Medical and Behavioral Health Policy Activity

Policies Effective: September 4, 2023 Notification Posted: July 3, 2023

Policies Developed
None

Policies Revised

- **Rituximab, II- 47**
  NOTE: This policy is not to be used for reviews of rituximab when administered in an inpatient setting.

I. Initial and Renewal Review for Oncologic Indications

Intravenous rituximab (Rituxan®, Truxima®, Ruxience™, Riabni™) may be considered **MEDICALLY NECESSARY AND APPROPRIATE** for oncologic indications when **ALL** of the following criteria are met:

- Diagnosis of ONE of the following:
  - Acute lymphoblastic/lymphocytic leukemia (ALL); OR
  - Central nervous system (CNS) lymphoma, including but not limited to:
    - Primary CNS lymphoma; or
    - Leptomeningeal metastases from lymphomas; OR
  - Nodular lymphocyte-predominant Hodgkin lymphoma; OR
  - Mature B-cell acute leukemia (B-AL); OR
  - Non-Hodgkin lymphoma (NHL), including but not limited to:
    - B-cell lymphoma; or
    - Burkitt lymphoma; or
    - Burkitt-like lymphoma; or
    - Castleman disease (angiofollicular lymph node hyperplasia); or
    - Chronic lymphocytic leukemia (CLL); or
    - Chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL); or
    - Diffuse large B-cell lymphoma (DLBCL); or
    - Extranodal marginal zone lymphoma of nongastric sites (noncutaneous); or
    - Extranodal marginal zone lymphoma of the stomach; or
    - Follicular lymphoma; or
    - Gastric mucosa-associated lymphoid tissue (MALT) lymphoma; or
    - Hairy cell leukemia; or
    - High grade B-cell lymphoma; or
    - Histologic transformation of CLL/SLL to diffuse large B-cell lymphoma; or
    - Histologic transformation of indolent lymphomas to diffuse large B-cell lymphoma; or
    - Histologic transformation of follicular lymphoma to diffuse large B-cell lymphoma; or
    - Histologic transformation of nodal marginal zone lymphoma to diffuse large B-cell lymphoma; or
    - HHV8-positive diffuse large B-cell lymphoma; or
    - HIV-related B-cell lymphoma; or
    - Lymphoblastic lymphoma; or
    - Mantle cell lymphoma; or
    - Mature B-cell NHL; or
    - Nodal marginal zone lymphoma; or
    - Non-gastric MALT lymphoma; or
    - Pediatric aggressive mature B-cell lymphoma; or
    - Post-transplant lymphoproliferative disorder (PTLD); or

        - Primary cutaneous B-cell lymphoma; or
        - Primary effusion lymphoma; or
        - Primary mediastinal large B-cell lymphoma; or
        - Splenic marginal zone lymphoma. OR
    - Waldenstrom's macroglobulinemia (lymphoplasmacytic lymphoma); **AND**
- No FDA labeled contraindications to therapy (see table 1 below); **AND**
- Requested dose is within the FDA labeled dose for the labeled indications or is supported in literature for additional indications.

Subcutaneous rituximab (Rituxan Hycela®) may be considered **MEDICALLY NECESSARY AND APPROPRIATE** for **oncologic indications** when **ALL** of the following criteria are met:

- Diagnosis of ONE of the following:
    - Nodular lymphocyte-predominant Hodgkin lymphoma; OR
    - Non-Hodgkin lymphoma (NHL):
        - Burkitt lymphoma; or
        - Castleman~~'s~~ disease (angiofollicular lymph node hyperplasia); or
        - Chronic lymphocytic leukemia (CLL); or
        - Chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL); or
        - Diffuse large B-cell lymphoma (DLBCL); or
        - Extranodal marginal zone lymphoma of nongastric sites (noncutaneous); or
        - Extranodal marginal zone lymphoma of the stomach; or
        - Follicular lymphoma (FL); or
        - Gastric mucosa-associated lymphoid tissue (MALT) lymphoma; or
        - Hairy cell leukemia; or
        - High grade B-cell lymphoma; or
        - Histologic transformation of indolent lymphomas to diffuse large B-cell lymphoma; or
        - Histologic transformation of marginal zone lymphoma to diffuse large B-cell lymphoma; or
        - HIV-related B-cell lymphoma; or
        - Mantle cell lymphoma; or
        - Nodal marginal zone lymphoma; or
        - Non-gastric MALT lymphoma; or
        - Post-transplant lymphoproliferative disorder (PTLD); or
        - Primary cutaneous B-cell lymphoma; or
        - Splenic marginal zone lymphoma; OR
    - Waldenstrom's macroglobulinemia (lymphoplasmacytic lymphoma);

