Artificial Intervertebral Discs Criteria Revised (corrected article)

Highmark Blue Shield has revised clinical criteria for Artificial Intervertebral Disc Replacement. This revised Medical Policy will apply to facility and professional providers. The effective date for the revised criteria is March 30, 2015.

Place of Service: Inpatient/Outpatient

The following criteria has been added to the medical policy in addition to the current established criteria:

Cervical Intervertebral Disc Replacement
Cervical intervertebral disc replacement or spinal arthroplasty may be considered medically necessary when performed at one level (22856, 22861, 22864) in individuals with symptomatic cervical degenerative disc disease (e.g., radicular neck and/or arm pain and/or functional/neurological deficit) or herniated disc when ALL of the following criteria are met:

- Use of an FDA approved device; and at least ONE of the following confirmed by radiographic studies (e.g., CT, MRI, x-rays)
  - Herniated nucleus pulposus OR
  - Spondylosis defined by presence of osteophytes,
  - And/or visible loss of disc height (not more than 50%) as compared to adjacent levels
- The operative level is at one level from C3 to C7; and
- The individual does not have a previously implanted cervical artificial intervertebral disc device at another cervical level; and
- The individual has not had a prior spinal fusion at an adjacent cervical level; and
- The procedure is performed in a skeletally mature individual; and
- The individual has failed at least six weeks of physician monitored/supervised conservative management which includes **ALL** of the following components:
  a. Exercise including core stabilization exercises; and
  b. Nonsteroidal and/or steroidal medication (unless contraindicated); and
  c. Physical therapy, including passive and active treatment modalities; and
  d. Activity/lifestyle modification

**Contraindications**

A cervical disc should not be implanted in patients with the following conditions:

- Active systemic infection or localized infection at the surgical site
- Osteoporosis defined as a DEXA bone mineral density T-score equal to or worse than -3.5 or a T-score equal to or worse than -2.5 with vertebral compression fracture, or osteopenia defined as a DEXA bone mineral density T-score ≤ -1.0
- Allergy or sensitivity to titanium, aluminum or vanadium
- Marked cervical instability on neutral resting lateral or flexion/extension radiographs; translation >3.5mm and/or >11° rotational difference from that of either adjacent level
- Severe spondylosis at the level to be treated, characterized by bridging osteophytes, loss of disc height >50%, an absence of motion (<2°) as this may lead to a limited range of motion and may encourage bone formation (e.g. heterotopic ossification, fusion)
- Severe facet joint arthropathy
- Significant cervical anatomical deformity or clinically compromised vertebral bodies at the affected level due to current or past trauma (e.g., by radiographic appearance of fracture callus, malunion or nonunion) or disease (e.g., ankylosing spondylitis, rheumatoid arthritis)
- Significant kyphotic deformity or significant reversal of lordosis; or
- Symptoms attributed to more than one cervical level

Artificial intervertebral disc replacement for the thoracic spine is considered experimental/investigational due to insufficient evidence in the peer reviewed published literature regarding its effectiveness and safety. There are currently no FDA approved thoracic artificial disc devices to support thoracic artificial disc replacement. Artificial intervertebral disc thoracic spine replacement is not covered and is not eligible for payment. A participating preferred, or network provider can bill the member for this service.

Please refer to Medical Policy S-187 for complete policy review.
REMINDER: Sleep Studies

Highmark Blue Shield is providing a reminder to all Providers.

OUT-OF-CENTER SLEEP TESTING (OCST)/PORTABLE MONITORING (PM)
UNATTENDED SLEEP STUDIES

Prior authorization is not required for a home based sleep study however, medical necessity criteria must be met in accordance with the clinical criteria established in the policy. Prior to scheduling a home-based sleep study, please refer to Medical Policy Z-8 Diagnosis and Treatment of Obstructive Sleep Apnea for Adults for detailed information.

FACILITY/LABORATORY ATTENDED SLEEP STUDIES

Requires prior authorization.

Coverage Established for High Resolution Anoscopy (HRA)

Highmark Blue Shield has established new clinical criteria for High Resolution Anoscopy (HRA). This new medical policy will apply to professional providers only. The effective date is June 1, 2015.

Place of Service: Outpatient

High Resolution Anoscopy (HRA) may be considered medically necessary for ANY ONE of the following conditions:

- Abnormal anal physical findings (e.g., anogenital warts, hypo-pigmented or hyper-pigmented plaques/lesions, lesions that bleed, high-grade suspicious intraepithelial lesion or any other lesion of uncertain etiology)
- anal dysplasia found in cytology/biopsy

High Resolution Anoscopy may be considered medically necessary for biopsy and ablation of high-grade anal intraepithelial neoplasia.

