SPECIAL BULLETIN

FOR PROFESSIONAL PROVIDERS **JUNE 30, 2014**

MEDICAL POLICY UPDATES AND NEWS

JUNE 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

Implementation of Monitored Anesthesia Care (MAC) policy delayed

The implementation of Monitored Anesthesia Care (MAC) will be delayed from its original implementation date of June 30, 2014. Highmark believes that its members deserve to receive the safest and most appropriate care according to established guidelines. That was the rationale behind the recent announcement to continue coverage of monitored anesthesia care for gastrointestinal procedures, but only for patients for whom such general anesthesia is medically necessary. This approach is in line with the guidelines of many national insurers and the Centers for Medicare and Medicaid (CMS) local carriers. After receiving feedback from some physicians, Highmark has decided to delay implementation of the policy as a further study is completed on all implications of this change. Subsequent communications will be issued with more details.

Accepting candidates for CPMC advisory subcommittees

Attention cardiologists, cardiac surgeons, hematologists/oncologists, neurologists, neurosurgeons, orthopedic surgeons, psychiatrists, physiatrists, and rheumatologists: Highmark Delaware is accepting new members for its four Clinical Policy Management Committee (CPMC) advisory subcommittees.

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

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

Subcommittee member qualifications

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

How to apply

If you would like to apply for appointment to one of the subcommittees, please send an e-mail detailing your current medical practice activities and location, along with a resume or curriculum vitae, to **cpmc@highmark.com**. Please respond by Aug. 1, 2014.

You will be notified by Dec. 1, 2014, if you are selected to serve on a subcommittee.

Reporting guideline changes to procedure codes 23130, 23412 and 23420

Beginning Sept. 1, 2014, Highmark Delaware will consider procedure code 23130 a component of procedure codes 23412 and 23420. This information is based on national code edits and also the AMA CPT Assistant.

Code	Terminology
23130	Acromioplasty or acromionectomy, partial, with or without coracoacromial ligament release
23412	Repair of ruptured musculotendinous cuff (e.g., rotator cuff) open; chronic
23420	Reconstruction of complete shoulder (rotator) cuff avulsion, chronic (includes acromioplasty)

Reporting guideline changes to procedure codes 29877, 29879, 29880, and 29881 with fee adjustments

Beginning Sept. 1, 2014, Highmark Delaware will consider procedure code 29877 a component of procedure codes 29879, 29880, and 29881. This information is based on the terminology description of the codes and also national code edits.

Code	Terminology
29877	Arthroscopy, knee, surgical; debridement/shaving of articular cartilage (chondroplasty)
29879	Arthroscopy, knee, surgical; abrasion arthroplasty (includes chondroplasty where necessary) or multiple drilling or microfracture
29880	Arthroscopy, knee, surgical; with meniscectomy (medial and lateral, including any meniscal shaving) including debridement/shaving of articular cartilage (chondroplasty), same or separate compartment(s), when performed

29881	Arthroscopy, knee, surgical; with meniscectomy (medial or lateral, including any meniscal shaving) including debridement/shaving of articular cartilage (chondroplasty), same or separate compartment(s), when performed

REVIEW

Correction to April 2014 PRN: genetic testing for hereditary breast and/or ovarian cancer criteria revised

Clinical criteria regarding family history only was incorrectly published.in the April 2014 **PRN**. The following is the correct revised criteria for genetic testing for hereditary breast and/or ovarian cancer.

BRCA1 and/or BRCA2 may be considered medically necessary when **ANY ONE** of the following criteria is met:

- Individual of a family with a known BRCA1/BRCA2 mutation; **or**
- Personal history of breast cancer (including invasive and ductal carcinoma in situ breast cancers) **and** with **ANY ONE** of the following:
    - Diagnosed at age 45 years or younger, with or without family history; **or**
    - Diagnosed at age 50 years or younger with at least one close blood relative with breast cancer at any age ; **or**
    - Diagnosed at age 50 years or younger with a limited family history; **or**
    - Two breast primary tumors when first breast cancer diagnosis occurred prior to age 50 years; **or**
    - Diagnosed at less than 60 years with a triple negative (ER-, PR-, HER2-) breast cancer; **or**
    - Diagnosed at any age, with ANY ONE of the following
        - at least one (1) close blood relative with breast cancer diagnosed at age 50 or younger; **or**
        - at least two (2) close blood relatives with breast cancer at any age; **or**
        - at least one (1) close blood relative epithelial ovarian/fallopian tube/primary peritoneal cancer at any age; **or**
        - at least two (2) close blood relatives with pancreatic cancer or prostate cancer (Gleason score ≥7) at any age; **or**
        - Close male blood relative with breast cancer; **or**
        - For an individual of an ethnicity associated with higher mutation frequency (e.g., Ashkenazi Jewish), no additional family history may be required.

OR

- Personal history of epithelial ovarian/fallopian tube/primary peritoneal cancer; **or**
- Personal history of male breast cancer; **or**
- Personal history of pancreatic cancer or prostate cancer (Gleason ≥7) at any age with two (2) or more close blood relatives with **ANY ONE** of the following:
    - breast cancer at any age; **or**
    - ovarian/fallopian tube/primary peritoneal cancer at any age; **or**
    - pancreatic cancer at any age; **or**
    - prostate cancer (Gleason ≥7) at any age
      *For Ashkenazi Jewish ancestry, only one additional affected relative is needed

OR

- Family history only:
  - First- or second-degree blood relative meeting any of the above criteria; **or**
  - Third-degree blood relative with breast cancer and/or ovarian/fallopian tube/primary peritoneal cancer with two or more close blood relatives with breast cancer (at least one with breast cancer and less than or equal to 50 years of age) and/or ovarian cancer

    *Clinical judgment should be used to determine if the patient has reasonable likelihood of a mutation, considering the unaffected patient's current age and the age of female unaffected relative who link the patient with the affected relatives.