  AND
- No FDA labeled contraindications to therapy (see table 1 below); **AND**
- For initial review, the patient has received one full dose of intravenous rituximab; **AND**
- Requested dose is within the FDA labeled dose for the labeled indications or is supported in literature for additional indications.

II. Initial Review for Non-Oncologic Indications

Intravenous rituximab (Rituxan®, Truxima®, Ruxience™, Riabni ™) may be considered **MEDICALLY NECESSARY AND APPROPRIATE** for **non-oncologic indications** when **ALL** of the following criteria are met:

- Diagnosis of ONE of the following:
    - Autoimmune hemolytic anemia (AIHA); OR
    - Autoimmune mucocutaneous blistering disease (pemphigus vulgaris, pemphigus foliaceus, paraneoplastic pemphigus, bullous pemphigoid, mucous membrane pemphigoid, or epidermolysis bullosa acquisita) **AND** ONE of the following:
        - Will receive glucocorticoid therapy in combination with rituximab; OR

- Documented intolerance, FDA labeled contraindication, or hypersensitivity to at least one glucocorticoid; OR
- Chronic graft versus host disease **AND** BOTH of the following:
  - Failed an immunosuppressant OR has a documented intolerance, FDA labeled contraindication, or hypersensitivity to at least one immunosuppressant; AND
  - Failed glucocorticoid therapy OR has a documented intolerance, FDA labeled contraindication, or hypersensitivity to at least one glucocorticoid; OR
- Chronic idiopathic/immune thrombocytopenic purpura (ITP) **AND** ONE of the following:
  - Had an inadequate response to splenectomy, glucocorticoid therapy, or immune globulin therapy; or
  - Documented intolerance, FDA labeled contraindication, or hypersensitivity to immune globulin therapy AND at least one glucocorticoid; OR
- Dermatomyositis **AND** BOTH of the following:
  - Failed an immunosuppressant OR has a documented intolerance, FDA labeled contraindication, or hypersensitivity to at least one immunosuppressant; AND
  - Failed glucocorticoid therapy OR has a documented intolerance, FDA labeled contraindication, or hypersensitivity to at least one glucocorticoid; OR
- Granulomatosis with polyangiitis (GPA or Wegener's granulomatosis) and microscopic polyangiitis (MPA) **AND** ONE of the following:
  - Will receive glucocorticoid therapy in combination with rituximab; or
  - Documented intolerance, FDA labeled contraindication, or hypersensitivity to at least one glucocorticoid; OR
- Idiopathic membranous nephropathy **AND** ONE of the following:
  - Failed an alkylating agent (e.g. cyclophosphamide) or a calcineurin inhibitor (e.g. cyclosporine); or
  - Documented intolerance, FDA labeled contraindication, or hypersensitivity to at least one alkylating agent (e.g. cyclophosphamide) AND at least one calcineurin inhibitor (e.g. cyclosporine); OR
- Management of immune checkpoint inhibitor related toxicity **AND** BOTH of the following:
  - ONE of the following:
    - Non-viral encephalitis related to immunotherapy AND ONE of the following:
      - Patient is autoimmune-encephalopathy-antibody positive; or
      - Patient is refractory to methylprednisolone with or without intravenous immunoglobulin (IVIG); OR
    - Bullous dermatitis related to their immunotherapy AND used as additional therapy for moderate (G2), severe (G3) or life-threatening (G4) disease; OR
    - Moderate, severe, or life-threatening myalgias or myositis that are steroid-refractory; OR
    - Severe (G3-4) myasthenia gravis related to their immunotherapy that is refractory to plasmapheresis or intravenous immunoglobulin (IVIG);

