Highmark Blue Cross Blue Shield has revised coverage guidelines for gonadotropin releasing hormone (GnRH) analogs. The coverage criteria has been revised for leuprolide acetate (Lupron®), leuprolide acetate for depot suspension (Lupron Depot®), and leuprolide acetate (Eligard®) to include recent Food and Drug administration (FDA) and National Comprehensive Cancer Network (NCCN) guidelines to including the following recommendations:

**Leuprolide acetate (Lupron):**
- For the treatment of prostate cancer

**Leuprolide acetate for depot suspension (Lupron Depot):**
- For ovarian cancer/fallopian tube cancer/primary peritoneal cancer-low grade serous/grade 1 endometrioid epithelial carcinoma

**Leuprolide acetate (Eligard):**
- For treatment of salivary gland tumors for androgen receptor positive recurrent disease with distant metastases

Coverage guidelines have also been established for triptorelin extended-release (Triptodur®), triptorelin pamoate (Trelstar®), histrelin acetate subcutaneous implant...
(Vantas®), and histrelin acetate subcutaneous implant (Supprelin LA®) based on FDA indications and NCCN recommendations including:

**Triptorelin extended-release (Triptodur):**
- For individuals 2 years of age and older for central precocious puberty

**Triptorelin pamoate (Trelstar):**
- Palliative treatment of advanced prostate cancer
- Premenopausal women with hormone-sensitive advanced breast cancer
- For the treatment of endometriosis

**Histrelin acetate subcutaneous implant (Vantas):**
- Palliative treatment of advanced prostate cancer

**Histrelin acetate subcutaneous implant (Supprelin LA):**
- For treatment of children with central precocious puberty

This Medical Policy will apply to both professional provider and facility claims. The effective date is May 27, 2019.

Please refer to Medical Policy I-16, Gonadotropin Releasing Hormone (GnRH) Analogs for additional information.

**Place of Service: Outpatient**

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**Coverage Guidelines Revised for Granulocyte Colony Stimulating Factors (G-CSF)**

Highmark Blue Cross Blue Shield has revised the coverage guidelines for Granulocyte Colony Stimulating Factors (G-CSF) and added pegfilgrastim-cbqv (Udenyca™). G-CSF may be considered medically necessary for the following indications for pegfilgrastim-cbqv (Udenyca):

**Addition of biosimilar Pegfilgrastim-cbqv (Udenyca) to policy:**

Pegfilgrastim-cbqv (Udenyca):
- Individuals with nonmyeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia to decrease the incidence of infection.

This Medical Policy will apply to both professional provider and facility claims. The effective date was February 25, 2019.

Please refer to Medical Policy I-88, Granulocyte-Colony Stimulating Factors for additional information.

**Place of Service: Outpatient**
Coverage Guidelines Established for Rituximab-abbs (Truxima)

Highmark Blue Cross Blue Shield has established coverage guidelines for rituximab-abbs (Truxima®). The use of rituximab-abbs (Truxima) may be considered medically necessary for the treatment of adults for the following:

Non-Hodgkin’s Lymphoma (NHL)
- Relapsed or refractory, low grade or follicular, CD20-positive B-cell NHL as a single agent; or
- Previously untreated follicular, CD20-positive, B-cell NHL in combination with first line chemotherapy and, in individuals achieving a complete or partial response to a rituximab product in combination with chemotherapy, as a single agent maintenance therapy; or
- Non-progressive (including stable disease), low-grade, CD20-positive, B-cell NHL as a single agent after first-line cyclophosphamide, vincristine, and prednisone (CVP) chemotherapy.

This Medical Policy will apply to both professional provider and facility claims. The effective date was February 25, 2019.

Please refer to Medical Policy I-38, Rituximab (Rituxan,Truxima) and Rituximab and Hyaluronidase Human (Rituxan Hycela) for additional information.

Place of Service: Outpatient

Coverage Guidelines Revised for Ixabepilone (Ixempra)

Highmark Blue Cross Blue Shield has revised coverage guidelines for ixabepilone (Ixempra®). The use of ixabepilone (Ixempra) may be considered medically necessary for the following:

- When used in the treatment of metastatic hormone refractory prostate cancer.

This Medical Policy will apply to both professional provider and facility claims. The effective date was February 11, 2019.

Please refer to Medical Policy I-133, Ixabepilone (Ixempra) for additional information.