All other uses of HRA are considered experimental and investigational, including screening of asymptomatic persons for anal dysplasia and anal cancer, and are non-covered. A participating preferred or network provider can bill the member for the non-covered service.

For further information, refer to Medical Policy M-76, High Resolution Anoscopy (HRA).
New Criteria for Mastectomy and Reconstructive Surgery

Highmark Blue Shield has established new clinical criteria for mastectomy and reconstructive surgery. This policy will apply to both professional provider and facility claims. The effective date is June 1, 2015.

Place of Service: Inpatient/Outpatient

Reconstructive breast surgery may be considered medically necessary after a medically necessary mastectomy, accidental injury, or trauma. Medically necessary mastectomies are most typically done as treatment for cancer. Reconstruction may be performed by an implant-based approach or through the use of autologous tissue.

Explantation of a silicone gel-filled breast implant may be considered medically necessary in all cases for a documented implant rupture, infection, extrusion, Baker class IV contracture, or surgical treatment of breast cancer.

Explantation of a ruptured saline-filled breast implant may be considered medically necessary only in those patients who had originally undergone breast implantation for reconstructive purposes. Otherwise, indications for the explantation of a saline-filled implant are similar to those of a silicone-filled implant.

Explantation of a breast implant associated with a Baker class III contracture may be considered medically necessary only in those patients who had originally undergone breast implantation for reconstructive purposes.

Reconstructive breast surgery after explantation of an implant is considered medically necessary only in those patients who had originally undergone breast implantation for reconstructive purposes.

Surgery on the contralateral breast to produce a symmetrical appearance after removal of an implant and reimplantation is considered reconstructive when the implant was originally placed for reconstructive purposes in an individual with a history of mastectomy, lumpectomy or treatment of breast cancer.

The following indications for explantation of implants are considered not medically necessary:

- Systemic symptoms, attributed to connective tissue diseases, autoimmune diseases, etc.; or
- Patient anxiety; or
- Baker class III contractures in patients with implants for cosmetic purposes; or
- Rupture of a saline implant in patients with implants for cosmetic purposes; or
- Pain not related to contractures or rupture.

The current indications for nipple sparing mastectomy (NSM), in the treatment of early invasive breast cancer remain uncertain. Nipple sparing mastectomy is considered to be experimental and investigational. The oncologic safety as well as functional and aesthetic outcomes remains unproven.

For more information, please refer to Medical Policy S-129 Mastectomy and Reconstructive Surgery.
Criteria Revised for Surgical Treatment of Varicose Veins

Highmark Blue Shield has revised the criteria for the Surgical Treatment of Varicose Veins; effective June 1, 2015. The following sections outline the revised clinical content:

ENDOVENOUS ABLATION and ENDOMECHANICAL ABLATION

Non-covered

Mechanochemical Ablation (MCA)

Mechanochemical ablation using the ClariVein® system is considered experimental/investigational and therefore, non-covered. Scientific evidence does not demonstrate the safety and efficacy of this treatment.

ACCESSORY SAPHENOUS VEINS

Treatment of accessory saphenous veins by surgery (ligation and stripping) or endovenous radiofrequency or laser ablation may be considered medically necessary for symptomatic varicose veins/venous insufficiency when the following criteria have been met.

Coverage criteria

- Incompetence of the accessory saphenous vein is isolated, OR the GSV or SSV had been previously eliminated (at least three (3) months); and
- There is demonstrated accessory saphenous reflux; and
- Ultrasound demonstrates vein size at least 5 mm in diameter; and

There is documentation of one (1) or more of the following indications:

- Ulceration secondary to venous stasis that fails to respond to compressive therapy; or
- Recurrent superficial thrombophlebitis that fails to respond to compressive therapy; or
- Hemorrhage or recurrent bleeding episodes from a ruptured superficial varicosity; or
- **Symptomatic** varicose veins: Persistent pain, swelling, itching, burning, or other symptoms are associated with saphenous reflux, AND the symptoms significantly interfere with activities of daily living, AND conservative management including compression therapy for at least 3 months has not improved the symptoms.

Sclerotherapy (LIQUID OR MICROFOAM)

Non-covered

Varithena™ (formerly known as Varisolve®), BTG Plc, London) is a sclerosant microfoam made with a proprietary gas mix and is considered experimental/investigational, and therefore, not covered. Scientific evidence does not demonstrate the effectiveness of this treatment.

Please refer to Medical Policy S -55 Surgical Treatment of Varicose Veins for additional information.
Ablation Procedures for Peripheral Neuromas Considered Experimental/Investigational

Highmark Blue Shield has determined Ablation Procedures for Peripheral Neuromas as experimental/investigational. Medical policy Z-67 Ablation Procedures for Peripheral Neuromas will apply to both professional provider and facility claims. The effective date is June 1, 2015.