    AND
  - Receiving therapy with an immune checkpoint inhibitor (e.g., cemiplimab, nivolumab, pembrolizumab, atezolizumab, avelumab, durvalumab, ipilimumab, etc.); OR
- Moderately to severely active rheumatoid arthritis in a patient 18 years of age or older **AND f**ailed at least one tumor necrosis factor (TNF) antagonist OR has a documented intolerance, FDA labeled contraindication, or hypersensitivity to at least one TNF antagonist; OR
- Neuromyelitis optica spectrum disorder; OR
- Polymyositis **AND** BOTH of the following:
  - Failed an immunosuppressant OR has a documented intolerance, FDA labeled contraindication, or hypersensitivity to at least one immunosuppressant; AND
  - Failed glucocorticoid therapy OR has a documented intolerance, FDA labeled contraindication, or hypersensitivity to at least one glucocorticoid; OR
- Prior to renal transplantation, at high risk of antibody-mediated rejection, including highly sensitized patients and those receiving an ABO incompatible organ; OR
- Thrombotic thrombocytopenic purpura (TTP) **AND** ONE of the following:

- Will receive plasma exchange and glucocorticoid therapy in combination with rituximab; or
- Documented intolerance, FDA labeled contraindication, or hypersensitivity to plasma exchange AND at least one glucocorticoid;

AND

- No FDA labeled contraindications to therapy (see table 1 below); **AND**
- Not currently being treated with another biologic immunomodulator; **AND**
- For patients not currently receiving rituximab, has been screened for hepatitis B infection and has begun therapy if appropriate; **AND**
- Requested dose is within the FDA labeled dose for the labeled indications or is supported in literature for additional indications (see table 2 below); **AND**
- For commercial health plan members only, rituximab is administered in accordance with site of service criteria (see policy XI-06); **AND**
- For commercial health plan members only, step therapy supplement criteria may apply for select conditions (see policy II-242: Step Therapy Supplement).

III. Renewal Review for Non-Oncologic Indications

Intravenous rituximab (Rituxan®, Truxima®, Ruxience™, Riabni ™) may be considered **MEDICALLY NECESSARY AND APPROPRIATE** for non- oncologic indications when **ALL** of the following criteria are met:

- Previously approved for the requested therapy through the initial review process; **AND**
- Has shown positive clinical response to rituximab therapy (e.g., stabilization and/or slowing of disease progression, or decrease in symptom severity and/or frequency); **AND**
- No FDA labeled contraindications to therapy with rituximab (see table 1 below); **AND**
- Not currently being treated with another biologic immunomodulator; **AND**
- Requested dose is within the FDA labeled dose for the labeled indications or is supported in literature for additional indications (see table 2 below); **AND**
- For commercial health plan members only, rituximab is administered in accordance with site of service criteria (see policy XI-06).

IV. Experimental/Investigative Uses

The use of intravenous rituximab (Rituxan®, Truxima®, Ruxience™, Riabni™) or subcutaneous rituximab (Rituxan Hycela®) is considered **EXPERIMENTAL/INVESTIGATIVE** for all other indications due to the lack of clinical evidence demonstrating an impact on improved health outcomes.

Table 1. FDA Labeled Contraindications

Agent	FDA Labeled Contraindications
Rituximab (Rituxan®)	None
Rituximab biosimilar (Truxima®)	None
Rituximab biosimilar (Ruxience™)	None
Rituximab biosimilar (Riabni™)	None
Rituximab and hyaluronidase (Rituxan Hycela™)	None

Table 2. Dosing for Non-Oncologic Indications

NOTE: See documentation submission requirements below if the requested dose is outside of the dosing criteria provided in this table.