    *Testing of unaffected family members when no affected member is available should be considered. Significant limitations of interpreting test results should be discussed.

Testing for genomic rearrangements of the BRCA1 and BRCA2 genes may be considered medically necessary in patients who meet criteria for BRCA testing, whose testing for point mutations is negative.

Genetic testing for hereditary breast and/or ovarian cancer for any other indications is considered not medically necessary.

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

Reminder: add-on procedure codes

Add-on procedure codes are classified by the American Medical Association as codes that are always reported by the provider in addition to the code for the primary procedure. Add-on codes should never be reported as stand-alone codes without the primary procedure code. This is considered misreporting, in which case the add-on code is denied.

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
I-36*	Palonosetron Hydrochloride (Aloxi®)	Outpatient	09/01/2014
I-88*	Granulocyte Colony-Stimulating Factors (Pegfilgrastim and Filgrastim)	Outpatient	09/01/2014
L-37*	Multi-panel Gene Expression Test	Outpatient	09/01/2014
L-86*	Genetic Testing for Cystic Fibrosis	Outpatient (Revised)	05/12/2014
L-96	Biomarkers in Risk Assessment and Management of Cardiovascular Disease	Outpatient	09/01/2014
M-4*	Thermography (Thermogram)	Outpatient (Revised)	04/28/2014
O-31*	Myoelectric Prosthetic Components for the Upper Limb	Outpatient	09/01/2014
R-11*	Intensity Modulated Radiation Therapy (IMRT)	Outpatient	09/01/2014

Policy #	Policy Topic	Place of Service	Effective Date
S-9*	Hearing Aids and Audiological Testing	Outpatient	09/01/2014
X-26*	Ultrasound Studies for the Diagnosis and Treatment of Infertility	Outpatient	09/01/2014
Z-68*	Telehealth Medical Consultations (Telemedicine Service)	Outpatient	09/01/2014

*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.

Corrections – Medical Policy Updates, April 2014

Policy #	Policy Topic	Place of Service	Effective Date
A-7*	Monitored Anesthesia Care (MAC)	Outpatient	Delayed Implementation
E-8	Patient Lifts	Outpatient (Revised)	04/21/2014

Medical Policy A-7, Monitored Anesthesia Care (MAC), was misidentified as Medical Policy A-2, and the effective date of the policy has been delayed.

Medical Policy E-8, Patient Lifts, was listed incorrectly. It is correct above: the asterisked statement isn't included on the policy for Place of Service.

Criteria for urine drug testing (UDT)

Effective Sept. 1, 2014, Highmark Delaware may consider Urine Drug Testing to be medically necessary based on position statements of the professional organizations (i.e., American Society of Interventional Pain Physicians (ASIPP), current peer-reviewed literature and the position of other insurers).

In the outpatient pain management setting, qualitative (i.e., immunoassay) urine drug testing may be considered medically necessary for:

- Baseline screening before initiating treatment or at the time treatment is initiated when **ALL** of the following conditions are met:
    - An adequate clinical assessment of patient history and risk of substance abuse is performed; and
    - Clinicians have knowledge of test interpretation; and
    - There is a plan in place regarding how to use test findings clinically.

In the outpatient substance abuse treatment setting, in an office or point-of-care facility, qualitative (i.e., immunoassay) urine drug testing may be considered medically necessary under the following conditions:

- Induction phase (one time per program entry) - baseline screening before initiating treatment or at the time treatment is initiated , **ALL** of the following conditions must be met:
    - An adequate clinical assessment of patient history and risk of substance abuse is performed; and
    - Clinicians have knowledge of test interpretation; and
    - There is a plan in place regarding how to use test findings clinically.
- Stabilization phase – targeted weekly qualitative screening for a maximum of 4 weeks
- Maintenance phase – targeted qualitative screening once every 1 to 3 months.

Quantitative (i.e., confirmatory) urine drug testing, in the pain management or substance abuse setting, may be considered medically necessary under the following circumstances:

- When immunoassays for the relevant drug(s) are not commercially available; or
- In specific situations for which quantitative drug levels are required for clinical decision making.

In the outpatient pain management setting and outpatient substance abuse setting, urine drug testing is considered not medically necessary when the above criteria are not met including but not limited to routine qualitative or quantitative urine drug testing (e.g., testing at every visit, without consideration for specific patient risk factors or without consideration for whether quantitative testing is required for clinical decision making).

Codes 80100, 80101, 80102, 80103, and 80104 will no longer be reimbursed because these codes are not specific enough to establish appropriate justification for reimbursement for qualitative drug testing.

Reimburse will be made for the following appropriate HCPCS qualitative drug screening codes:

- G0431—Drug screen, qualitative; multiple drug classes by high complexity test method (e.g., immunoassay, enzyme assay), per patient encounter) will be used to report more complex testing methods, such as multi-channel chemistry analyzers, where a more complex instrumented device is required to perform some or all of the screening tests for the patient

- G0434—Drug screen, other than chromatographic; any number of drug classes, by CLIA waived test or moderate complexity test, per patient encounter) will be used to report very simple testing methods, such as dipsticks, cups, cassettes, and cards, that are interpreted visually, with the assistance of a scanner, or are read utilizing a moderately complex reader device outside the instrumented laboratory setting (i.e., non-instrumented devices)

  G0431 and G0434 will have the following limitations:
  G0431 - *1 unit per encounter; 4 per calendar year
  G0434 - *1 unit per encounter; 12 per calendar year

  *Regardless of the number of drug classes tested, codes G0431and G0434 will deny when billed with ≥ 2 units per date of service.

Limits do not apply to ER visits.

Please refer to Medical Policy **L-102** for more information.

Gemcitabine HCL (Gemzar®)

Effective Sept. 1, 2014, Highmark Delaware will issue a new policy on Gemcitabine HCL (Gemzar®), Medical Policy I-59.