**Place of Service:** Outpatient

Please refer to Medical Policy Z-67 for more information.

Pre- and Post-Genetic Testing Required

Highmark Blue Shield will require pre- and post- genetic testing only when offered in a setting with adequately trained health care professionals. The effective date is June 1, 2015.

For further information, refer to Medical Policy L-33, Genetic Testing for Hereditary Breast and/or Ovarian Cancer.

Coverage Criteria Established for Treatment of Hereditary Angioedema (HAE)

Effective June 1, 2015, Highmark Blue Shield has established clinical criteria for treatment of hereditary angioedema (HAE). This policy is applicable to both professional and facility claims.

**Place of Service:** Outpatient

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

**C1 Esterase Inhibitor [Human] (Cinryze®)**

C1 Esterase Inhibitor [Human] (Cinryze) may be considered medically necessary when **ALL** of the following criteria are met:

**Hereditary Angioedema Type I and II**

- Administration is for routine **prophylaxis** against hereditary angioedema (HAE) attacks in adolescents (≥13 years of age) and adult patients diagnosed with HAE **AND**
- The individual must have a diagnosis of HAE where diagnosis is based on evidence of a low
C4 level (C4 less than 14 mg/dL; normal range 14 to 40 mg/dL, or C4 below the lower limit of normal as defined by the laboratory performing the test) AND ONE of the following laboratory tests*:

- A low C1 inhibitor (C1INH) antigenic level (C1INH less than 19 mg/dL; normal range 19 to 37 mg/dL, or C1INH antigenic level below the lower limit of normal as defined by the laboratory performing the test); OR
- A normal C1INH antigenic level (C1INH normal range to 19 to 37 mg/dL) and a low C1INH functional level (functional C1INH less than 50 %), OR
- Below the lower limit of normal as defined by the laboratory performing the test); AND

- History of severe attack(s) with swelling of hands, feet, limbs, face, intestinal tract or airway, AND
- Medications known to cause angioedema (i.e. ACE inhibitors, estrogens, angiotensin II receptor blockers) have been evaluated and discontinued when appropriate, AND
- Prior treatment with 17 alpha-alkylated androgens (e.g., danazol and stanozolol) or anti-fibrinolytic agents (e.g., tranexamic acid (Lysteda), aminocaproic acid (Amikar), tranexamic acid (Cyklokapron)) for HAE prophylaxis has been ineffective, not tolerated, or all are contraindicated.

### Hereditary Angioedema Type III

- Administration is for routine prophylaxis against hereditary angioedema (HAE) attacks in adolescents (≥13 years of age) and adult patients diagnosed with HAE AND
- Documented normal or near normal C4, C1INH antigen, and C1INH function; AND ONE of the following:
  - Demonstration of a F12 mutation that is associated with the disease; OR
  - A positive family history of angioedema AND
- History of severe attack(s) in the absences of concomitant hives with swelling of hands, feet, limbs, face, intestinal tract or airway, AND
- Medications known to cause angioedema (i.e. ACE inhibitors, estrogens, angiotensin II receptor blockers) have been evaluated and discontinued when appropriate, AND
- Prior treatment with 17 alpha-alkylated androgens (e.g., danazol and stanozolol) or anti-fibrinolytic agents (e.g., tranexamic acid (Lysteda), aminocaproic acid (Amikar), tranexamic acid (Cyklokapron)) for HAE prophylaxis has been ineffective, not tolerated, or all are contraindicated.

*Values defined by the laboratory performing the test.

**NOTE:** Dosage recommendations per the FDA label.

Icatibant (Firazyrr®), Ecallantide (Kalbitor®), C-1 Esterase Inhibitor [Human] (Berinert®)
and C1 esterase inhibitor [recombinant] (Ruconest®)

Hereditary Angioedema Type I and II

Icatibant (Firazyr), ecallantide (Kalbitor), C-1 Esterase Inhibitor [Human] (Berinert) or C1 esterase inhibitor [recombinant] (Ruconest®) may be considered medically necessary for the treatment of acute angioedema attacks when the following criteria are met:

- The individual meets the following age requirement:
  - Icatibant (Firazyr): ≥ 18 years
  - Ecallantide (Kalbitor): ≥ 12 years
  - C-1 esterase inhibitor [human] (Berinert): > 12 years
  - C1 esterase inhibitor [recombinant] (Ruconest®) >12 years; **AND**

