTMS in a previous depressive episode (at least 3 months since the prior episode); **or**
    - Is a candidate for electroconvulsive therapy (ECT) and ECT would not be clinically superior to rTMS (e.g., in cases with psychosis, acute suicidal risk, catatonia or life-threatening inanition rTMS should NOT be utilized);

AND

- Failure of a trial of a psychotherapy known to be effective in the treatment of major depressive disorder of an adequate frequency and duration, without significant improvement in depressive symptoms, as documented by standardized rating scales that reliably measure depressive symptoms; **and**
- **None** of the following conditions are present:
    - Seizure disorder or any history of seizure with increased risk of future seizure; **or**
    - Presence of acute or chronic psychotic symptoms or disorders (such as schizophrenia, schizophreniform or schizoaffective disorder) in the current depressive episode; **or**
    - Neurologic conditions that include epilepsy, cerebrovascular disease, dementia, increased intracranial pressure, having a history of repetitive or severe head trauma, or with primary or secondary tumors in the central nervous system (CNS); **or**
    - Presence of an implanted magnetic-sensitive medical device located 30 centimeters or less from the TMS magnetic coil or other implanted metal items, including but not limited to a cochlear implant, implanted cardioverter defibrillator (ICD), pacemaker, vagus nerve stimulator, or metal aneurysm clips or coils, staples, or stents.

rTMS should be performed using an FDA-cleared device in appropriately selected patients, by physicians who are adequately trained and experienced in the specific techniques used. A treatment course should not exceed 5 days a week for 6 weeks (total of 30 sessions), followed by a 3-week taper of 3 TMS treatments in week 1, 2 TMS treatments the next week, and 1 TMS treatment in the last week.

All of the following should be present for the administration of rTMS and documented in the medical record and available upon request:

- An attendant trained in basic cardiac life support and the management of complications such as seizures, as well as the use of the equipment must be present at all times; **and**
- Adequate resuscitation equipment including, for example, suction and oxygen; **and**
- The facility must maintain awareness of response times of emergency services (either fire/ambulance or "code team"), which should be available within five minutes. These relationships are reviewed on at least a one year basis and include mock drills.

rTMS for major depressive disorder that does not meet the criteria listed above is considered experimental/investigational and therefore, not covered. A participating, preferred, or network provider can bill the member for the denied service.

Continued treatment with rTMS of the brain as maintenance therapy is considered experimental/investigational and therefore, not covered. A participating, preferred, or network provider can bill the member for the denied service.

Transcranial magnetic stimulation of the brain is considered experimental/investigational and therefore not covered for any other indication. There is insufficient evidence in medical literature to support the effectiveness of this procedure. A participating, preferred, or network provider can bill the member for the denied service.

Please refer to Medical Policy **Z-4** for more information.

Implantable hypoglossal nerve stimulators are considered experimental/investigational for the treatment of obstructive sleep apnea in adults

Effective Jan. 1, 2015, Highmark Delaware will consider implantable hypoglossal nerve stimulators experimental/investigational for the treatment of adult obstructive sleep apnea (OSA) due to insufficient evidence in the peer-reviewed published medical literature regarding its effectiveness and safety.

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

Multi-biomarker serum blood test for assessing disease activity in rheumatoid arthritis is considered experimental/investigational

Effective Jan. 1, 2015, Highmark Delaware will consider multi-biomarker serum blood test for assessing disease activity in rheumatoid arthritis experimental/investigational (e.g., Vectra DA).

Although multi-biomarker serum testing is promising in the potential evaluation of rheumatoid disease activity, more studies are needed to define the optimal use of biomarkers in rheumatoid arthritis.

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

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

Sacroiliac joint fusion added to criteria

Effective Jan. 1, 2015, Highmark Delaware is revising the coverage criteria for Diagnosis and Treatment of Sacroiliac Joint Pain. The following guideline will be added to the existing patient selection criteria for diagnosis and treatment of sacroiliac joint pain.

Fusion/stabilization (0334T) of the sacroiliac joint for the treatment of back pain presumed to originate from the SI joint is considered experimental/investigational, including but not limited to percutaneous and minimally invasive techniques. A participating, preferred, or network provider can bill the member for the denied service.

Please refer to Medical Policy **Z-62** for more information.

Clinical criteria established for breast ductal lavage and breast fiberoptic ductoscopy

Effective Oct. 27, 2014, Highmark Delaware will include the following clinical criteria for breast ductal lavage and breast fiberoptic ductoscopy.

Breast ductal lavage and fiberoptic ductoscopy are not to be used as a routine breast cancer diagnostic tool.

Breast ductal lavage

Breast ductal lavage may be considered medically necessary for the following:

- When non-lactational nipple discharge is too low to permit adequate cytological analysis.

The following breast ductal lavage procedures are considered experimental/investigational due to insufficient evidence in peer-reviewed literature and will be denied:

- Breast ductal lavage in combination with ductoscopy for the evaluation of women with ipsilateral breast cancer; or
- For the purpose of breast cancer screening, breast cancer risk-assessment and for all other indications.