Gemcitabine (Gemzar®) is a cancer medication (chemotherapy) that interferes with the growth and spread of cancer cells in the body. Gemzar is used to treat cancers of the pancreas, lung and breast as well as other types of cancers. In addition to the Food and Drug Administration (FDA) – approved use, standard references compendia, including the National Comprehensive Cancer Network (NCCN) inclusive indications for Gemzar – the following conditions apply:

- Bladder cancer

- Bone cancer – Ewing's sarcoma
- Breast cancer
- Cervical cancer
- Head and neck cancers – cancer of the nasopharynx
- Hodgkin lymphoma
- Kidney cancer
- Malignant pleural mesothelioma
- Non Hodgkin lymphoma
- Non-small cell lung cancer
- Occult primary
- Osteosarcoma – Mesenchymal chondrosarcoma osteosarcoma, dedifferentiated chondrosarcoma
- Ovarian cancer
- Pancreatic cancer
- Small cell lung cancer
- Soft tissue sarcoma
- Testicular cancer
- Thymic malignancies
- Uterine malignancies

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

Criteria revised for continuous glucose monitors

Highmark Delaware is revising the coverage criteria for continuous glucose monitors. Effective Sept. 1, 2014, the following guidelines will be added to the existing criteria for continuous glucose monitors.

Use of an artificial pancreas system, including but not limited to closed-loop monitoring devices with low-glucose suspend (LGS) features, are considered experimental/investigational. The safety and/or effectiveness cannot be established by review of the published peer-reviewed literature. A participating preferred, or network provider can bill the member for the denied service.

Please refer to Medical Policy **E-42** for more information.

External counterpulsation criteria revision

Highmark Delaware is revising the coverage criteria for External Counterpulsation (ECP). Effective Sept. 1, 2014, the following guideline will be revised to the existing criteria for External Counterpulsation.

External counterpulsation (G0166) may be considered medically necessary for use for patients who have been diagnosed with disabling angina (Class III or Class IV, Canadian Cardiovascular Society Classification or equivalent classification) who, in the opinion of a cardiologist or cardiothoracic surgeon, are not readily amenable to surgical intervention, such as percutaneous transluminal coronary angioplasty (PTCA) or cardiac bypass because:

1. their condition is inoperable, or at high risk of operative complications or post-operative failure;
2. their coronary anatomy is not readily amenable to such procedures; or
3. they have co-morbid states which create excessive risk.

Limitations

Although these and similar devices are cleared by the Food and Drug Administration (FDA) for use in treating a variety of conditions, including stable or unstable angina pectoris, acute myocardial infarction, and cardiogenic

shock, coverage is limited to its use in patients with stable angina pectoris, since only that use has developed sufficient evidence to demonstrate its medical effectiveness.

Hydraulic versions of these types of devices remain non-covered and non-billable.

Documentation in the medical record must contain a history and physical pertinent to the indications of this policy, and be available upon request.

Please refer to Medical Policy **M-52** for more information.

ALCAT allergy testing considered experimental/investigational

Highmark Delaware has revised the criteria on Medical Policy L-3, In Vitro Allergy Testing. ALCAT (Antigen Leukocyte Cellular Antibody Test) Allergy Testing is considered experimental/investigational, and not eligible for payment. There is insufficient data available to demonstrate the usefulness of this testing.

Please refer to Medical Policy **L-3** In Vitro Allergy Testing, for more information.

Criteria for sacral nerve stimulation revised

Highmark Delaware is revising the coverage criteria for Sacral Nerve Modulation/Stimulation (SNS) for Pelvic Floor Dysfunction. Effective April 28, 2014, the following guideline was revised to the existing criteria for Sacral Nerve Modulation/Stimulation (SNS) for Pelvic Floor Dysfunction.

- A sacral nerve stimulation trial (64561) of the device has provided at least a 50% reduction in incontinence symptoms or a 50% reduction in residual urine volume.

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

POEMS syndrome added to criteria

Highmark Delaware is updating its coverage criteria for Hematopoietic Stem-Cell Transplantation for Multiple Myeloma and POEMS Syndrome. The new guidelines will become effective Sept. 1, 2014.

Autologous hematopoietic stem-cell transplantation may be considered medically necessary to treat disseminated POEMS syndrome. Patients with disseminated POEMS syndrome may have diffuse sclerotic lesions or disseminated bone marrow involvement.

Allogeneic and tandem hematopoietic stem-cell transplantation is considered experimental/investigational to treat POEMS syndrome. A participating preferred, or network provider can bill the member for the denied service.

Please refer to Medical Policy **S-207** for more information.

Laparoscopic power morcellators to treat uterine fibroids considered experimental/investigational

Effective Sept. 1, 2014, Highmark Delaware will consider laparoscopic uterine power morcellation in hysterectomy and myomectomy for the treatment of fibroids considered experimental/investigational. A participating preferred, or network provider can bill the member for such procedures.

Please refer to Medical Policy **S-179** for more information.

Coverage criteria established for endovascular procedure, Pipeline Embolization Device (PED)

Effective Sept. 1 2014, Highmark Delaware will add coverage criteria for endovascular procedure "pipeline embolization device," as a covered procedure when the following clinical criteria are met:

The Pipeline Embolization Device (PED) approved by the US Food and Drug Administration (FDA) April 6, 2011, may be considered medically necessary for individuals for endovascular treatment of adults (22 years of age or older) with rare large or giant wide-necked intracranial aneurysms (IA's)(e.g., maximum fundus diameter 10-20 mm, giant (>25 mm) and wide necked (≥4 mm) in the internal carotid artery from the petrous , cavernous, paraophthalmic including paraclinoid ophthalmic and superior hypohyseal segments) when any one of the following conditions are met:

- Individuals with complex giant wide-neck intracranial aneurysms who have no other surgical intervention available to them whereby the potential benefit of PED offers the only possible means of treatment due to high risk of aneurysm rupture; or
- Individuals who have mass effect of aneurysms, (i.e., headache, diplopia, nystagmus, or other neurological dysfunction) or at high risk of future bleeding, and are unsuitable for either stent-coiling or surgical treatment.
  AND
- Are fit for general anesthesia and have the necessary mental capacity to participate and are willing and able to comply with prior protocol requirements:
  - Prior protocol indications: aspirin 325 mg for two days and clopidogrel, 75 mg for 7 days or a single 600 mg dose 1 day prior to placement of procedure.

