Geisinger Medicare
2023
Part B Step Therapy List & Criteria

TABLE OF CONTENTS

BEOVU (BROLUCIZUMAB)

Affected Drugs
BEOVU INTRAVITREAL SOLUTION 6MG/0.05ML VIAL
BEOVU INTRAVITREAL SOLUTION 6MG/0.05ML PREFILLED SYRINGE

Step Therapy Criteria

- Medical record documentation of a diagnosis of neovascular age-related macular degeneration **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to intravitreal bevacizumab (Avastin)

OR

- Medical record documentation of a diagnosis of diabetic macular edema **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to intravitreal bevacizumab (Avastin)

AUTHORIZATION DURATION: Approvals will be given for a lifetime duration.

QUANTITY LIMIT: 12mg per 25 days (6mg per eye per 25 days)

Step 1 Drugs
Intravitreal Avastin (bevacizumab)

Number of days for claims review for select or first line drugs: 365 days, Geisinger Health Plan new starts only

BYOOVIZ (RANIBIZUMAB-NUNA)

Affected Drugs
BYOOVIZ INTRAVITREAL SOLUTION 0.5MG/0.05ML VIAL

Step Therapy Criteria

- Medical record documentation of a diagnosis of neovascular age-related macular degeneration **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to intravitreal bevacizumab (Avastin)

OR

- Medical record documentation of a diagnosis of diabetic retinopathy with or without macular edema **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to intravitreal bevacizumab (Avastin)

OR

- Medical record documentation of a diagnosis of macular edema following retinal vein occlusion **OR** myopic choroidal neovascularization

AUTHORIZATION DURATION: Approvals will be given for a lifetime duration.

QUANTITY LIMIT: 0.1mL (1mg) per 28 days (0.5mg per eye per 28 days)

Step 1 Drugs
Intravitreal Avastin (bevacizumab)

Number of days for claims review for select or first line drugs: 365 days, Geisinger Health Plan new starts only

CIMERLI (RANIBIZUMAB-EQRN)

Affected Drugs
CIMERLI INTRAVITREAL SOLUTION 0.5MG/0.05ML VIAL
CIMERLI INTRAVITREAL SOLUTION 0.3MG/0.05ML VIAL

Step Therapy Criteria

- Medical record documentation of a diagnosis of neovascular age-related macular degeneration **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to intravitreal bevacizumab (Avastin)

OR

- Medical record documentation of a diagnosis of diabetic retinopathy with or without macular edema **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to intravitreal bevacizumab (Avastin)

OR

- Medical record documentation of a diagnosis of macular edema following retinal vein occlusion **OR** myopic choroidal neovascularization

AUTHORIZATION DURATION: Approvals will be given for a lifetime duration.

QUANTITY LIMIT: 0.1mL (1mg) per 28 days (0.5mg per eye per 28 days)

Step 1 Drugs
Intravitreal Avastin (bevacizumab)

Number of days for claims review for select or first line drugs: 365 days, Geisinger Health Plan new starts only

EYLEA (AFLIBERCEPT)

Affected Drugs
EYLEA INTRAVITREAL SOLUTION 2MG/0.05ML VIAL
EYLEA INTRAVITREAL SOLUTION 2MG/0.05ML PREFILLED SYRINGE

Step Therapy Criteria

- Medical record documentation of a diagnosis of neovascular age-related macular degeneration **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to intravitreal bevacizumab (Avastin)

OR

- Medical record documentation of a diagnosis of diabetic retinopathy with or without macular edema **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Avastin **OR** medical record documentation of baseline best-corrected visual acuity 20/50 or worse

OR

- Medical record documentation of a diagnosis of macular edema following retinal vein occlusion

AUTHORIZATION DURATION: Approvals will be given for a lifetime duration.

QUANTITY LIMIT: 0.1mL (4mg) per 25 days (2mg per eye per 25 days)

Step 1 Drugs
Intravitreal Avastin (bevacizumab)

Number of days for claims review for select or first line drugs: 365 days, Geisinger Health Plan new starts only

LUCENTIS (RANIBIZUMAB)

Affected Drugs
LUCENTIS INTRAVITREAL SOLUTION 0.5MG/0.05ML VIAL
LUCENTIS INTRAVITREAL SOLUTION 0.3MG/0.05ML VIAL
LUCENTIS INTRAVITREAL SOLUTION 0.5MG/0.05ML PREFILLED SYRINGE
LUCENTIS INTRAVITREAL SOLUTION 0.3MG/0.05ML PREFILLED SYRINGE

Step Therapy Criteria

- Medical record documentation of a diagnosis of neovascular age-related macular degeneration **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to intravitreal bevacizumab (Avastin)

OR

- Medical record documentation of a diagnosis of diabetic retinopathy with or without macular edema **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to intravitreal bevacizumab (Avastin)

OR

- Medical record documentation of a diagnosis of macular edema following retinal vein occlusion **OR** myopic choroidal neovascularization

AUTHORIZATION DURATION: Approvals will be given for a lifetime duration.