FDA Labeled Indications	Dosing
Rheumatoid arthritis (RA)	Two 1000 mg infusions separated by 2 weeks. Subsequent courses every 24 weeks or based on clinical response, not less than every 16 weeks.
Granulomatosis with polyangiitis (GPA or Wegener's granulomatosis) and microscopic polyangiitis (MPA) (Ruxience™ and Riabni™ only)	IV induction: 375 mg/m^2 once weekly for 4 weeks. IV maintenance: Two 500 mg infusions separated by 2 weeks. Subsequent courses every 6 months based on clinical response.
Granulomatosis with polyangiitis (GPA or Wegener's granulomatosis) and microscopic polyangiitis (MPA)—adults (Rituxan® only)	IV induction: 375 mg/m^2 once weekly for 4 weeks. IV maintenance: Two 500 mg infusions separated by 2 weeks. Subsequent courses every 6 months based on clinical response.
Granulomatosis with polyangiitis (GPA or Wegener's granulomatosis) and microscopic polyangiitis (MPA)—pediatric patients (Rituxan® only)	IV induction: 375 mg/m^2 once weekly for 4 weeks. IV maintenance: Two 250 mg/m^2 infusions separated by 2 weeks. Subsequent courses every 6 months based on clinical response.
Pemphigus Vulgaris (PV)	Two 1000 mg infusions separated by 2 weeks. Subsequent courses as 500 mg infusion at Month 12 and every 6 months thereafter or based on clinical response. For relapse, administer as a single 1000 mg infusion.
Off Label Indications	**Dosing**
Autoimmune hemolytic anemia (AHA)	375 mg/m^2 once weekly for 4 weeks
Chronic graft-versus-host disease (cGVHD)	375 mg/m^2 once weekly for 4 weeks
Idiopathic/immune thrombocytopenic purpura (ITP)	375 mg/m^2 once weekly for 4 weeks
Immune checkpoint inhibitor related	Bullous dermatitis: Two 1,000 mg infusions separated by 2

toxicities	weeks followed by 500 mg infusions at months 12 and 18 as needed Myalgias/ myositis: 375 mg/m^2 once weekly for 4 weeks Myasthenia gravis: 375 mg/m^2 once weekly for 4 weeks OR Two 500 mg/m^2 infusions separated by 2 weeks Encephalitis: 375 mg/m^2 once weekly for 4 weeks OR two 1000 mg infusions separated by 2 weeks
Autoimmune mucocutaneous blistering diseases other than pemphigus vulgaris (pemphigus foliaceus, paraneoplastic pemphigus, bullous pemphigoid, mucous membrane pemphigoid, or epidermolysis bullosa acquista)	375 mg/m^2 once weekly for 4 weeks OR two 1000 mg infusions separated by 2 weeks
Neuromyelitis optica spectrum disorder	Two 1,000 mg infusions separated by 2 weeks. Subsequent courses every 6 months based on clinical response; OR 375 mg/m^2 once weekly for 4 weeks. Subsequent courses every 6 months based on clinical response.
Thrombotic thrombocytopenic purpura (TTP)	375 mg/m^2 once weekly for 4 weeks
Dermatomyositis	375 mg/m^2 once weekly for 4 weeks OR two 1000 mg infusions separated by 2 weeks
Polymyositis	375 mg/m^2 once weekly for 4 weeks OR two 1000 mg infusions separated by 2 weeks
Prior to renal transplantation, for patients at high risk of antibody-mediated rejection	375 mg/m^2 or 1000 mg prior to transplantation
Idiopathic membranous nephropathy	Two 1,000 mg infusions separated by 2 weeks. Subsequent courses every 6 months based on clinical response.