Contraindications

- Patients with an active bacterial infection;
- Patients in whom dual antiplatelet therapy (aspirin and clopidogrel) is contraindicated;
- Patients who have not received dual antiplatelet agents prior to the procedure; or
- Patients in whom a pre-existing stent is in place in the parent artery at the target aneurysm location

Pipeline embolization procedure is considered not medically necessary and, therefore, not covered for individuals with any of the above contraindications.

Please refer to Medical Policy **S-200**, Percutaneous Intracranial and Extracranial Balloon Angioplasty With or Without Stenting, for more information.

Change in criteria for anesthesia services rendered in conjunction with dental procedures

Effective Sept. 1, 2014, Highmark Delaware will revise the criteria for anesthesia provided in conjunction with dental services.

Anesthesia services rendered in conjunction with routine non-covered dental procedures and bony impacted wisdom teeth will be covered for children and special needs members for the following criteria which must be verified by appropriate medical documentation:

1. The member is seven years of age or younger or is developmentally disabled and is an individual for whom a successful result cannot be expected from dental care provided under local anesthesia because of a

physical, intellectual, or other medically compromising condition and for whom a superior result can be expected from dental care provided under general anesthesia; or

2. A child who is twelve years of age or younger with documented phobias, or with documented mental illness, and with dental needs of such magnitude that treatment should not be delayed or deferred; and for whom lack of treatment can be expected to result in infection, loss of teeth or other increased oral or dental morbidity; and for whom a successful result cannot be expected from dental care provided under local anesthesia because of such condition and for whom a superior result can be expected from dental care provided under general anesthesia.

Medical documentation must be part of the medical record and available upon request.

Monitored Anesthesia Care (MAC)/general anesthesia and associated facility charges are covered in conjunction with dental surgery or procedures performed by a dentist, oral surgeon, or oral maxillofacial surgeon when it meets the above criteria and there is an appropriately trained and licensed professional to both administer and monitor MAC/general anesthesia in EITHER of the following locations:

- A properly-equipped and staffed office or clinic;
- A hospital or outpatient surgery center

Services that do not meet the criteria of this policy will not be considered medically necessary.

Please refer to Medical Policy **A-1** for more information.

Diagnosis codes revised for automatic external defibrillators.

Highmark Delaware is revising diagnosis codes for wearable defibrillators. The new guidelines will become effective Sept. 1, 2014.

Diagnosis codes for wearable defibrillators have been revised. These diagnosis codes will affect procedure codes K0606, K0607, K0608, and K0609.

Please refer to Medical Policy **E-58** for more information.

New criteria for Aloxi®

Highmark Delaware is updating its coverage criteria for Aloxi®. The new guidelines will become effective Sept. 1, 2014.

Aloxi may be considered medically necessary when any of the following criteria are met:

- Prevention of chemotherapy induced nausea or vomiting from low or minimally emetogenic cancer chemotherapy for members who have a treatment failure or contraindication to granisetron (Kytril) and ondansetron (Zofran); or

- Prevention of acute nausea or vomiting associated with initial and repeat courses of moderate or highly emetogenic cancer chemotherapy; or

- Prevention of postoperative nausea and vomiting (PONV) and there is a treatment failure or contraindication to ondansetron (Zofran).

Palonosetron hydrochloride (Aloxi) injection performed for indications other than those listed above will be denied as not medically necessary.

For additional information refer to the following link:
http://www.nccn.org/professionals/physician_gls/pdf/antiemesis.pdf.

NOTE: Dosage recommendations per the FDA label.

Please refer to Medical Policy **I-36** for more information.

New policy created for injectable granulocyte colony–stimulating factors

Effective Sept. 1, 2014, Highmark Delaware will have a new medical policy for filgrastim (Neupogen®) and pegfilgrastim (Neulasta®).

Filgrastim (Neupogen) may be considered medically necessary when used for any of the following:

A. Primary prophylaxis of febrile neutropenia (FN) in individuals with a risk of FN of 20% or *greater* based on chemotherapy regimen.
B. Primary prophylaxis of developing FN *is* greater than or equal to 10% and less than or equal to 20% based on chemotherapy regimen and individuals have one or more of the following risk factors for FN:
    - Age greater than 65 years; or
    - Poor performance status; or
    - Previous episodes of FN; or
    - History of previous chemotherapy or radiation therapy; or
    - After completion of combined chemoradiotherapy; or
    - Bone marrow involvement by tumor producing cytopenias; or
    - Preexisting neutropenia; or
    - Poor nutritional status; or
    - Poor renal function; or
    - Liver dysfunction (i.e., elevated bilirubin); or
    - The presence of open wounds or active infections; or
    - Recent surgery (generally within the past 12 weeks); or
    - Advanced cancer; or
    - Other serious comorbidities.
C. Secondary prophylaxis of FN in individuals who experienced a neutropenic complication from a prior cycle of chemotherapy (for which primary prophylaxis was not received), in which a reduced dose may compromise disease-free or overall survival or treatment outcome.
D. Adjunctive treatment of individuals with FN and high risk for infection-associated complications as demonstrated by any of the following:
    - Expected prolonged (greater than 10 days) and profound (less than 0.1 x 10^9/L) neutropenia; or
    - Age greater than 65 years; or
    - Uncontrolled primary disease; or
    - Pneumonia; or
    - Hypotension and multi organ dysfunction (sepsis syndrome); or
    - Invasive fungal infection; or
    - Hospitalized at the time of the development of fever.
E. In an individual with acute lymphocytic leukemia (ALL) after completion of the first few days of initial induction chemotherapy or first post-remission course of chemotherapy; or
F. Use in adult individuals with acute myeloid leukemia (AML) shortly after the completion of induction or repeat induction chemotherapy, or after the completion of consolidation chemotherapy for AML; or
G. Treatment of moderate to severe aplastic anemia; or
H. Treatment of severe neutropenia in individuals with hairy cell leukemia; or