- The individual must have a diagnosis* of hereditary angioedema (HAE), where diagnosis is based on evidence of a low C4 level (C4 less than 14 mg/dL; normal range 14 to 40 mg/dL, or C4 below the lower limit of normal as defined by the laboratory performing the test) **AND**
  - A low C1 inhibitor (C1INH) antigenic level (C1INH less than 19 mg/dL; normal range 19 to 37 mg/dL, or C1INH antigenic level below the lower limit of normal as defined by the laboratory performing the test); **OR**
  - A normal C1INH antigenic level (C1INH normal range to 19 to 37 mg/dL) and a low C1INH functional level (functional C1INH less than 50 %), **OR**
  - Below the lower limit of normal as defined by the laboratory performing the test); **AND**

- The individual must be experiencing at least 1 symptom of the moderate or severe attack (e.g., airway swelling, severe abdominal pain, facial swelling, nausea and vomiting, painful facial distortion); **AND**

- Medications known to cause angioedema (i.e. ACE inhibitors, estrogens, angiotensin II receptor blockers) have been evaluated and discontinued when appropriate.

Hereditary Angioedema Type III

Icatibant (Firazyr), Ecallantide (Kalbitor), C-1 Esterase Inhibitor [Human] (Berinert), or C1 esterase inhibitor [recombinant] (Ruconest) may be considered medically necessary in an individual who experiences attacks associated with HAE when the following criteria are met:

- The individual meets the following age requirements:
  - Icatibant (Firazyr): ≥ 18 years
  - Ecallantide (Kalbitor): ≥ 12 years
  - C-1 esterase inhibitor [human] (Berinert): > 12 years
  - C1 esterase inhibitor [recombinant] (Ruconest®) >12 years; **AND**

- Documented normal or near normal C4, C1INH antigen, and C1INH function; **AND**
ONE of the following:
  o Demonstration of a F12 mutation that is associated with the disease;
  o A positive family history of angioedema; AND
• History of severe attack(s) in the absences of concomitant hives with swelling of hands, feet, limbs, face, intestinal tract or airway, AND
• Medications known to cause angioedema (i.e. ACE inhibitors, estrogens, angiotensin II receptor blockers) have been evaluated and discontinued when appropriate, AND
• Prior treatment with 17 alpha-alkylated androgens (e.g., danazol and stanozolol) or anti-fibrinolytic agents (e.g., tranexamic acid (Lysteda), aminocaproic acid (Amikar), tranexamic acid (Cyklokapron)) for HAE prophylaxis has been ineffective, not tolerated, or all are contraindicated.

*According to an International Consensus Statement on Hereditary Angioedema testing must be performed more than once to confirm the diagnosis.

Refer to Medical Policy I-122 for additional information.

Refer to Pharmacy Policy J-141 for more information on Icatibant (Firazyr®), and Pharmacy Policy J-151 for Berinert and Ruconest.

New Policy Created for Urological Supplies

Highmark Blue Shield has established new clinical criteria for urological supplies. This new policy will apply to both professional provider and facility claims. The effective date is June 1, 2015.

Place of Service: Outpatient

The new policy contains medical necessity criteria, limitations, frequency, and lists covered and non-covered urological supplies.

For further information, refer to Medical Policy O-27, Urological Supplies.

New Procedure Code and Modifiers for Reporting

The following new code and modifiers will be available and effective for reporting purposes on April 1, 2015:

Q9975- Injection, Factor VIII, FC Fusion Protein (Recombinant), per iu
EX- Expatriate beneficiary
JF- Compounded drug
Modifier Q0 or Q1 Required When Reporting Clinical Trials

Reminder: Highmark Blue Shield requires providers to use modifier Q0 or Q1 when reporting clinical trials. This information can be found on Medical Policy G-27.

Facility Added to Infrared Coagulation of Hemorrhoids

Highmark Blue Shield Medical Policy S-170, Infrared Coagulation of Hemorrhoids, will apply to both professional provider and facility claims. The effective date is June 1, 2015.

Facility Added to Autonomic Nervous System Function Testing

Highmark Blue Shield Medical Policy M-61, Autonomic Nervous System Function Testing, will apply to both professional provider and facility claims, effective June 1, 2015.

Facility Added to Gender Reassignment Surgery

Highmark Blue Shield Medical Policy S-184, Gender Reassignment Surgery, will apply to both professional provider and facility claims, effective June 1, 2015.

