MEDICAL POLICY UPDATE

FOR PROFESSIONAL AND FACILITY PROVIDERS

HIGHMARK

May 2018

In This Issue

Policy

Clinical Guidelines Revised for Pertuzumab (Perjeta)

NEWS FOR ALL PROVIDER TYPES

Highmark Blue Cross Blue Shield has revised coverage guidelines for Pertuzumab (Perjeta®) to include coverage for preoperative systemic therapy for HER2-positive stage IIA T0, N1, M0 and T1, N1, M0 disease and for those who have node-positive disease likely to become node-negative with preoperative systemic therapy. These revised guidelines will apply to both professional provider and facility claims. The effective date is April 30, 2018.

Please refer to Medical Policy I-40 Pertuzumab (Perjeta) for additional information.

Place of Service: Outpatient

Clinical Guidelines Revised for Zoledronic Acid (Reclast, Zometa)

Highmark Blue Cross Blue Shield has revised coverage guidelines for Zoledronic acid (Reclast®, Zometa®) to amend the current coverage criteria for:

Zoledronic Acid (Zometa) to include coverage for the following:

- Prevention or treatment of osteoporosis during androgen deprivation therapy (ADT) for patients with high fracture risk.
- Prevention of skeletal-related events in men with castration-resistant prostate cancer who have documented bone metastases and creatinine clearance greater that 30mL/min.
- In breast cancer for individuals receiving adjuvant therapy along with calcium and vitamin D supplementation to maintain or improve bone mineral density and reduce risk of fractures.

Zoledronic Acid (Reclast) to include coverage for the following:

- Prevention of osteoporosis in postmenopausal women who have documented failure of oral bisphosphonate therapy with recommended regimen is once every two (2) years.
- Treatment and prevention of glucocorticoid-induced osteoporosis who are either initiating or continuing systemic glucocorticoids in a daily dosage equivalent to 7.5 mg or greater of prednisone and who are expected to remain on glucocorticoids for at least 12 months and with documented failure of oral bisphosphonate therapy is required.

Expand the definition of osteoporosis to include:

- Osteoporosis may also be diagnosed in individuals with osteopenia (Bone Mineral Density (BMD) or T-score between 1 - 2.5 standard deviations below normal adult reference population) AND Fracture Risk Assessment Tool (FRAX) indicates ten (10) year probability for major osteoporotic fracture of greater than or equal to 20% or the ten (10) year probability of hip fracture is greater than or equal to 3%.

Include the following contraindications:

- Hypocalcemia.
- Individuals with creatinine clearance less than 35 mL/min and in those with evidence of acute renal impairment.

These revised guidelines will apply to both professional provider and facility claims. The effective date is April 30, 2018.

Please refer to Medical Policy I-42 Zoledronic Acid (Reclast, Zometa) for additional information.

Place of Service: Outpatient

Coverage Criteria Revised for Rituximab (Rituxan), Coverage Criteria Established for Rituximab and Hyaluronidase Human (Rituxan Hycela)

Highmark Blue Cross Blue Shield has revised the coverage criteria for rituximab (Rituxan) according to Food and Drug Administration (FDA) labeled indications and National Comprehensive Cancer Network (NCCN) recommendations. Highmark Blue Cross Blue Shield has also established coverage criteria for rituximab and hyaluronidase human (Rituxan Hycela) according to FDA labeled indications and NCCN recommendations. This Medical Policy will apply to both professional provider and facility claims. The effective date is July 30, 2018.

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

Coverage Guidelines Revised for Azacitidine (Vidaza)

Highmark Blue Cross Blue Shield has revised the coverage criteria for Azacitidine (Vidaza®). This Medical Policy will apply to both professional provider and facility claims. The effective date is July 30, 2018.

Coverage criteria revised:

Azacitidine may be considered medically necessary:

- Myelofibrosis
  - For the treatment of myelofibrosis (MF)-accelerated phase
  - For the treatment of MF-acute myeloid leukemia
- Acute Myeloid Leukemia
  - Used as lower-intensity treatment induction in individuals age 60 years or older when not a candidate for intensive remission induction therapy or declines intensive therapy
  - Used as post-remission maintenance therapy in individuals age 60 years or older following complete response to previous intensive therapy
  - As a component of repeating the initial successful induction regimen if late response (≥12 months)
- MDS:
  - When used for treatment of patients for ANY ONE of the following French-American-British MDS subtypes:
    - Refractory anemia; or
    - Refractory anemia with ringed sideroblasts (if accompanied by neutropenia, thrombocytopenia, or requiring transfusions); or
    - Refractory anemia with excess blasts (RAEB); or
    - Refractory anemia with excess blasts in transformation (RAEB-T); or
    - chronic myelomonocytic leukemia (CMMoL),
    - When used for the initial treatment of lower risk disease associated with clinically relevant thrombocytopenia, neutropenia, or increased marrow blasts, following disease progression or no response to immunosuppressive therapy or clinical trial