Place of Service: Outpatient
Coverage Guidelines Established for Tagraxofusp-erzs (Elzonris)

Highmark Blue Cross Blue Shield has established coverage guidelines for tagraxofusp-erzs (Elzonris™). The use of tagraxofusp-erzs (Elzonris) for the treatment of blastic plasmacytoid dendritic cell neoplasm (BPDCN) may be considered medically necessary when all of the following criteria are met:

- Documentation of diagnosis of BPDCN; and
- Medication prescribed by or in consultation with an oncologist or hematologist; and
- Individual is 2 years of age or older; and
- Pre-medications administered prior to each tagraxofusp-erzs (Elzonris) infusion including ALL of the following:
  - H1-histamine antagonist; and
  - Acetaminophen; and
  - Corticosteroid; and
  - H2-histamine antagonist; and
- Prior to first dose of initial treatment cycle, documentation of serum albumin is greater than or equal to 3.2 g/dL; and
- Initial treatment cycle MUST be administered in an inpatient setting and individual will be monitored for at least 24 hours after last infusion:
  - Subsequent treatment cycles can be administered in appropriate outpatient setting.

This Medical Policy will apply to both professional provider and facility claims. The effective date was February 25, 2019.

Please refer to Medical Policy I-207, Tagraxofusp-erzs (Elzonris) for additional information.

Place of Service: Inpatient/Outpatient

Coverage Guidelines Revised for Foot Orthotics for Conditions Other than Diabetes

Highmark Blue Cross Blue Shield has revised coverage guidelines for Foot Orthotics for Conditions Other than Diabetes. This will apply to both professional provider and facility claims. The effective date is May 27, 2019.

Foot orthotics may be considered medically necessary for an individual with ANY ONE of the following conditions AFTER the individual has failed to respond to a course of appropriate first line conservative treatment (e.g., physical therapy, injections, strapping, anti-inflammatory medications, etc.):

- Achilles tendonitis; or
- Calcaneal apophysitis; or
- Calcaneal Spur; or
- Chondromalacia of the patella secondary to pronation deformity of the foot; or
- Degenerative joint disease/osteoarthrosis of ankle and foot; or
- Neuroma; or
- Neuroma; or
- Plantar fasciitis; or
- Posterior tibial insufficiency (Posterior tibial tendon dysfunction; or
- Status post recurrent ankle sprain with high calcaneal varus; or
• Tibialis anterior tendonitis; or
• Tibialis posterior tendonitis; or
• Peroneal tendonitis

Foot orthotics may be considered medically necessary for an individual as a first line treatment for ANY ONE of the following conditions:
• Juvenile osteochondrosis of foot; or
• Clubfoot/acquired equinovarus deformity/talipes equinovarus, congenital/talipes; or
• Hallus rigidus; or
• Hammertoe digit syndrome; or
• Limb length discrepancy; or
• Metatarsus adductus in children/metatarsus varus, congenital/metatarsus varus, congenital; or
• Pes cavus deformity; or
• Rheumatoid arthritis/Felty’s syndrome/polyarthropathies; or
• Sever’s Disease; or
• Status post foot surgery for continued correction (e.g., surgically treated fractures); or
• Symptomatic hallux valgus/other congenital anomalies of toes; or
• Symptomatic intractable plantar keratosis; or
• Peripheral neuropathy; or
• Vascular ulcers.

Foot orthotics for non-surgically treated fractures is considered not medically necessary unless documentation satisfactorily establishes the medical necessity of the orthotics.

**Quantity Level Limits (QLL) for Foot Orthotics for Conditions other than Diabetes**

Individuals meeting the above orthotic coverage is limited to:
• One (1) orthotic per foot within one (1) calendar year

Foot Orthotics will be denied as not medically necessary if the above criteria are not met. Quantity level limits or quantity of supplies that exceed the frequency guidelines listed on the policy will be denied as not medically necessary.

**Replacement**

Replacement of foot orthotics every one (1) or two (2) calendar years may be considered medically necessary in cases of:
• Loss: or
• Irreparable damage; or
• Wear and tear with normal use: or
• When required because of a change in the individual’s condition.

Separate foot orthotics for multiple pairs of footwear is considered not medically necessary.