Facility Now Applicable to Hematopoietic Stem-Cell Transplantation for Chronic Lymphocytic Leukemia and Small Lymphocytic Lymphoma

Effective June 1, 2015, Highmark Blue Shield’s policy on Hematopoietic Stem-Cell Transplantation for Chronic Lymphocytic Leukemia and Small Lymphocytic Lymphoma will apply to both professional provider and facility claims.
Facility Now Applicable to Hematopoietic Stem-Cell Transplantation for Multiple Myeloma and POEMS Syndrome

Highmark Blue Shield Medical Policy S-207, Hematopoietic Stem-Cell Transplantation for Multiple Myeloma and POEMS Syndrome will apply to both professional provider and facility claims effective June 1, 2015.

Facility Now Applicable to Non-Powered Negative Pressure Wound Therapy System

Effective June 1, 2015, Highmark Blue Shield's policy on Non-Powered Negative Pressure Wound Therapy System will apply to both professional provider and facility claims.

Facility Added to Enteral Nutrition

Highmark Blue Shield Medical Policy O-6, Enteral Nutrition will apply to both provider and facility claims effective June 1, 2015.

Facility Added to Thermography (Thermogram)

Highmark Blue Shield will apply both professional provider and facility claims to Medical Policy M-4, Thermography (Thermogram), effective June 1, 2015.

Facility Now Applicable to Parenteral Nutrition

Highmark Blue Shield Medical Policy O-16 Parenteral Nutrition will apply to both professional provider and facility claims effective June 1, 2015.
Facility Applied to Braces and Supports

Highmark Blue Shield Medical Policy O-8, Braces and Supports will apply to both professional provider and facility claims effective June 1, 2015.

Facility Added to Knee Orthosis

Highmark Blue Shield will apply both professional provider and facility claims to Medical Policy O-28, Knee Orthosis, effective June 1, 2015.

Facility Added to Hematopoietic Stem-Cell Transplantation for Non-Hodgkin Lymphomas

Highmark Blue Shield will apply both professional provider and facility claims to Medical Policy S-208, Hematopoietic Stem-Cell Transplantation for non-Hodgkin Lymphomas effective June 1, 2015.

Facility Applied to Hematopoietic Stem-Cell Transplantation for Acute Myeloid Leukemia

Highmark Blue Shield Medical Policy S-214, Hematopoietic Stem-Cell Transplantation for Acute Myeloid Leukemia will apply to both professional provider and facility claims effective June 1, 2015.

Facility Added to Lymphedema Therapy

Highmark Blue Shield will apply both professional provider and facility claims to Medical Policy Y-11, Lymphedema Therapy, effective June 1, 2015.
**Oxaliplatin (Eloxatin) Criteria Revised**

Highmark Blue Shield has revised the clinical criteria for the use of oxaliplatin (Eloxatin®) chemotherapy effective April 6, 2015. The clinical criteria have been aligned with most recent National Comprehensive Cancer Network (NCCN) compendia guidelines.

Please see Medical Policy I-87 for the revised guidelines per the NCCN.

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**Facility Applied to Eye Prosthesis**

Highmark Medical Policy Bulletin O-23, Eye Prosthesis will apply to both professional provider and facility claims effective June 1, 2015.

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**Facility Added to Ultraviolet Light Therapies**

Highmark Blue Shield Medical Policy Z-1, Ultraviolet Light Therapies, will apply to both provider and facility claims effective June 1, 2015.

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**Facility Added to Intra-Arterial/Intravenous Therapeutic Procedures**

Highmark Blue Shield Medical Policy S-82, Intra-Arterial/Intravenous Therapeutic Procedures will apply to both provider and facility claims effective June 1, 2015.

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**Facility Added to Diagnosis and Treatment of Obstructive Sleep Apnea in Children**

Highmark Blue Shield Medical Policy Z-64, Diagnosis and Treatment of Obstructive Sleep Apnea in Children, will apply to both provider and facility claims effective June 1, 2015.

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**Facility Added to Cardiac Event Detection Monitoring**

Highmark Blue Shield Medical Policy M-31 Cardiac Event Detection Monitoring, will apply to both professional and facility claims, effective June 1, 2015.
Facility Added to External Counterpulsation

Highmark Blue Shield’s Medical Policy M-52, External Counterpulsation (ECP), will apply to both professional provider and facility claims effective June 1, 2015.

Coverage Criteria Revised for Pegloticase (Krystexxa)

Effective March 23, 2015, Highmark Blue Shield has revised clinical criteria for Pegloticase (Krystexxa™).

Pegloticase (Krystexxa) is indicated for patients who meet the following criteria:

1. For the treatment of chronic gout in adult patients refractory to conventional therapy. Refractory will be defined as:
   - Failure to normalize serum uric acid to less than 6 mg/dL after three months of maximum medically appropriate dose of xanthine oxidase inhibitors (e.g., allopurinol, febuxostat) or
   - Contraindication to xanthine oxidase inhibitors.