Documentation Submission:

Documentation supporting the medical necessity criteria described in the policy must be included in the prior authorization. In addition, the following documentation must also be submitted:

Initial Review for Non-Oncologic Indications

1. Clinical notes describing the diagnosis and clinical features of the diagnosis.
2. For patients not currently receiving rituximab, laboratory results for hepatitis B screening. If the test was positive, describe follow-up therapy.
3. Clinical notes describing current and past medications for the diagnosis, including response to the medications.
4. The dose being requested, including the patient's weight if the diagnosis requires weight-based dosing. If the requested dose is outside of the dosing criteria provided in the table above, a clear explanation for the medical necessity of the requested dose MUST be submitted, including prior dosing (strength and frequency) associated with inadequate response.
5. For commercial health plan members only, the site of service for rituximab administration is specified, including CMS place of service code (see policy XI-06). If rituximab is administered in a hospital outpatient facility, a clear explanation for the medical necessity of the site of service MUST be submitted, including documentation for one or more of the site of service criteria provided in policy XI-06.
6. For commercial health plan members only, when step therapy requirements apply for the requested indication, documentation for one or more of the step therapy supplement criteria MUST be provided (see policy II-242).

Renewal Review for Non-Oncologic Indications

1. Documentation of prior approval for rituximab through the initial review process.
2. Documentation supporting positive clinical response (e.g., slowing of disease progression or decrease in symptom severity and/or frequency).
3. Clinical notes describing current and past medications for the diagnosis, including response to the medications.
4. The dose being requested, including the patient's weight if the diagnosis requires weight-based dosing. If the requested dose is outside of the dosing criteria provided in the table above, a clear explanation for the medical necessity of the requested dose MUST be submitted, including prior dosing (strength and frequency) associated with inadequate response.
5. For commercial health plan members only, the site of service for rituximab administration is specified, including CMS place of service code (see policy XI-06). If rituximab is administered in a hospital outpatient facility, a clear explanation for the medical necessity of the site of service MUST be submitted, including documentation for one or more of the site of service criteria provided in policy XI-06.

- **Intravitreal Angiogenesis Inhibitors for Treatment of Retinal & Choroidal Vascular Conditions, II-71**

I. Initial Review for Bevacizumab (Avastin®)

Intravitreal injection of bevacizumab may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when **ALL** of the following criteria are met:

- Diagnosis of ONE of the following:
  - Diabetic macular edema; OR
  - Diabetic retinopathy; OR
  - Neovascular (wet) age-related macular degeneration or choroidal neovascularization; OR
  - Macular edema (e.g., cystoid) following retinal vein occlusion; OR
  - Neovascular glaucoma; OR
  - Rubeosis (i.e., neovascularization of the iris); OR
  - Retinopathy of prematurity;

  AND
- Prescribed by or in consultation with an ophthalmologist; **AND**
- Not used in combination with intravitreal corticosteroids or verteporfin photodynamic therapy; **AND**
- No concomitant use of another anti-VEGF agent in the same eye; **AND**
- No FDA labeled contraindications to bevacizumab (see table 1 below).

II. Initial Review for Ranibizumab (Lucentis®, Byooviz™, Cimerli™)

Intravitreal injection of ranibizumab (Lucentis®, Byooviz™, Cimerli™) may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when **ALL** of the following criteria are met:

- ONE of the following:
  - Diagnosis of diabetic macular edema, with or without diabetic retinopathy; OR
  - BOTH of the following:
    1. Diagnosis of ONE of the following:
       - Diabetic retinopathy without diabetic macular edema; OR
       - Neovascular (wet) age-related macular degeneration or choroidal neovascularization; OR
       - Macular edema (e.g., cystoid) following retinal vein occlusion; AND
    2. ONE of the following:
       - Previously tried and failed intravitreal bevacizumab; OR
       - Documented intolerance, FDA labeled contraindication, or hypersensitivity to intravitreal bevacizumab;

  AND
- Prescribed by or in consultation with an ophthalmologist; **AND**
- Not used in combination with intravitreal corticosteroids or verteporfin photodynamic therapy; **AND**
- No concomitant use of another anti-VEGF agent in the same eye; **AND**
- No FDA labeled contraindications to ranibizumab (see table 1 below); **AND**
- For commercial health plan members only, step therapy supplement criteria may apply for select conditions (see policy II-242: Step Therapy Supplement).