- When used for the treatment of lower risk disease associated with symptomatic anemia for ANY ONE of the following indications:
  - With del(5q), with or without other cytogenetic abnormalities (except those involving chromosome 7), and serum erythropoietin levels greater than >500 mU/mL with no response or intolerance to lenalidomide and low probability of response to immunosuppressive therapy; or
  - Without del(5q), with or without other cytogenetic abnormalities, and serum erythropoietin levels ≤500 mU/mL with no response to erythropoietin in combination with lenalidomide and no response or intolerance to immunosuppressive therapy; or
  - without del(5q), with or without other cytogenetic abnormalities, with serum erythropoietin ≤500 mU/mL, with no response to erythropoietin alone, followed by and no response to erythropoietin in combination with lenalidomide, and poor probability of response to immunosuppressive therapy, or
- Treatment of higher risk disease, also:
  - In transplant candidates with a donor stem cell source available, followed by hematopoietic stem cell transplant

Please refer to Medical Policy I-124, Azacitidine (Vidaza) for additional information.

Coverage Guidelines Revised for Fulvestrant (Faslodex)

Highmark Blue Cross Blue Shield has revised the coverage criteria for Fulvestrant (Faslodex®). This Medical Policy will apply to both professional provider and facility claims. The effective date is April 30, 2018.

Coverage criteria revised:

Fulvestrant may be considered medically necessary:

- For use in combination with abemaciclib (Verzenio®) in women with hormone receptor-positive(HR-positive), human epidermal growth receptor 2-negative (HER2-negative) advanced or metastatic breast cancer with disease progression after endocrine therapy
- For use as monotherapy in HR-positive, HER2-negative advanced breast cancer in postmenopausal women not previously treated with endocrine therapy
- For use as treatment for HR-positive advanced disease in postmenopausal women with disease progression following endocrine therapy
- For use as a single agent for postmenopausal women or for premenopausal women treated with ovarian ablation/suppression who have recurrent or stage IV HR-positive non-visceral or asymptomatic visceral disease characterized as either HER2-negative or HER2-positive
- For use in recurrent or stage IV HR-positive non-visceral or asymptomatic visceral disease in combination with everolimus for HER2-negative disease in postmenopausal women who have had prior endocrine therapy within one (1) year or for premenopausal women treated with ovarian ablation/suppression who have had prior endocrine therapy within one (1) year

- For use in combination with trastuzumab for the treatment of recurrent or stage IV HR-positive, HER2-positive non-visceral or asymptomatic disease in postmenopausal women or premenopausal women treated with ovarian ablation/suppression
- For use in treatment of uterine neoplasms of endometrial carcinoma

Note: Men with breast cancer are treated in a similar manner as postmenopausal women.

Please refer to Medical Policy I-123, Fulvestrant (Faslodex) for additional information.

Coverage Guidelines Revised for Brentuximab vedotin (Adcetris)

Highmark Blue Cross Blue Shield has revised the coverage criteria for Brentuximab vedotin (Adcetris®). This Medical Policy will apply to both professional provider and facility claims. The effective date is April 30, 2018.

Coverage criteria revised:

Brentuximab vedotin may be considered medically necessary:

- For use in Classical Hodgkin Lymphoma as second line or subsequent systemic therapy in relapsed or refractory disease as a single agent or component of specified therapies
- For use in previously treated histologic transformations to CD30+ diffuse large B-cell lymphoma
- For use in various stages and presentations of Mycosis Fungoides (MF) and Sezary Syndrome (SS)
- For use in treatment of adults with CD30-expressing MF who have received prior systemic therapy
- For use in post-transplant lymphoproliferative disorders as second-line and subsequent therapy

Please refer to Medical Policy I-136, Brentuximab vedotin (Adcetris) for additional information.

Coverage Guidelines Revised for Male Erectile Dysfunction

Highmark Blue Cross Blue Shield has revised the coverage guidelines for diagnosis and treatment of male erectile dysfunction. This revision clarifies the procedures and laboratory tests used to diagnose male erectile dysfunction. The Medical Policy will apply to both professional provider and facility claims. The effective date is May 7, 2018.

Revised Coverage Criteria:
The following procedures and tests for the diagnosis of erectile dysfunction may be considered medically necessary:

- Comprehensive history and physical examination
- Lab tests for hormone levels of testosterone
    - Abnormal hormone levels may indicate further endocrine testing for pituitary, thyroid, and adrenal dysfunction.

Please refer to Medical Policy G-9, Diagnosis and Treatment of Male Sexual Dysfunction for additional Information.