2. Pegloticase is not recommended for the treatment of asymptomatic hyperuricemia. Adult patients must have a documented diagnosis of symptomatic gout. Symptomatic is defined as one of the following:
   - Greater than or equal to three gout flares in the previous 18 months or
   - Greater than or equal to one gout tophus or
   - Gouty arthritis.

**NOTE:** Dosage recommendations per the FDA label

Pegloticase should be administered in a healthcare setting by a healthcare provider prepared to manage anaphylaxis. Patients should receive pre-infusion medications (e.g. antihistamines, corticosteroids), to minimize infusion reactions. Glucose-6-phosphate dehydrogenase (G6PD) Deficiency: Before starting Pegloticase, patients at higher risk for G6PD deficiency (e.g. those of African and Mediterranean ancestry should be screened due to risk of hemolysis and methemoglobinemia). G6PD deficiency is contraindication for pegloticase.
Facility Now Applicable to Leuprolide Acetate (Lupron, Lupron Depot, Lutrepulse, Viadur)

Effective June 1, 2015, Highmark Blue Shield’s Medical Policy I-16 Leuprolide Acetate (Lupron, Lupron Depot, Lutrepulse, Viadur™) will apply to both professional provider and facility claims.

Facility Applied to Hematopoietic Stem-Cell Transplantation for Acute Myeloid Leukemia

Highmark Blue Shield Medical Policy S-214, Hematopoietic Stem-Cell Transplantation for Acute Myeloid Leukemia will apply to both professional provider and facility claims effective June 1, 2015.

Facility Now Applicable to Extracorporeal Photopheresis

Effective June 1, 2015, Highmark Blue Shield’s Medical Policy S-75 Extracorporeal Photopheresis, will apply to both professional provider and facility claims.

Revised Criteria for Allogeneic Stem-Cell Transplantation for Myelodysplastic Syndromes and Myeloproliferative Neoplasms

Highmark Blue Shield has revised the criteria for Allogeneic Stem-Cell Transplantation for Myelodysplastic Syndromes and Myeloproliferative Neoplasms. This revised medical policy will apply to professional provider claims, effective June 1, 2015.

Myeloablative allogeneic HSCT or reduced-intensity conditioning allogeneic HSCT for myelodysplastic syndromes and myeloproliferative neoplasms that does not meet the criteria is considered experimental/investigational.

Place of Service: Inpatient/Outpatient

For further information, refer to Medical Policy S-209, Allogeneic Stem-Cell Transplantation for Myelodysplastic Syndromes and Myeloproliferative Neoplasms.
Facility Guidelines Added to Hearing Aids and Audiological Testing

Highmark Blue Shield’s Medical Policy S-9, Hearing Aids and Audiological Testing will apply to both professional provider and facility claims effective June 1, 2015.

Medical Necessity Criteria and Facility Added to Team Surgery Policy

Highmark Blue Shield has established new clinical criteria for Team Surgery. This change will apply to both professional provider and facility claims. The effective date is June 1, 2015.

Place of Service: Inpatient/Outpatient

To be eligible for reimbursement, the component surgery billed by a member of the surgical team must be a medically necessary covered service if performed alone and operative records may be requested to determine medical necessity and accurate payment for the reported surgical procedures.

Coverage Criteria Revised for Radiofrequency Facet Denervation

Effective February 23, 2015, Highmark Blue Shield has revised the clinical criteria for Radiofrequency Facet Denervation.

The following criteria has been revised as follows:

- A successful trial of controlled diagnostic medial branch blocks consists of 2 separate positive blocks on different days with local anesthetic only (no steroids or other drugs), or a placebo-controlled series of blocks, under fluoroscopic guidance, that has resulted in at least a 50% reduction in pain for the duration of the local anesthetic used (e.g., 3 hours longer with bupivacaine than lidocaine).

- No therapeutic intra-articular injections (i.e., steroids, saline, or other substances) should be administered for a period of at least 4 weeks prior to the diagnostic medial branch block. The diagnostic blocks should involve the levels being considered for RF treatment and should not be conducted under intravenous sedation unless specifically indicated (e.g., patient is unable to cooperate with the procedure).

Please see Medical Policy S-150 for complete policy details.
Coverage Position for Ostomy Supplies

Highmark Blue Shield has established new clinical criteria for Ostomy Supplies, including tracheostomy supplies. Quantity level limits have been placed on ostomy and tracheostomy supplies. This new criteria will apply to both professional provider and facility claims. The effective date is June 1, 2015.

**Place of Service: Outpatient**

Ostomy supplies may be considered medically necessary when all of the following are met:

- The individual has a surgically created opening (stoma) to divert urine or fecal contents outside of the body; **and**
- The ostomy supplies replace all or part of an absent body organ or the function of a permanently inoperative or malfunctioning organ.