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

Fiberoptic ductoscopy

Fiberoptic ductoscopy may be considered medically necessary for the following:

- When combined with cytology testing for diagnosing intra-ductal lesions in women with non-lactational sporadic nipple discharge accompanied by documented positive cytology, or
- As a guide for resection of known breast intra ductal cancer.

Due to insufficient evidence in the peer-reviewed literature, fiberoptic ductoscopy is considered experimental/investigational and denied when used for breast cancer screening and all other indications.

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

Please refer to Medical Policy **S-147** for more information.

Pre- and post-test counseling for genetic testing

Effective Jan. 1, 2015, Highmark Delaware will consider genetic testing appropriate only when offered in a setting with adequately trained health care professionals to provide appropriate pre- and post-test counseling. A qualified Clinical Laboratory Improvement Amendments (CLIA) laboratory should perform the test.

Please refer to Medical Policy **L-33** for more information.

Next-generation gene sequencing (NGS) for oncology

Effective Jan. 1, 2015, Highmark Delaware will consider the use of next-generation gene sequencing (NGS) for oncology to identify targeted therapies as experimental/investigational.

The following next-generation sequencing platforms are considered experimental/investigational:

ABI™

Foundation One™
GridION™
HeliScope
HiSeq™ X Ten
Illumina HiSeq™ 2000/2500
Illumina MiSeq™
Ion PGM™
Ion Proton™
Ion Torrent™
Life Tech SOLiD™
Methyl-Maxi Seq™
Methy-Midi Seq™
MiniON™
NextSeq™ 500
PacBio®RS II
Roche 454™

Claims that are submitted for these services will be denied as experimental/investigational. A participating, preferred, or network provider can bill the member for the denied item or service.

Please refer to Medical Policy **L-105** for more information.

Coverage criteria established for panitumumab (Vectibix®)

Effective Jan. 1, 2015, Highmark Delaware will provide coverage for panitumumab (Vectibix®)(J9303). The following coverage criteria guidelines per the Federal Drug Administration and the National Comprehensive Cancer Network (NCCN) will be established.

Coverage for panitumumab (Vectibix®) is determined according to individual or group customer benefits.

Highmark considers panitumumab (Vectibix) medically necessary for the following indications:

1. Advanced or metastatic colorectal cancer in tumors expressing the wild-type KRAS and NRAS genes (i.e., negative for the KRAS and NRAS mutations); or
2. Advanced or metastatic anal adenocarcinoma expressing the wild-type KRAS and NRAS genes; or
3. Metastatic penile cancer.

Highmark considers panitumumab medically necessary as single-agent therapy for second-line treatment of metastatic penile cancer.

Continued use of panitumumab is considered experimental/investigational for persons whose disease has progressed with panitumumab or who have developed intolerance to this drug.

Highmark considers panitumumab experimental/investigational for persons who have had clinical failure (disease progression) on cetuximab (Erbitux) because there is insufficient evidence to support the use of panitumumab after clinical failure on cetuximab.

All other indications are considered experimental/investigational.

Please refer to Medical Policy **I-117** for more information.

New coverage criteria for the drug ofatumumab (Arzerra®)

Coverage for ofatumumab (Arzerra®) is determined according to individual or group customer benefits.

Ofatumumab (Arzerra) may be considered medically necessary for adults for the treatment of any of the following indications:

A. Chronic lymphocytic leukemia (CLL), Previously untreated:
    - for whom fludarabine-based treatment is inappropriate.
B. Chronic lymphoid leukemia (CLL), Refractory:
    - to fludarabine; OR
    - CLL or small lymphocytic lymphoma (SLL) for individuals with relapsed or refractory disease.
C. Waldenström's macroglobulinemia/lymphoplasmacytic lymphoma (off-label use):
    - as single-agent or combination salvage therapy in rituximab-intolerant individuals for disease that does not respond to primary therapy or for progressive or relapsed disease

All other uses for ofatumumab (Arzerra) are considered experimental/investigational and, therefore, not covered. A participating, preferred, or network provider can bill the member for the denied service.

Safety and effectiveness in pediatric patients has not been established.

Dosing greater than the FDA label recommendation for age and/or weight will be considered experimental/investigational. A participating, preferred, or network provider can bill the member for the denied service.

See Medical Policy Bulletin **G-16** for information on chemotherapy services and off-labeled use for anti-cancer drugs.

See Medical Policy Bulletin **S-206** for information on Hematopoietic Stem-Cell Transplantation for Chronic Lymphocytic Leukemia and Small Lymphocytic Lymphoma.

See Medical Policy Bulletin **S-224** for information on Hematopoietic Stem-Cell Transplantation for Waldenstrom Macroglobulinemia.

See Medical Policy Bulletin **I-38** for information on Rituximab (Rituxan®).

Please refer to Medical Policy **I-116** for more information.

ImPACT program considered experimental/investigational

Effective Jan. 1, 2015, Highmark Delaware will consider ImPACT as experimental/investigational.