Please refer to Medical Policy O-12, Foot Orthotics for Conditions Other than Diabetes, for additional information.
Criteria Established for Nerve Grafts

Highmark Blue Cross Blue Shield has established coverage guidelines for Nerve Grafts. This new policy will apply to both professional provider and facility claims. The effective date is May 27, 2019.

Nerve grafting is considered experimental/investigational.

**Place of Service:** Inpatient/Outpatient.

Please refer to Medical Policy S-263, Nerve Grafts, for additional information.
Coverage Guidelines Established for Rituximab-abbs (Truxima)

Highmark’s Medicare Advantage products have established coverage guidelines for rituximab-abbs (Truxima®). The use of rituximab-abbs (Truxima) may be considered medically necessary for the treatment of adults for the following:

Non-Hodgkin’s Lymphoma (NHL)
- Relapsed or refractory, low grade or follicular, CD20-positive B-cell NHL as a single agent; or
- Previously untreated follicular, CD20-positive, B-cell NHL in combination with first line chemotherapy and, in individuals achieving a complete or partial response to a rituximab product in combination with chemotherapy, as a single agent maintenance therapy; or
- Non-progressive (including stable disease), low-grade, CD20-positive, B-cell NHL as a single agent after first-line cyclophosphamide, vincristine, and prednisone (CVP) chemotherapy.

This Medical Policy will apply to both professional provider and facility claims. The effective date was February 25, 2019.

Please refer to Medical Policy I-38, Rituximab (Rituxan, Truxima) for additional information.

Coverage Guidelines Revised for Granulocyte Colony Stimulating Factors (G-CSF)

Highmark’s Medicare Advantage products have revised the coverage guidelines for Granulocyte Colony Stimulating Factors (G-CSF) and added pegfilgrastim-cbqv (Udenyca™). G-CSF may be considered medically necessary for the following indications for pegfilgrastim-cbqv (Udenyca):

Addition of biosimilar Pegfilgrastim-cbqv (Udenyca) to policy:

Pegfilgrastim-cbqv (Udenyca):
- Individuals with nonmyeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia to decrease the incidence of infection.

This Medical Policy will apply to both professional provider and facility claims. The effective date was February 25, 2019.

Please refer to Medical Policy I-56, Granulocyte Colony Stimulating Factor (G-CSF) for additional information.
Coverage Guidelines Established for Tagraxofusp-erzs (Elzonris)

Highmark's Medicare Advantage products have established coverage guidelines for tagraxofusp-erzs (Elzonris™). The use of tagraxofusp-erzs (Elzonris) for the treatment of blastic plasmacytoid dendritic cell neoplasm (BPDCN) may be considered medically necessary when all of the following criteria are met:

- Documentation of diagnosis of BPDCN; and
- Medication prescribed by or in consultation with an oncologist or hematologist; and
- Individual is 2 years of age or older; and
- Pre-medications administered prior to each tagraxofusp-erzs (Elzonris) infusion including ALL of the following:
  - H1-histamine antagonist; and
  - Acetaminophen; and
  - Corticosteroid; and
  - H2-histamine antagonist; and
- Prior to first dose of initial treatment cycle, documentation of serum albumin is greater than or equal to 3.2 g/dL; and
- Initial treatment cycle MUST be administered in an inpatient setting and individual will be monitored for at least 24 hours after last infusion:
  - Subsequent treatment cycles can be administered in appropriate outpatient setting.

This Medical Policy will apply to both professional provider and facility claims. The effective date was February 25, 2019.

Please refer to Medical Policy I-207, Tagraxofusp-erzs (Elzonris) for additional information.
Comments on these new medical policies?
We want to know what you think about our new medical policy changes. Send us an email with any questions or comments that you may have on the new medical policies in this edition of Medical Policy Update.

Write to us at medicalpolicy@highmark.com.

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About this newsletter

Medical Policy Update is the monthly newsletter for most health care professionals (and office staff) and facilities who participate in our networks and submit claims to Highmark using the 837P HIPAA transaction or the CMS 1500 form, or the 837I HIPAA transaction.

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.highmarkbcbs.com.

Inquiries about Eligibility, Benefits, Claims Status or Authorizations
For inquiries about eligibility, benefits, claim status or authorizations, Highmark Blue Cross Blue Shield encourages providers to use the electronic resources available to them - Navinet® and the applicable HIPAA transactions – prior to placing a telephone call to the Provider Service Center at 1-800-242-0514.

Acknowledgement

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