Tracheostomy care kits/supplies may be considered medically necessary following an open surgical tracheostomy that has been, or is expected to remain open for at least three months.

Prosthetic devices dispensed to a patient prior to performance of the procedure that will necessitate use of the device are not covered. Dispensing a prosthetic device in this manner would not be considered medically necessary for the treatment of the patient's condition and will be denied as non-covered.

For further information, refer to Medical Policy O-19, Ostomy Supplies.

Facility Now Applicable To Outpatient Pulmonary Rehabilitation

Effective June 1, 2015, Highmark Blue Shield Medical Policy G-17, Outpatient Pulmonary Rehabilitation, will apply to both professional provider and facility claims.

Criteria Revised for Telestroke

Effective June 1, 2015, Highmark Blue Shield Medical Policy Z-65, Telestroke, will apply to both professional and facility claims.
Facility and Place of Service added to Miscellaneous Services

Highmark Blue Shield Medical Policy Z-24, Miscellaneous Services will apply to both professional provider and facility claims for experimental/investigational services and not medically necessary services. No professional service rendered will apply to professional only. These changes will take effect June 1, 2015.

**Place of Service:** Outpatient/Inpatient
Coverage Criteria Established for the use of C-1 Esterase Inhibitor [Human] (Berinert)

Highmark Senior Health Company's Medicare Advantage product, has established new clinical criteria for the use of C-1 Esterase Inhibitor [Human] (Berinert®). This new Medicare Advantage Medical Policy will apply to both professional provider and facility claims. The effective date is June 1, 2015.

C-1 Esterase Inhibitor [Human] (Berinert) may be considered medically necessary for treatment of adolescents (12 years of age or older) and adults with acute abdominal, facial, or laryngeal attacks associated with hereditary angioedema (HAE) when the following criteria are met:

- There is a history of moderate or severe attacks (for example, airway swelling, severe abdominal pain, facial swelling, nausea and vomiting, painful facial distortion); AND
- The drug is being used for treatment of acute HAE attacks (not for prophylaxis).

The use of C-1 Esterase Inhibitor [Human] (Berinert) for all other indications is considered not medically necessary.

For further information, refer to Medicare Advantage Medical Policy I-122, Treatment of Hereditary Angioedema (HAE).

Coverage Criteria Established for the Use of Ecallantide (Kalbitor)

Highmark Senior Health Company's Medicare Advantage product, has established new clinical criteria for the use of Ecallantide (Kalbitor®). This new Medicare Advantage Medical Policy will apply to both professional provider and facility claims. The effective date is June 1, 2015.

Ecallantide (Kalbitor) may be considered medically necessary for the treatment of acute attacks of hereditary angioedema (HAE) in individuals 12 years of age and older. The use of Ecallantide (Kalbitor) for all other indications is considered not medically necessary.

For further information, refer to Medicare Advantage Medical Policy I-122, Treatment of Hereditary Angioedema (HAE).
Coverage Criteria Established for the Use of Icatibant (Firazyr)

Highmark Senior Health Company's Medicare Advantage product, has established new clinical criteria for the use of Icatibant (Firazyr®). This new Medicare Advantage Medical Policy will apply to both professional provider and facility claims. The effective date is June 1, 2015.

Icatibant (Firazyr) may be considered medically necessary in an individual 18 years of age and older for the treatment of acute attacks of hereditary angioedema (HAE). The use of Icatibant (Firazyr) for all other indications is considered not medically necessary.

For further information, refer to Medicare Advantage Medical Policy I-122, Treatment of Hereditary Angioedema (HAE) and Pharmacy Policy Bulletin J-141, Firazyr (Icatibant).

Coverage Criteria Established for the Use of C1 Esterase Inhibitor [Human] (Cinryze)

Highmark Senior Health Company's Medicare Advantage product, has established new clinical criteria for the use of C1 Esterase Inhibitor [Human] (Cinryze®). This new Medicare Advantage Medical Policy will apply to both professional provider and facility claims. The effective date is June 1, 2015.

C1 Esterase Inhibitor [Human] (Cinryze) may be considered medically necessary for:

- Routine prophylaxis of angioedema attacks in adolescent (greater than 12 years of age) and adult patients diagnosed with hereditary angioedema (HAE): or
- Adult patients with acute ST segment elevation myocardial infarction undergoing an emergency coronary artery bypass graft (CABG).

The use of C1 Esterase Inhibitor [Human] (Cinryze) for all other indications is considered not medically necessary.