ImPACT addresses the need for an accurate, medically accepted assessment system that is used as part of an overall concussion management protocol. This model builds partnerships with healthcare professionals and athletic trainers to offer training and resources for affordable concussion management.

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

Coverage clarified for tumor markers

Highmark Delaware is revising the coverage criteria for tumor markers. Effective Jan. 1, 2015, the following guidelines will be added to the existing criteria.

Prostate specific antigen (PSA) (84152, 814153, 84154, G0103)

Prostate-specific antigen (PSA) may be considered medically necessary for ANY ONE of the following:

- Staging; or
- Monitoring response to therapy; or

- Detecting disease recurrence.

Note: Only covered by certain groups or programs as indicated in benefits.

Alpha-fetoprotein (AFP); serum (82105, 82107)

Alpha-fetoprotein (AFP); serum may be medically necessary for ANY ONE of the following:

- Serial measurements of alpha fetoprotein (AFP) to diagnose germ cell tumors in members with adenocarcinoma, or carcinoma not otherwise specified, involving mediastinal nodes; or the diagnosis and monitoring of hepatocellular carcinoma; or
- Serial measurements of AFP and HCG together to diagnose and monitor testicular cancer.

Carcinoembryonic antigen (CEA) (82378)

Carcinoembryonic antigen (CEA) may be medically necessary for ANY ONE of the following:

- As a preoperative prognostic indicator with known colorectal carcinoma or mucinous appendiceal carcinoma when it will assist in staging and surgical treatment planning; or
- To detect asymptomatic recurrence of colorectal cancer after surgical and/or medical treatment for the diagnosis of colorectal cancer (not as a screening test for colorectal cancer); or
- To monitor response to treatment for metastatic cancer.

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

Coverage criteria established for levoleucovorin (Fusilev®)

Effective Jan. 1, 2015, Highmark Delaware will provide coverage for levoleucovorin (Fusilev)(J0641). The following coverage criteria guidelines per the Federal Drug Administration and the National Comprehensive Cancer Network (NCCN) will be established as follows:

Coverage for levoleucovorin (Fusilev) is determined according to individual or group customer benefits.

Levoleucovorin (Fusilev) may be considered medically necessary for ANY of the following:

- To counteract the effects of impaired methotrexate elimination and diminish the associated toxicity of inadvertent over dosage of folic acid antagonists; or
- Levoleucovorin rescue after high-dose methotrexate during osteosarcoma therapy; or
- Use in combination chemotherapy with 5-FU in the palliative treatment of patients with advanced metastatic colorectal cancer; and
- Levoleucovorin is not attainable due to short supply.

All other indications are considered experimental/investigational.

Please refer to Medical Policy **I-114** for more information.

Coverage criteria established for optic nerve decompression surgery

Effective Jan. 1, 2015, Highmark Delaware will provide coverage for optic nerve decompression surgery. The following coverage criteria guidelines will be established:

Optic nerve decompression surgery (67570) may be considered medically necessary when performed for the following:

- Treatment of papilledema accompanying pseudotumor cerebri (idiopathic intracranial hypertension); or
- Traumatic optic neuropathy

Optic nerve decompression surgery for any other indications/conditions is considered experimental/investigational and not eligible for payment. A participating, preferred, or network provider can bill the member for the denied service.

Please refer to Medical Policy **S-63** for more information.

Prostatic arterial embolization considered experimental/investigational

Effective Jan. 1, 2015, Highmark Delaware will consider prostatic arterial embolization for the treatments of the prostate experimental/investigational and, therefore, not covered. The available evidence does not demonstrate prostatic arterial embolization as an effective treatment for the prostate. A participating, preferred, or network provider can bill the member for the denied service.

Please refer to Medical Policy **S-97** for more information.

Coverage criteria established for transesophageal endoscopic radiofrequency

Effective Jan. 1, 2015, Highmark Delaware will provide coverage for transesophageal endoscopic radiofrequency (43257). The following coverage criteria guidelines will be established.

Transesophageal endoscopic radiofrequency therapy (Stretta) may be considered medically necessary for a select population of patients, who are at least 18 years of age with refractory gastroesophageal reflux disease (GERD), who meet all of the following criteria:

- Daily heartburn or regurgitation or both for at least six months or more; and
- Exhibit inadequate or partial symptom response to anti-secretory therapy; and
- Have a 24-hour pH study demonstrating pathologic acid reflux (total acid exposure time greater than 4 percent, or a DeMeester composite score > 14.7); and
- Have nonerosive reflux disease; and
- Have grade I and II esophagitis by Savary-Miller criteria, or have grades of esophagitis healed by drug therapy.

Patient exclusion criteria are as follow:

- 2cm or greater hiatal hernia; or
- Signifcant dysphagia; or
- Inadequate esophageal peristalsis; or
- Incomplete lower esophageal sphincter relaxation.

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

Please refer to Medical Policy **S-156** for more information.

Comments on these new medical policies?

We want to know what you think about our new medical policy changes. Send us an email with any questions or comments that you may have on the new medical policies in this Special Bulletin.

Write to us at **medicalpolicy@highmark.com**.