I. In an individual with myelodysplastic syndromes (MDS) with severe neutropenia (absolute neutrophil count (ANC) less than or equal to 500 mm^3 or experiencing recurrent infection; or
J. In an individual receiving dose dense therapy (treatment given more frequently, such as every two weeks instead of every three weeks) for adjuvant treatment of breast cancer; or
K. Chronic administration to reduce the incidence and duration of sequelae of neutropenia (e.g., fever, infections, oropharyngeal ulcers) in symptomatic individuals with congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia; or
L. Treatment of (non-chemotherapy) drug-induced neutropenia; or
M. Treatment of low neutrophil counts in individuals with glycogen storage disease type 1b; or
N. Treatment for neutropenia associated with human immunodeficiency virus (HIV) infection and antiretroviral therapy; or
O. In individuals receiving radiation therapy in the absence of chemotherapy if prolonged delays secondary to neutropenia are expected; or
P. After accidental or intentional total body radiation of 3 to 10 Grays (Gy); or
Q. After autologous hematopoietic progenitor stem cell transplant (HPCT/HSCT); or
R. To mobilize progenitor cells into peripheral blood for collection by leukapheresis, as an adjunct to peripheral blood/hematopoietic stem cell transplantation (PBSCT/PHSCT); or
S. Use as an alternate or adjunct to donor leukocyte infusions (DLI) in individuals with leukemic relapse after an allogeneic hematopoietic stem cell transplant.

Pegfilgrastim (Neulasta™) may be considered medically necessary when used for any of the following:

A. Primary prophylaxis of febrile neutropenia (FN) in individuals with a risk of FN of 20% or greater based on chemotherapy regimen.
B. Primary prophylaxis of developing FN is greater than or equal to 10% and less than or equal to 20% based on chemotherapy regimen and individuals have one or more of the following risk factors for FN:
    - Age greater than 65 years; or
    - Poor performance status; or
    - Previous episodes of FN; or
    - History of previous chemotherapy or radiation therapy; or
    - After completion of combined chemoradiotherapy; or
    - Bone marrow involvement by tumor producing cytopenias; or
    - Preexisting neutropenia; or
    - Poor nutritional status; or
    - Poor renal function; or
    - Liver dysfunction (i.e., elevated bilirubin); or
    - The presence of open wounds or active infections; or
    - Recent surgery (generally within the past 12 weeks); or
    - Advanced cancer; or
    - Other serious comorbidities.
C. Secondary prophylaxis of FN in individuals who experienced a neutropenic complication from a prior cycle of chemotherapy (for which primary prophylaxis was not received), in which a reduced dose may compromise disease-free or overall survival or treatment outcome.
D. Adjunctive treatment of individuals with FN and high risk for infection-associated complications as demonstrated by any of the following:
    - Expected prolonged (greater than 10 days) and profound (less than 0.1 x 109/L) neutropenia; or
    - Age greater than 65 years; or
    - Uncontrolled primary disease; or
    - Pneumonia; or

- Hypotension and multi organ dysfunction (sepsis syndrome); or
- Invasive fungal infection; or
- Hospitalized at the time of the development of fever.

E. In an individual with acute lymphocytic leukemia (ALL) after completion of the first few days of initial induction chemotherapy or first post-remission course of chemotherapy; or
F. In an individual with myelodysplastic syndromes (MDS) with severe neutropenia (absolute neutrophil count (ANC) less than or equal to 500 mm3 or experiencing recurrent infection; or
G. In an individual receiving dose dense therapy (treatment given more frequently, such as every two weeks instead of every three weeks) for adjuvant treatment of breast cancer; or
H. After autologous hematopoietic progenitor stem cell transplant (HPCT/HSCT).

The use of colony stimulating factors (filgrastim and pegfilgrastim) is considered not medically necessary for any of the following:

A. As prophylaxis for FN, except when criteria above are met; or
B. As treatment of neutropenia in individuals who are afebrile, except when criteria above are met; or
C. As adjunctive therapy in individuals with uncomplicated febrile neutropenia, defined as: fever less than 10 days duration, no evidence of pneumonia, cellulitis, abscess, sinusitis, hypotension, multi-organ dysfunction, or invasive fungal infection; and no uncontrolled malignancies; or
D. Chemo sensitization of myeloid leukemias; or
E. As prophylaxis for FN during concomitant chemotherapy and radiation therapy; or
F. Continued use if no response is seen within 28-42 days (individuals who have failed to respond within this time frame are considered non-responders); or
G. For uses not meeting the criteria above.

NOTE: Coverage for pegfilgrastim is determined according to individual or group customer benefits.

NOTE: Dosage recommendations per the FDA label.

Please refer to Medical Policy **I-88** for more information.

Vivitrol® intramuscular formulation considered medically necessary when criteria is met

Effective June 16, 2014, Highmark Delaware may consider the intramuscular formulation of Vivitrol® medically necessary for the initial treatment of alcohol or opioid dependence when the following criteria are met:

The individual:
- must currently be in treatment for alcohol or opioid addiction;
- must be currently receiving ongoing psychosocial support;
- has had an initial response and tolerates oral naltrexone, but is unable to comply with daily dosing;
- is able to abstain from alcohol and opioids (including buprenorphine and methadone)for at least 7 days in an outpatient setting prior to treatment initiation;
- is not actively using alcohol or opioids at the time of initial injectable naltrexone (Vivitrol) administration

Ongoing treatment with injectable naltrexone (Vivitrol) may be considered medically necessary for the individual when the additional criteria are met.