Place of Service Revised for Total Hip and Total Knee Arthroplasty

Highmark Blue Cross Blue Shield has revised the place of service for total hip and total knee arthroplasty to Outpatient/Inpatient. This Medical Policy will apply to both professional provider and facility claims. The effective date is July 30, 2018.

Please refer to Medical Policy S-247, Total Hip and Total Knee Arthroplasty for additional information.

Facility Added to Treatment of Acne Policy

Highmark Blue Cross Blue Shield Medical Policy S-92, Treatment of Acne will apply to both professional provider and facility claims effective July 30, 2018.

Guidelines Established For Laparoscopic Radiofrequency Ablation of Uterine Fibroids

Highmark Blue Cross Blue Shield has established coverage guidelines for laparoscopic ultrasound-guided radiofrequency ablation of uterine fibroids and will apply to both professional provider and facility claims. The effective date is May 14, 2018.

Laparoscopic ultrasound-guided radiofrequency ablation (e.g., Acessa™) for the treatment of uterine fibroids may be considered medically necessary when the individual is experiencing ANY ONE of the following symptoms:

- Menorrhagia (excessive menstrual bleeding lasting more than eight (8) days) as a direct result of the fibroid (e.g., not resulting from hyperplasia, atypia, or cancer) that interferes with daily activities or causes anemia; or
- Pelvic pain or pressure as a direct result of the fibroid; or
- Lower back pain as a direct result of the fibroid; or
- Urinary symptoms (e.g., urinary frequency, urgency)related to compression of the bladder as a direct result of the fibroid; or
- Gastrointestinal symptoms related to compression of the bowel (e.g., constipation, bloating) as a direct result of the fibroid; or
- Dyspareunia (painful or difficult sexual relations) as a direct result of the fibroid; or
- An abdominally palpable fibroid.

Please refer to medical policy S-179, Treatment of Abnormal Uterine Bleeding and Fibroids for more information

Place of Service Established for Abortions

Highmark Blue Cross Blue Shield has established the place of service for abortions as Outpatient. This Medical Policy will apply to both professional provider and facility claims. The effective date is July 30, 2018.

Please refer to Medical Policy S-2, Abortions for additional information.

REMINDER: Molecular and Genomic Testing

Highmark Blue Cross Blue Shield is providing a reminder to all providers.

As previously announced in the May 2, 2018 Special Bulletin, the molecular and genomic testing medical policies and requirements will be updated and take effect July 2, 2018. This applies to both professional provider and facility claims.

At that time, policies can be accessed from the medical policy homepage.

REMINDER: Radiation Therapy

Highmark Blue Cross Blue Shield is providing a reminder to all providers.

As previously announced in the Special Bulletin, the radiation therapy medical policies and requirements will be updated and take effect August 1, 2018. This applies to both professional provider and facility claims.

At that time, policies can be accessed from the medical policy homepage.

Medicare Advantage Policy

Clinical Guidelines Developed for Zoledronic Acid (Reclast, Zometa)

Highmark's Medicare Advantage products have established new guidelines for Zoledronic Acid (Reclast®, Zometa®) based upon FDA indications and NCCN guidelines. These revised guidelines will apply to both professional provider and facility claims. The effective date is July 30, 2018.

Please refer to Medical Policy I-42 Zoledronic Acid (Reclast, Zometa) for additional information.

Place of Service: Outpatient

Coverage Guidelines Revised for Brentuximab vedotin (Adcetris)

Highmark's Medicare Advantage products have revised the coverage criteria for Brentuximab vedotin (Adcetris®). This Medical Policy will apply to both professional provider and facility claims. The effective date is April 30, 2018.

Coverage criteria revised:

Brentuximab vedotin may be considered medically necessary:

- For use in Classical Hodgkin Lymphoma as second line or subsequent systemic therapy in relapsed or refractory disease as a single agent or component of specified therapies
- For use in previously treated histologic transformations to CD30+ diffuse large B-cell lymphoma
- For use in various stages and presentations of Mycosis Fungoides (MF) and Sezary Syndrome (SS)
- For use in treatment of adults with CD30-expressing MF who have received prior systemic therapy
- For use in post-transplant lymphoproliferative disorders as second-line and subsequent therapy

Please refer to Medical Policy I-136, Brentuximab vedotin (Adcetris) for additional information.

Coverage Guidelines Revised for Fulvestrant (Faslodex)

Highmark's Medicare Advantage products have revised the coverage for Fulvestrant (Faslodex®). This Medical Policy will apply to both professional provider and facility claims. The effective date is April 30, 2018.