For further information, refer to Medicare Advantage Medical Policy I-122, Treatment of Hereditary Angioedema (HAE).
Coverage Criteria Established for the Use of C1 Esterase Inhibitor [Recombinant] (Ruconest)

Highmark Senior Health Company’s Medicare Advantage product, has established new clinical criteria for the use of C1 Esterase Inhibitor [Recombinant] (Ruconest®). This new Medicare Advantage Medical Policy will apply to both professional provider and facility claims. The effective date is June 1, 2015.

C1 Esterase Inhibitor [Recombinant] (Ruconest) may be considered medically necessary for the treatment of acute attacks of hereditary angioedema (HAE) in adolescent (13 years or older) and adult patients. The use of C1 Esterase Inhibitor [Recombinant] (Ruconest) for all other indications is considered not medically necessary.

For further information, refer to Medicare Advantage Medical Policy I-122, Treatment of Hereditary Angioedema (HAE) and Pharmacy Policy Bulletin J-151, C1 Esterase Inhibitors.

Facility Added for Monitored Anesthesia Care (MAC) Policy

Effective March 2, 2015, Highmark Senior Health Company’s Medicare Advantage product, applied Medical Policy A-4 Monitored Anesthesia Care (MAC) to both professional provider and facility claims.

Facility Added to Oncotype DX Colon Cancer Assay policy

Effective February 27, 2015, Highmark Senior Health Company’s Medicare Advantage product began to apply Medical Policy L-95 Oncotype DX Colon Cancer Assay, to both professional provider and facility claims.

Facility Added to Heartsbreath Test for Heart Transplant Rejection

Effective February 23, 2015, Highmark Senior Health Company’s Medicare Advantage product, began to apply both professional provider and facility claims to Medical Policy N-171, Heartsbreath Test for Heart Transplant Rejection.
New Medicare Advantage Policy for Screening for Lung Cancer with Low Dose Computed Tomography

Highmark Senior Health Company’s Medicare Advantage products, will now consider screening for lung cancer with low dose computed tomography medically necessary when the member is between the ages of 55 and 77 years old, has a smoking history of at least 30 pack years and has no signs or symptoms of lung cancer, effective February 5, 2015, with the policy having been issued on March 16, 2015.

Please reference Medical Policy, N-238.

Facility application has also been added to this medical policy.

Speech-Language Pathology Service Update for LCD Issuance

Highmark Senior Health Company’s Medicare Advantage product, Medical Policy V-16, Speech-Language Pathology (SLP Services: Communication Disorders) has been updated to reflect LCD L27531, effective June 1, 2014. No clinical changes resulted from this update.

Facility Added to Transthoracic Echocardiography Policy

Highmark Senior Health Company’s Medicare Advantage product, Medical Policy X-68, Transthoracic Echocardiography, applies to both professional provider and facility claims effective March 16, 2015.

Facility Added to Mohs Micrographic Surgery

Facility Added to Vertebroplasty, Vertebral Augmentation (Kyphoplasty), Percutaneous

Highmark Senior Health Company’s Medicare Advantage product, Medical Policy S-147 for Vertebroplasty, Vertebral Augmentation (Kyphoplasty), Percutaneous, now applies to both professional provider and facility claims effective February 23, 2014.

Facility Added to Application of Bioengineered Skin Substitutes to Lower Extremity Chronic Non-Healing Wounds

Highmark Senior Health Company’s Medicare Advantage product, will apply both professional provider and facility claims to medical policy S-139, Application of Bioengineered Skin Substitutes to Lower Extremity Chronic Non-Healing Wounds, effective April 9, 2015, with the policy being issued April 13, 2015.

New Procedure Code and Modifiers for Reporting

The following new code and modifiers will be available and effective for reporting purposes on April 1, 2015:

Q9975- Injection, Factor VIII, FC Fusion Protein (Recombinant), per iu
EX- Expatriate beneficiary
JF- Compounded drug
Facility Has Been Added to the Bone Mass Measurement Policy

Highmark Senior Solutions Company’s Medicare Advantage product, Medical Policy X-24, Bone Mass Measurement, now applies to both professional provider and facility claims effective March 9, 2015.

Facility Added to Ambulance Ground Services

Highmark Senior Health Company’s Medicare Advantage Product, Medical Policy T-2, Ambulance Ground Services, will apply to both professional provider and facility claims effective March 30, 2015.

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 edition of Medical Policy Update.

Write to us at medicalpolicy@highmark.com.
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Medical Policy Update focuses only on medical policy and claims administration updates, including coding guidelines and procedure code revisions, and is the sole source for this information. For all other news, information and updates, be sure to read Provider News, available on the Provider Resource Center at www.highmarkblueshield.com.

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Acknowledgement

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