Criteria Revised for Bendamustine (Treanda®) and Coverage Criteria Added for Bendamustine (Bendeka®)

Highmark Blue Cross Blue Shield has established new clinical criteria for Bendamustine (Treanda®). Clinical coverage criteria added for Bendamustine (Bendeka®).

The effective date is April 3, 2017 and will apply to both professional provider and facility claims.

The use of Bendamustine (Treanda, Bendeka) may be considered medically necessary for the following conditions:

**Hodgkin lymphoma:**
- Palliative therapy as a single agent for older adults (age > 60).

**Multiple myeloma:**
- Therapy for previously treated myeloma for disease relapse or for progressive or refractory disease;
  - In combination with bortezomib and dexamethasone.

**Non-Hodgkin lymphoma (NHL):**
- First-line therapy with or without rituximab for CLL/SLL without del(17p)/TP53 mutation with or without del(11q)/TP53 mutation and with or without del(11q) in patients age ≥ 65 years or for younger patients with or without significant comorbidities who have indications for treatment.
Gastric MALT Lymphoma used in patients with indications for treatment as:
First-line therapy in combination with rituximab for stage IIIE-IV disease.

Non-Gastric MALT Lymphoma as a:
First-line therapy for stage IV disease or recurrent stage I-II disease in combination with rituximab.

Primary Cutaneous B-Cell Lymphoma, primary cutaneous marginal zone, or follicle center lymphoma used in combination with rituximab as a:
First-line therapy for generalized extracutaneous disease.
Second-line or subsequent therapy with or without rituximab for relapsed or refractory primary cutaneous diffuse large B-cell lymphoma, leg type in non-candidates for high dose therapy.

Splenic Marginal Zone Lymphoma as a:
First-line therapy in combination with rituximab for progressive disease following initial treatment for splenomegaly.

Indolent B-cell non-Hodgkin lymphoma (NHL)
That has progressed during or within six months of treatment with rituximab or a rituximab-containing regimen.

For more information, refer to Medical Policy I-98, Bendamustine (Treanda®).

**Place of Service:** Outpatient.

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**Criteria Revised for Mepolizumab (NUCALA) and Coverage Criteria Added for Reslizumab (CINQAIR)**

Highmark Blue Cross Blue Shield has established new clinical criteria for **Mepolizumab (NUCALA®)**. Clinical coverage criteria added for **Reslizumab (CINQAIR®)**.

The effective date is April 3, 2017 and will apply to both professional provider and facility claims.

The below coverage criteria removed for Mepolizumab (NUCALA®);
- Evidence of severe asthma as demonstrated by **BOTH** of the following:
  - A pretreatment forced expiratory volume in 1 second (FEV1) less than 80% predicted; **and**
  - FEV1 reversibility of at least 12% and 200 milliliters (ml) after albuterol (salbutamol) administration.

Coverage criteria added for Mepolizumab (NUCALA®);
- Patient is not receiving mepolizumab in combination with omalizumab or reslizumab.
Coverage criteria added for Reslizumab (CINQAIR®);

Reslizumab may be considered medically necessary as an add-on maintenance treatment for a period of up to 12 months for patients with severe eosinophilic asthma when **ALL** of the following criteria are met:

- Patient is 18 years of age or older; **and**
- Is currently being treated with high-dose inhaled corticosteroids (ICS) (with or without oral corticosteroids) plus an additional controller (e.g., long-acting beta agonist [LABA], leukotriene inhibitor, theophylline) medication, unless contraindicated; **and**
- Has a history of 2 or more exacerbations requiring systemic glucocorticoids while being treated with fluticasone propionate at doses of 880 μg or more or its equivalent in the last year; **and**
- Has eosinophilic phenotype (blood eosinophils of 400 cells/μL or higher within 4 weeks of initiation of therapy); **and**
- Patient is not receiving Reslizumab in combination with Omalizumab or Mepolizumab.

Reslizumab for the treatment of any other condition other than severe eosinophilic asthma is considered experimental/investigational, there is a lack of scientific documentation supporting its use for any other indication.

Continuation of therapy with Reslizumab after 12 months may be considered medically necessary for the treatment of an individual with documented severe eosinophilic asthma when the following criteria are met:

- Treatment with Reslizumab has resulted in clinical improvement as documented by **ONE** or more of the following:
  - Decreased utilization of rescue medications; **or**
  - Decreased frequency of exacerbations (defined as worsening of asthma that requires an increase in ICS dose or treatment with systemic corticosteroids); **or**
  - Increase in predicted FEV1 from pretreatment baseline; **or**
  - Reduction in reported asthma-related symptoms, such as, asthmatic symptoms upon awakening, coughing, fatigue, shortness of breath, sleep disturbance, or wheezing.

For more information, refer to Medical Policy I-146, Mepolizumab (NUCALA®).
Coverage for Removal of Skin Lesions

Highmark Blue Cross Blue Shield has revised the clinical criteria for the removal of skin lesions. Removal of skin tags was considered medically necessary and is now considered cosmetic.