III. Initial Review for Ranibizumab (Susvimo™)

Intravitreal injection of ranibizumab (Susvimo™) via ocular implant may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when **ALL** of the following criteria are met:

- Diagnosis of neovascular (wet) age-related macular degeneration or choroidal neovascularization; **AND**
- ONE of the following:
  - Previously tried and failed intravitreal bevacizumab; OR
  - Documented intolerance, FDA labeled contraindication, or hypersensitivity to intravitreal bevacizumab;

  AND
- Previously responded to at least two intravitreal injections of ranibizumab (e.g., Lucentis®, Byooviz™); **AND**
- Prescribed by or in consultation with an ophthalmologist; **AND**
- Not used in combination with intravitreal corticosteroids or verteporfin photodynamic therapy; **AND**
- No concomitant use of another anti-VEGF agent in the same eye; **AND**
- No FDA labeled contraindications to ranibizumab (see table 1 below); **AND**
- For commercial health plan members only, step therapy supplement criteria may apply for select conditions (see policy II-242: Step Therapy Supplement).

IV. Initial Review for Aflibercept (Eylea®)

Intravitreal injection of aflibercept may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when **ALL** of the following criteria are met:

- ONE of the following:
  - Diagnosis of diabetic macular edema, with or without diabetic retinopathy; OR
  - Diagnosis of retinopathy of prematurity (ROP) AND ONE of the following:

1. Type I ROP (i.e., ROP zone I stage 1+, 2+, 3, 3+ OR ROP zone II stage 2+, 3+); OR
2. Aggressive posterior ROP (AP-ROP);

OR

- BOTH of the following:
  1. Diagnosis of ONE of the following:
     - Diabetic retinopathy without diabetic macular edema; OR
     - Neovascular (wet) age-related macular degeneration or choroidal neovascularization; OR
     - Macular edema (e.g., cystoid) following retinal vein occlusion;

     AND
  2. ONE of the following:
     - Previously tried and failed intravitreal bevacizumab; OR
     - Documented intolerance, FDA labeled contraindication, or hypersensitivity to intravitreal bevacizumab;

AND

- Prescribed by or in consultation with an ophthalmologist; **AND**
- Not used in combination with intravitreal corticosteroids or verteporfin photodynamic therapy; **AND**
- No concomitant use of another anti-VEGF agent in the same eye; **AND**
- No FDA labeled contraindications to aflibercept (see table 1 below); **AND**
- For commercial health plan members only, step therapy supplement criteria may apply for select conditions (see policy II-242: Step Therapy Supplement).

V. Initial Review for Pegaptanib (Macugen®)

Intravitreal injection of pegaptanib may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when **ALL** of the following criteria are met:

- Diagnosis of neovascular (wet) age-related macular degeneration or choroidal neovascularization; **AND**
- ONE of the following:
  - Previously tried and failed intravitreal bevacizumab; OR
  - Documented intolerance, FDA labeled contraindication, or hypersensitivity to intravitreal bevacizumab;

  AND
- Prescribed by or in consultation with an ophthalmologist; **AND**
- Not used in combination with intravitreal corticosteroids or verteporfin photodynamic therapy; **AND**
- No FDA labeled contraindications to pegaptanib (see table 1 below); **AND**
- No concomitant use of another anti-VEGF agent in the same eye; **AND**
- For commercial health plan members only, step therapy supplement criteria may apply for select conditions (see policy II-242: Step Therapy Supplement).

VI. Initial Review for Brolucizumab (Beovu®)

Intravitreal injection of brolucizumab may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when **ALL** of the following criteria are met:

- Diagnosis of neovascular (wet) age-related macular degeneration or choroidal neovascularization; **AND**
- ONE of the following:
  - Previously tried and failed intravitreal bevacizumab; OR
  - Documented intolerance, FDA labeled contraindication, or hypersensitivity to intravitreal bevacizumab;

  AND
- Prescribed by or in consultation with an ophthalmologist; **AND**
- Not used in combination with intravitreal corticosteroids or verteporfin photodynamic therapy; **AND**

- No concomitant use of another anti-VEGF agent in the same eye; **AND**
- No FDA labeled contraindications to brolucizumab (see table 1 below); **AND**
- For commercial health plan members only, step therapy supplement criteria may apply for select conditions (see policy II-242: Step Therapy Supplement).