QUANTITY LIMIT: 0.1mL (1mg) per 28 days (0.5mg per eye per 28 days)

Step 1 Drugs
Intravitreal Avastin (bevacizumab)

Number of days for claims review for select or first line drugs: 365 days, Geisinger Health Plan new starts only

RENFLEXIS (INFLIXIMAB-ABDA)

Affected Drugs
RENFLEXIS INTRAVENOUS SOLUTION RECONSTITUTED 100 MG VIAL

Step Therapy Criteria

For Treatment of Rheumatoid Arthritis:
- Must be 18 years of age or greater **AND**
- Requesting provider must be a rheumatologist **AND**
- Diagnosis of moderate to severe rheumatoid arthritis according the American College of Rheumatology Criteria for the Classification and Diagnosis of Rheumatoid Arthritis **AND**
- Medical record documentation that the infliximab product is not being used concurrently with a TNF blocker or other biologic agent **AND**
- Continuation of effective dose of methotrexate during infliximab therapy **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to two of the following: infliximab-dyyb (Inflectra), infliximab (unbranded infliximab or Remicade), and/or infliximab-axxq (Avsola)

For Treatment of Crohn's Disease, Pediatric Crohn's Disease, and/or Fistulizing Crohn's Disease:
- Must be 6 years of age or older; **AND**
- Prescription is written by a gastroenterologist **AND**
- Medical record documentation of a diagnosis of moderate to severe Crohn's disease **AND**
- Medical record documentation that the infliximab product is not being used concurrently with a TNF blocker or other biologic agent **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to two of the following: infliximab-dyyb (Inflectra), infliximab (unbranded infliximab or Remicade), and/or infliximab-axxq (Avsola)

For Treatment of Ulcerative Colitis:
- Must be at least 6 years of age; **AND**
- Must be prescribed by a gastroenterologist; **AND**
- Physician provided documentation of a diagnosis of moderate to severe ulcerative colitis **AND**
- Medical record documentation that the infliximab product is not being used concurrently with a TNF blocker or other biologic agent **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to two of the following: infliximab-dyyb (Inflectra), infliximab (unbranded infliximab or Remicade), and/or infliximab-axxq (Avsola)

For Treatment of Ankylosing Spondylitis:
- Physician documentation of a diagnosis of ankylosing spondylitis **AND**
- Prescribing physician must be a rheumatologist **AND**
- Must be at least 18 years of age **AND**
- Medical record documentation that the infliximab product is not being used concurrently with a TNF blocker or other biologic agent **AND**

- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to two of the following: infliximab-dyyb (Inflectra), infliximab (unbranded infliximab or Remicade), and/or infliximab-axxq (Avsola)

For the treatment of Plaque Psoriasis:

- Prescribed by a dermatologist **AND**
- Insured individual must be at least 18 years of age **AND**
- Physician provided documentation of a diagnosis of moderate to severe plaque psoriasis characterized by greater than or equal to 5% body surface area involved or disease affecting crucial body areas such as the hands, feet, face, or genitals **AND**
- Medical record documentation that the infliximab product is not being used concurrently with a TNF blocker or other biologic agent **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to two of the following: infliximab-dyyb (Inflectra), infliximab (unbranded infliximab or Remicade), and/or infliximab-axxq (Avsola)

For the treatment of Psoriatic Arthritis:

- Physician provided documentation of a diagnosis of moderately to severely active psoriatic arthritis which must include the following:
    - Documentation of either active psoriatic lesions or a documented history of psoriasis

  AND
- Must be prescribed by a rheumatologist or dermatologist **AND**
- Must be at least 18 years of age **AND**
- Medical record documentation that the infliximab product is not being used concurrently with a TNF blocker or other biologic agent **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to two of the following: infliximab-dyyb (Inflectra), infliximab (unbranded infliximab or Remicade), and/or infliximab-axxq (Avsola)

AUTHORIZATION DURATION: Approval will be given for an initial duration of six (6) months. For continuation of coverage, medical record documentation of clinical improvement or lack of progression in the signs and symptoms of the treated indication at six (6) months of infliximab therapy is required.

After the initial six (6) month approval, subsequent approvals for coverage will be for a duration of one (1) year. Reevaluation of coverage will be every one (1) year requiring medical record documentation of continued or sustained improvement in the signs and symptoms of the treated indication while on infliximab therapy.

Step 1 Drugs
Avsola (infliximab-axxq), Inflectra (infliximab-dyyb), Remicade (infliximab), Unbranded infliximab

Number of days for claims review for select or first line drugs: 365 days, Geisinger Health Plan new starts only

RITUXAN (RITUXIMAB)

Affected Drugs

RITUXAN INTRAVENOUS SOLUTION 100 MG/10 ML VIAL
RITUXAN INTRAVENOUS SOLUTION 500 MG/50 ML VIAL

Step Therapy Criteria
For Rheumatoid Arthritis:

- Physician documentation of a diagnosis of moderate to severe rheumatoid arthritis in accordance with the American College of Rheumatology Criteria for the Classification and Diagnosis of Rheumatoid Arthritis; **AND**
- At least 18 years of age or older; **AND**
- Prescription written by a rheumatologist; **AND**
- Medical record documentation that an effective dose of methotrexate will be continued during rituximab therapy; **AND**
- Medical record documentation that Rituxan is not being used concurrently with a TNF blocker **AND**
- For rituximab reference product requests (i.e. Rituxan), medical record documentation of a therapeutic failure on, intolerance to, or contraindication to two (2) of the following: rituximab-pvvr (Ruxience), rituximab-arrx (Riabni), or rituximab-abbs (Truxima).