Coverage subject to review every six months.

Please refer to Medical Policy **I-92** for more information.

New criteria for brain natriuretic peptide (BNP)

Highmark Delaware is updating the coverage criteria for Biomarkers in Risk Assessment and Management of Cardiovascular Disease. The updated guidelines will become effective Sept. 1, 2014.

The measurement of plasma brain natriuretic peptide (BNP) or NT-proBNP may be medically necessary for ANY ONE of the following indications:

- differentiating heart failure from pulmonary disease in a dyspneic individual; or
- monitoring response to treatment for heart failure; or
- risk stratification in a suspected acute coronary syndrome (ACS)

The measurement of plasma BNP or NT-proBNP testing for any other indication is considered experimental/investigational.

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

Post-cryptogenic cardiac monitoring considered experimental/investigational

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.

Criteria established for multiple procedure payment reduction (MPPR) for the professional component of certain diagnostic imaging procedures

In accordance with The Patient Protection and Affordable Care Act of 2010 (ACA), Highmark Delaware is developing a new Medical Policy X-70, titled Multiple Procedure Payment Reduction (MPPR) for the Professional Component of Certain Diagnostic Imaging Procedures, to address multiple procedure payment guidelines for the professional component of certain diagnostic imaging procedures. This new criteria will become effective Sept. 1, 2014.

When certain diagnostic imaging services or procedures are performed for the same patient during the same imaging session on the same date of service by the same physician, payment will be made at 100% for the professional component of the imaging procedure with the highest allowance.

For the additional imaging services performed for the same patient during the same imaging session on the same date of service by the same physician, payment for the professional component portion only will be reduced to 75% of the allowance for the professional component.

Please refer to Medical Policy **X-70** for more information.

Criteria established for multi-panel gene expression test

Effective Sept. 1, 2014, Highmark Delaware may consider the Multi-panel Gene Expression Test (e.g., Afirma® Thyroid FNA Analysis) medically necessary when ALL three (3) of the following criteria are met:

1. Patients have an indeterminate follicular pathology on fine needle aspiration; and
2. To evaluate adult patients (21 or older) with nodules ≥ 1 cm in size; and
3. Patients with one or more thyroid nodules with a history or characteristics suggesting malignancy including but not limited to:
    - Nodule growth over time; or
    - Family history of thyroid cancer; or
    - Hoarseness, difficulty swallowing or breathing; or
    - History of exposure to ionizing radiation; or
    - Hard nodule compared with rest of gland consistency; or
    - Presence of cervical adenopathy

Note: Indeterminate includes but is not limited to follicular lesion of undetermined significance (FLUS), atypia of undetermined significance (AUS) and (suspicious for) Hürthle/follicular neoplasm.

This test is expected to be performed once per patient lifetime. Should the unlikely situation of a second, unrelated thyroid nodule with indeterminate pathology occur, coverage may be considered upon review with support documentation.

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

Criteria revised for allogeneic and autologous HSCT for acute lymphoblastic leukemia in adults and children

Highmark Delaware is revising the coverage criteria for allogeneic and autologous HSCT for acute lymphoblastic leukemia in adults and children. Effective June 16, 2014, the following guideline was added to the existing criteria for allogeneic and autologous HSCT for acute lymphoblastic leukemia (ALL) in adults and children.

Autologous HSCT is considered experimental/investigational to treat adult ALL in second or greater remission or those with refractory disease.

Please refer to Medical Policy **S-220** for more information.

Clinical criteria added for myoelectric prostheses for the upper limb

Effective Sept. 1, 2014, Highmark Delaware will add limitations of coverage for myoelectric prostheses for the upper limb.

Upper myoelectric prostheses and myoelectric hand prostheses would be contraindicated and not medically necessary in ANY ONE of the following circumstances:

- Patients that routinely lift heavy items; or
- Environmental exposure to dirt, dust, grease, water and solvents; or
- Upper extremity residual limb neuromas or phantom pain exacerbated by upper extremity prosthesis use.

A prosthesis with individually powered digits (L6715), including a partial hand prosthesis (L6025), is considered experimental/investigational and, therefore, not covered because the safety and/or effectiveness of this service cannot be established by review of the available published peer-reviewed literature. A participating preferred, or network provider can bill the member for the denied service.

Terminal devices (L6704) are considered not medically necessary when used solely for activities related to sports or recreation. Terminal devices (L6704) may be considered medically necessary for work or when essential to activities of daily living.

High-definition silicone used to make prosthesis resemble a patient's skin is considered cosmetic.

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

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

Medical criteria for arthrocentesis or needling of a bursa and trigger point injections

Effective Sept. 1, 2014, Highmark Delaware will consider arthrocentesis or needling of a bursa and trigger point injections as approved when clinical criteria is met.

Arthrocentesis or needling of a bursa

Arthrocentesis or needling of a bursa may be considered medically necessary when ALL of the following criteria are met:

- Conservative therapy (rest area and avoid activity, cryotherapy, compression dressings, elevation of affected area above heart, other modalities like electrical stimulation/ultrasonography/phonophoresis, NSAIDs, or corticosteroid injections) to control pain and inflammation has failed, and
- Affected area continues with symptoms of severe pain along with swelling and inflammation, and
- Movement of joint remains limited due to pain, and
- The response to therapy must be documented for medical review prior to additional therapy authorizations.