Coverage criteria revised:

Fulvestrant may be considered medically necessary:

- For use in combination with abemaciclib (Verzenio®) in women with hormone receptor-positive(HR-positive), human epidermal growth receptor 2-negative (HER2-negative) advanced or metastatic breast cancer with disease progression after endocrine therapy
- For use as monotherapy in HR-positive, HER2-negative advanced breast cancer in postmenopausal women not previously treated with endocrine therapy
- For use as treatment for HR-positive advanced disease in postmenopausal women with disease progression following endocrine therapy
- For use as a single agent for postmenopausal women or for premenopausal women treated with ovarian ablation/suppression who have recurrent or stage IV HR-positive non-visceral or asymptomatic visceral disease characterized as either HER2-negative or HER2-positive
- For use in recurrent or stage IV HR-positive non-visceral or asymptomatic visceral disease in combination with everolimus for HER2-negative disease in postmenopausal women who have had prior endocrine therapy within one (1) year or for premenopausal women treated with ovarian ablation/suppression who have had prior endocrine therapy within one (1) year
- For use in combination with trastuzumab for the treatment of recurrent or stage IV HR-positive, HER2-positive non-visceral or asymptomatic disease in postmenopausal women or premenopausal women treated with ovarian ablation/suppression
- For use in treatment of uterine neoplasms of endometrial carcinoma

Note: Men with breast cancer are treated in a similar manner as postmenopausal women.

Please refer to Medical Policy I-123, Fulvestrant (Faslodex) for additional information.

Clinical Guidelines Revised for Pertuzumab (Perjeta)

Highmark's Medicare Advantage products have established new guidelines for Pertuzumab (Perjeta®) to include coverage for preoperative systemic therapy for HER2-positive stage IIA T0, N1, M0 and T1, N1, M0 disease and for those who have node-positive disease likely to become node-negative with preoperative systemic therapy. These revised guidelines will apply to both professional provider and facility claims. The effective date is April 30, 2018.

Please refer to Medical Policy I-115 Pertuzumab (Perjeta) for additional information.

Place of Service: Outpatient

Coverage Guidelines Revised for Azacitidine (Vidaza)

Highmark's Medicare Advantage products have revised the coverage criteria for Azacitidine (Vidaza®). This Medical Policy will apply to both professional provider and facility claims. The effective date is July 30, 2018.

Coverage criteria revised:

Azacitidine may be considered medically necessary:

- Myelofibrosis
  - For the treatment of myelofibrosis (MF)-accelerated phase
  - For the treatment of MF-acute myeloid leukemia
- Acute Myeloid Leukemia
  - Used as lower-intensity treatment induction in individuals age 60 years or older when not a candidate for intensive remission induction therapy or declines intensive therapy
  - Used as post-remission maintenance therapy in individuals age 60 years or older following complete response to previous intensive therapy
  - As a component of repeating the initial successful induction regimen if late response (≥12 months)
- MDS:
  - When used for treatment of patients for ANY ONE of the following French-American-British MDS subtypes:
    - Refractory anemia; or
    - Refractory anemia with ringed sideroblasts (if accompanied by neutropenia, thrombocytopenia, or requiring transfusions); or
    - Refractory anemia with excess blasts (RAEB); or
    - Refractory anemia with excess blasts in transformation (RAEB-T); or
    - chronic myelomonocytic leukemia (CMMoL),
    - When used for the initial treatment of lower risk disease associated with clinically relevant thrombocytopenia, neutropenia, or increased marrow blasts, following disease progression or no response to immunosuppressive therapy or clinical trial
  - When used for the treatment of lower risk disease associated with symptomatic anemia for ANY ONE of the following indications:

  - With del(5q), with or without other cytogenetic abnormalities (except those involving chromosome 7), and serum erythropoietin levels greater than >500 mU/mL with no response or intolerance to lenalidomide and low probability of response to immunosuppressive therapy; or
  - Without del(5q), with or without other cytogenetic abnormalities, and serum erythropoietin levels ≤500 mU/mL with no response to erythropoietin in combination with lenalidomide and no response or intolerance to immunosuppressive therapy; or
  - without del(5q), with or without other cytogenetic abnormalities, with serum erythropoietin ≤500 mU/mL, with no response to erythropoietin alone, followed by and no response to erythropoietin in combination with lenalidomide, and poor probability of response to immunosuppressive therapy, or
- Treatment of higher risk disease, also:
  - In transplant candidates with a donor stem cell source available, followed by hematopoietic stem cell transplant

Please refer to Medical Policy I-124 Azacitidine (Vidaza) for additional information.

Facility Added to Blood Transfusions Policy

Highmark's Medicare Advantage products have established facility processing for Blood Transfusions - NCD 110.7. The effective date is July 30, 2018.

Please refer to Medical Policy N-191 Blood Transfusions - NCD 110.7 for additional information.

Facility Added to Diagnostic Breath Analysis Policy

Highmark's Medicare Advantage products, Medical Policy N-47, for Diagnostic Breath Analysis will apply to both professional provider and facility claims. This change will become effective when the policy issues on July 30, 2018.

Please refer to Medical Policy N-47 Diagnostic Breath Analysis 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**.

Contents

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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