VII. Initial Review for Faricimab (Vabysmo™)

Intravitreal injection of faricimab may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when **ALL** of the following criteria are met:

- ONE of the following:
  - Diagnosis of diabetic macular edema; OR
  - BOTH of the following:
    - Diagnosis of neovascular (wet) age-related macular degeneration; AND
    - ONE of the following:
      - Previously tried and failed intravitreal bevacizumab; OR
      - Documented intolerance, FDA labeled contraindication, or hypersensitivity to intravitreal bevacizumab;

  AND
- Prescribed by or in consultation with an ophthalmologist; **AND**
- Not used in combination with intravitreal corticosteroids or verteporfin photodynamic therapy; **AND**
- No concomitant use of another anti-VEGF agent in the same eye; **AND**
- No FDA labeled contraindications to faricimab (see table 1 below); **AND**
- For commercial health plan members only, step therapy supplement criteria may apply for select conditions (see policy II-242: Step Therapy Supplement).

VIII. Renewal Review for Bevacizumab (Avastin®), Ranibizumab (Lucentis®, Byooviz™, Cimerli™), Ranibizumab (Susvimo™), Aflibercept (Eylea®), Pegaptanib (Macugen®), Brolucizumab (Beovu®), or Faricimab (Vabysmo™)

Intravitreal injection of bevacizumab, ranibizumab, aflibercept, pegaptanib, brolucizumab, or faricimab may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when **ALL** of the following criteria are met:

- Previously approved for the requested agent through the initial review process; **AND**
- Demonstrated positive clinical response to the requested therapy (e.g., improvement or stabilization of visual acuity, macular thickness, subretinal/intraretinal cystic fluid, or subretinal hemorrhage); **AND**
- Prescribed by or in consultation with an ophthalmologist; **AND**
- Not used in combination with intravitreal corticosteroids or verteporfin photodynamic therapy; **AND**
- No concomitant use of another anti-VEGF agent in the same eye; **AND**
- No FDA labeled contraindications to the requested agent (see table 1 below).

IX. Experimental/Investigative Uses

All other uses of ranibizumab, pegaptanib, brolucizumab, or faricimab are considered **EXPERIMENTAL/ INVESTIGATIVE** due to the lack of clinical evidence demonstrating an impact on improved health outcomes.

All other non-oncologic uses of bevacizumab and aflibercept are considered **EXPERIMENTAL/ INVESTIGATIVE** due to the lack of clinical evidence demonstrating an impact on improved health outcomes.

Table 1. FDA Labeled Contraindications

Agent	FDA Labeled Contraindications
Bevacizumab (Avastin®)	None*
Ranibizumab (Lucentis®, Byooviz™, Cimerli™)	Ocular or periocular infection; Known hypersensitivity to ranibizumab or any of its excipients
Ranibizumab (Susvimo™)	Ocular or periocular infections; Known hypersensitivity to ranibizumab products or any of its excipients; Active intraocular inflammation
Aflibercept (Eylea®)	Ocular or periocular infection; Known hypersensitivity to aflibercept or any of its excipients; Active intraocular inflammation
Pegaptanib (Macugen®)	Ocular or periocular infection; Known hypersensitivity to pegaptanib sodium or any of its excipients
Brolucizumab (Beovu®)	Ocular or periocular infection; Known hypersensitivity to brolucizumab or any of its excipients; Active intraocular inflammation
Faricimab (Vabysmo™)	Ocular or periocular infection; Active intraocular inflammation; Hypersensitivity to faricimab or any of its excipients

*Bevacizumab is not FDA-approved for treatment of ocular conditions; therefore, there are no FDA labeled contraindications related to intravitreal administration.