Trigger point injections

Trigger point injections (TPI) with a local anesthetic with or without steroid may be considered medically necessary when ALL of the following general and specific criteria are met:

General criteria

- There is a regional pain complaint; and
- A neurological, orthopedic or musculoskeletal system evaluation, which includes the member's description of pain as it relates to location, quality, severity, duration, timing, context, and modifying factors, followed by a physical examination of associated signs and symptoms; and
- Conservative therapy (for example, physical or chiropractic therapy, oral analgesia, steroids, relaxants or activity modification) fails or is not feasible; and
- When necessary to facilitate mobilization and return to activities of daily living, an aggressive regimen of physical therapy or other therapeutic modalities; and
- The response to therapy must be documented for medical review prior to additional therapy authorizations.

Specific criteria

- Pain complaint or altered sensation in the expected distribution of referred pain from a trigger point; and
- Taut band palpable in an accessible muscle when the trigger point is myofascial; and
- Exquisite spot tenderness at one point along the length of the taut band when the pain is myofascial; and
- Some degree of restricted range of motion of the involved muscle or joint, when measurable; and
- The above specific criteria are associated with at least ONE of the following MINOR CRITERIA:
    - Reproduction of clinical pain complaint or altered sensation by pressure on the tender spot; or

- Local response (twitch) elicited by snapping palpation at the tender spot or by needle insertion into the tender spot; or
- Pain alleviation by elongating (stretching) the muscle or by injecting the tender spot.

Trigger point injections (TPI) with a local anesthetic with or without steroid may be considered medically necessary for the treatment of pain associated with fibromyalgia when ALL of the American College of Rheumatology diagnostic criteria for fibromyalgia are met.

These are:

- History of widespread pain for at least 3 months. To be considered wide spread, the pain must be present on both right and left sides and both above and below the waist. In addition, axial skeletal pain (cervical spine or anterior chest or thoracic spine or low back) must be present. In this definition, shoulder and buttock pain is considered as pain for each involved side. "Low back pain" is considered lower segment pain, and
- Pain, on digital palpation, must be present in at least 11 of the following 18 sites:
    - Occiput: Bilateral, at the suboccipital muscle insertions;
    - Low cervical: bilateral, at the anterior aspects of the intertransverse spaces at C5-C7;
    - Trapezius: bilateral, at the midpoint of the upper border;
    - Supraspinatus: bilateral, at origins, above the scapula spine near the medial border;
    - Second rib: bilateral, at the second costochondral junctions, just lateral to the junctions on upper surfaces;
    - Lateral epicondyle: bilateral, 2 cm distal to the epicondyles;
    - Gluteal: bilateral, in upper outer quadrants of buttocks in anterior fold of muscle;
    - Greater trochanter: bilateral, posterior to the trochanteric prominence;
    - Knee: bilateral, at the medial fat pad proximal to the joint line

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

Magnetic resonance guided focused ultrasound surgery considered experimental/investigational for all indications

Effective Sept. 1, 2014, Highmark Delaware will consider magnetic resonance guided focused ultrasound surgery experimental/investigational for all indications.

Magnetic resonance imaging- (MRI) guided high intensity ultrasound surgery (MRgFUS)(e.g., ExAblate)(C9734, 0071T, 0072T) is considered experimental/investigational. The published data regarding this procedure are inadequate to permit scientific conclusions regarding the long-term safety and effect on health outcomes. MRI-guided high intensity ultrasound ablation is not covered and not eligible for payment. A participating, preferred, or network provider can bill the member for this service.

MRgFUS is considered experimental/investigational for treatment of uterine fibroids, localized prostate cancer, chronic neuropathic pain, pain palliation in patients with bone metastases, and any other applications.

Please refer to Medical Policy **S-186** for more information.

Coverage criteria established for irinotecan (Camptosar®)

Highmark Delaware is updating its coverage criteria for irinotecan (Camptosar®). The new guidelines will become effective Sept. 1, 2014.

Irinotecan (Camptosar) may be considered medically necessary for the following indications when specific criteria are met:

- Colon Cancer (Adenocarcinoma)
- Bone Cancer – Ewing's Sarcoma Family of Tumors
- Central Nervous System Cancers – Anaplastic Gliomas and Glioblastomas
- Cervical Cancer (Squamous cell carcinoma; Adenocarcinoma)
- Esophageal and Esophagogastric Junction Cancers (Squamous cell carcinoma; Adenocarcinoma)
- Gastric Cancer (Adenocarcinoma)
- Non-Small Cell Lung Cancer (NSCLC)(Adenocarcinoma [with mixed subtypes]; Squamous cell carcinoma; Large cell carcinoma)
- Ovarian Cancer – Epithelial Ovarian Cancer/Fallopian Tube Cancer/Primary Peritoneal Cancer
- Pancreatic Adenocarcinoma
- Rectal Cancer (Adenocarcinoma)
- Small Cell Lung Cancer (SCLC)(Small cell carcinoma)
- Soft Tissue Sarcoma – Rhabdomyosarcoma

The use of irinotecan (Camptosar) for all other indications is considered experimental/investigational, and therefore, non-covered. Peer reviewed literature does not support the use of irinotecan (Camptosar) for any indications other than those listed on the medical policy.

For further information, refer to Medical Policy **I-109** Irinotecan (Camptosar®).

CODES

New codes

Here are 39 new codes that will be available for your reporting purposes on July 1, 2014.