The title of Medical Policy S-36 has been changed to "Removal of Benign or Premalignant Skin Lesions." This revision applies to both professional provider and facility claims. The effective date is April 3, 2017.

Refer to Medical Policy S-36, Removal of Benign or Premalignant Skin Lesions, for additional information.
Criteria Revised for Bendamustine (Treanda) and Coverage Criteria Added for Bendamustine (Bendeka)

Highmark’s Medicare Advantage products have established new clinical criteria for **Bendamustine (Treanda®)**. Clinical coverage criteria added for **Bendamustine (Bendeka®)**.

The effective date is April 3, 2017 and will apply to both professional provider and facility claims.

The use of Bendamustine (Treanda, Bendeka) may be considered medically necessary for the following conditions:

**Hodgkin lymphoma:**
- Palliative therapy as a single agent for older adults (age > 60).

**Multiple myeloma:**
- Therapy for previously treated myeloma for disease relapse or for progressive or refractory disease;
  - In combination with bortezomib and dexamethasone.

**Non-Hodgkin lymphoma (NHL):**
- First-line therapy with or without rituximab for CLL/SLL without del(17p)/TP53 mutation with or without del(11q)/TP53 mutation and with or without del(11q) in patients age ≥ 65 years or for younger patients with or without significant comorbidities who have indications for treatment.

  Gastric MALT Lymphoma used in patients with indications for treatment as:
  - First-line therapy in combination with rituximab for stage IIIE-IV disease.

  Non-Gastric MALT Lymphoma as a:
  - First-line therapy for stage IV disease or recurrent stage I-II disease in combination with rituximab.

  Primary Cutaneous B-Cell Lymphoma, primary cutaneous marginal zone, or follicle center lymphoma used in combination with rituximab as a:
  - First-line therapy for generalized extracutaneous disease.

  Second-line or subsequent therapy with or without rituximab for relapsed or refractory primary cutaneous diffuse large B-cell lymphoma, leg type in non-candidates for high dose therapy.
Splenic Marginal Zone Lymphoma as a:
First-line therapy in combination with rituximab for progressive disease following initial treatment for splenomegaly.

Indolent B-cell non-Hodgkin lymphoma (NHL)
That has progressed during or within six months of treatment with rituximab or a rituximab-containing regimen.

For more information, refer to Medical Policy I-55, Bendamustine (Treanda®).

Criteria Revised for Mepolizumab (NUCALA) and Coverage Criteria Added for Reslizumab (CINQAIR)

Highmark’s Medicare Advantage products have established new clinical criteria for Mepolizumab (NUCALA®). Clinical coverage criteria added for Reslizumab (CINQAIR®).

The effective date is April 3, 2017 and will apply to both professional provider and facility claims.

The below coverage criteria removed for Mepolizumab (NUCALA®):
- Evidence of severe asthma as demonstrated by BOTH of the following:
  - A pretreatment forced expiratory volume in 1 second (FEV1) less than 80% predicted; and
  - FEV1 reversibility of at least 12% and 200 milliliters (ml) after albuterol (salbutamol) administration.

Coverage criteria added for Mepolizumab (NUCALA®):
- Patient is not receiving mepolizumab in combination with omalizumab or reslizumab.

Coverage criteria added for Reslizumab (CINQAIR®):
Reslizumab may be considered medically necessary as an add-on maintenance treatment for a period of up to 12 months for patients with severe eosinophilic asthma when ALL of the following criteria are met:
- Patient is 18 years of age or older; and
- Is currently being treated with high-dose inhaled corticosteroids (ICS) (with or without oral corticosteroids) plus an additional controller (e.g., long-acting beta agonist [LABA], leukotriene inhibitor, theophylline) medication, unless contraindicated; and
- Has a history of 2 or more exacerbations requiring systemic glucocorticoids while being treated with fluticasone propionate at doses of 880 μg or more or its equivalent in the last year; and
- Has eosinophilic phenotype (blood eosinophils of 400 cells/μL or higher within 4 weeks of initiation of therapy); and
- Patient is not receiving Reslizumab in combination with Omalizumab or Mepolizumab.
Reslizumab for the treatment of any other condition other than severe eosinophilic asthma is considered experimental/investigational, there is a lack of scientific documentation supporting its use for any other indication.

Continuation of therapy with Reslizumab after 12 months may be considered medically necessary for the treatment of an individual with documented severe eosinophilic asthma when the following criteria are met:

- Treatment with Reslizumab has resulted in clinical improvement as documented by ONE or more of the following:
  - Decreased utilization of rescue medications; or
  - Decreased frequency of exacerbations (defined as worsening of asthma that requires an increase in ICS dose or treatment with systemic corticosteroids); or
  - Increase in predicted FEV1 from pretreatment baseline; or
  - Reduction in reported asthma-related symptoms, such as, asthmatic symptoms upon awakening, coughing, fatigue, shortness of breath, sleep disturbance, or wheezing.

For more information, refer to Medical Policy I-146, Mepolizumab (NUCALA®).
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 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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