Documentation Submission:

Documentation supporting the medical necessity criteria described in the policy must be included in the prior authorization, when prior authorization is required. In addition, the following documentation must also be submitted:

Initial Review

1. Clinical notes describing the diagnosis and clinical features of the diagnosis.
2. Clinical notes describing current and past medications for the diagnosis, including response to the medications.
3. Clinical notes documenting absence of active ocular or periocular infection.
4. For commercial health plan members only, when step therapy requirements apply for the requested indication, documentation for one or more of the step therapy supplement criteria MUST be provided (see policy II-242).

Renewal Review

1. Documentation of prior approval through the initial review process.
2. Documentation since most recent approval supporting continued positive clinical response (e.g., improvement or stabilization of visual acuity, macular thickness, subretinal/intraretinal cystic fluid).

- **Bunionectomy, IV-171**

NOTE:

- This policy addresses surgical treatment of bunions by exostectomy and/or osteotomy only. It does not address more complex bunionectomy procedures, such as arthrodesis, or alternate procedures for surgical complications.

- Refer to medical policy IV-153 for synthetic cartilage implants for metatarsophalangeal joint disorders.

I. Initial Procedure

Surgical treatment of bunions by exostectomy or osteotomy may be considered **MEDICALLY NECESSARY AND APPROPRIATE** for patients who meet **ALL** of the following criteria:

- Pain or skin breakdown at first metatarsophalangeal (MTP) joint; **AND**
- Clinically significant functional limitation resulting in impaired ambulation; **AND**
- Imaging confirms BOTH of the following:
  - Hallux valgus angle (HVA) >15 degrees; and
  - No arthritis or mild arthritis;

AND

- Previously tried and failed conservative treatment for ≥ 12 weeks including BOTH of the following:
  - Well-fitted footwear with wide toe box and low heel; and
  - Bunion pad or orthotic;

AND

- Continued symptoms with clinically significant functional limitation despite treatment with well-fitted footwear AND bunion pads/orthotics.

II. Revision Procedure

Surgical revision of bunions by exostectomy or osteotomy may be considered **MEDICALLY NECESSARY AND APPROPRIATE** for patients who meet **ALL** of the following criteria:

- Pain or skin breakdown at first metatarsophalangeal (MTP) joint; **AND**
- Clinically significant functional limitation resulting in impaired ambulation; **AND**
- Imaging confirms reoccurrence by BOTH of the following:
  - Hallux valgus angle (HVA) >15 degrees; and
  - No arthritis or mild arthritis;

AND

- Post-operative surgical shoe and well-fitted footwear with wide toe box and low heel have been utilized since the previous surgical procedure; **AND**
- Continued symptoms with clinically significant functional limitation despite treatment.

III. All other uses of exostectomy or osteotomy are considered **NOT MEDICALLY NECESSARY** when the criteria above are not met.

- **Wireless Gastric Motility Monitoring, II-134**

Use of a wireless gastric motility monitoring system for any indication, including, but not limited to, the evaluation of gastroparesis, is considered **EXPERIMENTAL/INVESTIGATIVE** due to a lack of evidence demonstrating its impact on improved health outcomes.

Use of a wireless patch system for any indication, including, but not limited to, the evaluation of gastrointestinal (GI) motility, is considered **EXPERIMENTAL/INVESTIGATIVE** due to a lack of evidence demonstrating its impact on improved health outcomes.

- **Nasal Swell Body Reduction, IV-172**

NOTE: Refer to medical policy IV-170 for Ablation Procedures for Treatment of Chronic Rhinitis.

Nasal swell body reduction by destruction, ablation, or coblation is considered **EXPERIMENTAL/ INVESTIGATIVE for all indications,** including but not limited to nasal obstruction due to a lack of clinical evidence demonstrating an impact on improved health outcomes.

Nasal tissue reduction by ablative techniques (e.g., radiofrequency ablation) **for the treatment of nasal obstruction** is considered **EXPERIMENTAL/ INVESTIGATIVE for all indications,** including but not limited to treatment of nasal valve collapse, due to a lack of clinical evidence demonstrating an impact on improved health outcomes.

Policies Delegated to eviCore
None

Policies Inactivated
None