Code	Terminology	Effective
0347T	Placement of interstitial device(s) in bone for radiostereometric analysis (RSA)	07/01/2014
0348T	Radiologic examination, radiostereometric analysis (RSA); spine, (includes, cervical, thoracic and lumbosacral, when performed)	07/01/2014
0349T	Radiologic examination, radiostereometric analysis (RSA); upper extremity(ies), (includes shoulder, elbow and wrist, when performed)	07/01/2014
0350T	Radiologic examination, radiostereometric analysis (RSA); lower extremity(ies), (includes hip, proximal femur, knee and ankle, when performed)	07/01/2014
0351T	Optical coherence tomography of breast or axillary lymph node, excised tissue, each specimen; real time intraoperative	07/01/2014
0352T	Optical coherence tomography of breast or axillary lymph node, excised tissue, each specimen interpretation and report, real time or referred	07/01/2014
0353T	Optical coherence tomography of breast, surgical cavity; real time intraoperative	07/01/2014

Code	Terminology	Effective
0354T	Optical coherence tomography of breast, surgical cavity; interpretation and report, real time or referred	07/01/2014
0355T	Gastrointestinal tract imaging, intraluminal (e.g., capsule endoscopy), colon, with interpretation and report	07/01/2014
0356T	Insertion of drug-eluting implant (including punctual dilation and implant removal when performed) into lacrimal canaliculus, each	07/01/2014
0358T	Bioelectrical impedance analysis whole body composition assessment, supine position, with interpretation and report.	07/01/2014
0359T	Behavior identification assessment, by the physician or other qualified health care professional, face-to-face with patient and caregiver(s), includes administration of standardized and non-standardized tests, detailed behavioral history, patient observation and caregiver interview, interpretation of test results, discussion of findings and recommendations with the primary guardian(s)/caregiver(s), and preparation of report.	07/01/2014
0360T	Observational behavioral follow-up assessment, includes physician or other qualified health care professional direction with interpretation and report, administered by one technician; first 30 minutes of technician time, face-to-face with the patient.	07/01/2014
0361T	Observational behavioral follow-up assessment, includes physician or other qualified health care professional direction with interpretation and report, administered by one technician; each additional 30 minutes of technician time, face-to-face with the patient (List separately in addition to code for primary service)	07/01/2014
0362T	Exposure behavioral follow-up assessment, includes physician or other qualified health care professional direction with interpretation and report, administered by physician or other qualified health care professional with the assistance of one or more technicians; first 30 minutes of technician(s) time, face-to-face with the patient	07/01/2014
0363T	Exposure behavioral follow-up assessment, includes physician or other qualified health care professional direction with interpretation and report, administered by physician or other qualified health care professional with the assistance of one or more technicians; each additional 30 minutes of technician(s) time, face-to-face with the patient (List separately in addition to code for primary procedure)	07/01/2014
0364T	Adaptive behavior treatment by protocol, administered by technician, face-to-face with one patient; first 30 minutes of technician time	07/01/2014

Code	Terminology	Effective
0365T	Adaptive behavior treatment by protocol, administered by technician, face-to-face with one patient; each additional 30 minutes of technician time (List separately in addition to code for primary procedure)	07/01/2014
0366T	Group adaptive behavior treatment by protocol, administered by technician, face-to-face with two or more patients; first 30 minutes of technician time.	07/01/2014
0367T	Group adaptive behavior treatment by protocol, administered by technician, face-to-face with two or more patients; each additional 30 minutes of technician time (List separately in addition to code for primary procedure).	07/01/2014
0368T	Adaptive behavior treatment with protocol modification administered by physician or other qualified health care professional with one patient; first 30 minutes of patient face-to-face time.	07/01/2014
0369T	Adaptive behavior treatment with protocol modification administered by physician or other qualified health care professional with one patient; each additional 30 minutes of patient face-to-face time (List separately in addition to code for primary procedure).	07/01/2014
0370T	Family adaptive behavior treatment guidance, administered by physician or other qualified health care professional (without the patient present).	07/01/2014
0371T	Multiple-family group adaptive behavior treatment guidance, administered by physician or other qualified health care professional (without the patient present)	07/01/2014
0372T	Adaptive behavior treatment social skills group, administered by physician or other qualified health care professional face-to-face with multiple patients	07/01/2014
0373T	Exposure adaptive behavior treatment with protocol modification requiring two or more technicians for severe maladaptive behavior(s); first 60 minutes of technicians' time, face-to-face with patient	07/01/2014
0374T	Exposure adaptive behavior treatment with protocol modification requiring two or more technicians for severe maladaptive behavior(s); each additional 30 minutes of technicians' time face-to-face with patient (List separately in addition to code for primary procedure)	07/01/2014
0006M	Oncology (hepatic), mRNA expression levels of 161 genes, utilizing fresh hepatocellular carcinoma tumor tissue, with alpha-fetoprotein level, algorithm reported as a risk classifier	07/01/2014
0007M	Oncology (gastrointestinal neuroendocrine tumors), real-time	07/01/2014

Code	Terminology	Effective
	PCR expression analysis of 51 genes, utilizing whole peripheral blood, algorithm reported as a nomogram of tumor disease index	
0008M	Oncology (breast), mRNA analysis of 58 genes using hybrid capture, on formalin-fixed paraffin-embedded (FFPE) tissue, prognostic algorithm reported as a risk score	07/01/2014
3126F	Esophageal biopsy report with statement about dysplasia (present, absent, or indefinite, and if present contains appropriate grading) (PATH)	07/01/2014
Q9970	Injection, ferric carboxymaltose, 1 mg	07/01/2014
Q9974	Injection, morphine sulfate, preservative-free, for epidural or intrathecal use, 10 mg	07/01/2014
S0144	Injection, propofol, 10 mg	07/01/2014
S1034	Artificial pancreas device system (e.g., low glucose suspend [LGS] feature) including continuous glucose monitor, blood glucose device, insulin pump and computer algorithm that communicates with all of the devices	07/01/2014
S1035	Sensor; invasive (e.g., subcutaneous), disposable, for use with artificial pancreas device system, 1 unit = 1 day supply	07/01/2014
S1036	Transmitter; external, for use with artificial pancreas device system	07/01/2014
S1037	Receiver (monitor); external, for use with artificial pancreas device system	07/01/2014
L1	Provider attestation that the hospital laboratory test(s) is not packaged under the hospital OPPS	07/01/2014
SZ	Habilitative Services	07/01/2014