For Chronic Immunothrombocytopenia (ITP):

- Diagnosis of primary chronic ITP **AND**
- Platelet count of < 30,000/mm3 with active bleeding; or platelet count < 30,000/mm3 and a documented history of significant bleeding; or < 20,000/mm3 **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to corticosteroids and/or IVIG* (*prior authorization required) **AND**
- For rituximab reference product requests (i.e. Rituxan), medical record documentation of a therapeutic failure on, intolerance to, or contraindication to two (2) of the following: rituximab-pvvr (Ruxience), rituximab-arrx (Riabni), or rituximab-abbs (Truxima).

For Chronic Lymphoid Leukemia:

- Medical record documentation of a diagnosis of Chronic Lymphocytic Leukemia (CLL) **AND**
- For rituximab reference product requests (i.e. Rituxan), medical record documentation of a therapeutic failure on, intolerance to, or contraindication to two (2) of the following: rituximab-pvvr (Ruxience), rituximab-arrx (Riabni), or rituximab-abbs (Truxima).

For Microscopic Polyarteritis Nodosa (PAN)

- Medical record documentation of a diagnosis of microscopic polyarteritis nodosa used in combination with glucocorticoids **AND**
- For rituximab reference product requests (i.e. Rituxan), medical record documentation of a therapeutic failure on, intolerance to, or contraindication to two (2) of the following: rituximab-pvvr (Ruxience), rituximab-arrx (Riabni), or rituximab-abbs (Truxima).

For Granulomatosis with Polyangiitis (GPA) (Wegener's Granulomatosis) and Microscopic Polyangiitis (MPA)

- Medical record documentation of a diagnosis of Granulomatosis with Polyangiitis (GPA) (Wegener's granulomatosis) or Microscopic Polyangiitis (MPA) used in combination with glucocorticoids
  AND
- For rituximab reference product requests (i.e. Rituxan), medical record documentation of a therapeutic failure on, intolerance to, or contraindication to two (2) of the following: rituximab-pvvr (Ruxience), rituximab-arrx (Riabni), or rituximab-abbs (Truxima).

For Non-Hodgkin Lymphoma

- Medical record documentation of a diagnosis of Non-Hodgkin Lymphoma
  AND
- For rituximab reference product requests (i.e. Rituxan), medical record documentation of a therapeutic failure on, intolerance to, or contraindication to two (2) of the following: rituximab-pvvr (Ruxience), rituximab-arrx (Riabni), or rituximab-abbs (Truxima).

For Multiple Sclerosis (MS)

- Medical record documentation of a diagnosis of Multiple Sclerosis
  AND
- For rituximab reference product requests (i.e. Rituxan), medical record documentation of a therapeutic failure on, intolerance to, or contraindication to two (2) of the following: rituximab-pvvr (Ruxience), rituximab-arrx (Riabni), or rituximab-abbs (Truxima).

For Refractory Chronic Debilitating Myasthenia Gravis

- Medical record documentation of refractory Chronic Debilitating Myasthenia Gravis **AND**
- Prescribed by or in consultation with a neuromuscular specialist **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least one corticosteroid **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least one cholinesterase inhibitor **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least one non-steroidal immunosuppressive therapy
  AND
- For rituximab reference product requests (i.e. Rituxan), medical record documentation of a therapeutic failure on, intolerance to, or contraindication to two (2) of the following: rituximab-pvvr (Ruxience), rituximab-arrx (Riabni), or rituximab-abbs (Truxima).

For Pemphigus Vulgaris (PV)

- Prescription written by a dermatologist **AND**
- Member is 18 years of age or older **AND**
- Medical record documentation of a diagnosis of moderate to severe pemphigus vulgaris
  AND
- Medical record documentation of use in combination with corticosteroids or a contraindication or intolerance to corticosteroids
  AND
- For rituximab reference product requests (i.e. Rituxan), medical record documentation of a therapeutic failure on, intolerance to, or contraindication to two (2) of the following: rituximab-pvvr (Ruxience), rituximab-arrx (Riabni), or rituximab-abbs (Truxima).

AUTHORIZATION DURATION:
For Multiple Sclerosis: Initial approval will be for 12 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if patient experiences toxicity or worsening of disease.
For all other indications: Initial approval will be for 6 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if patient experiences toxicity or worsening of disease.

Step 1 Drugs
Ruxience (rituximab-pvvr)
Riabni (rituximab-arrx)
Truxima (rituximab-abbs)

Number of days for claims review for select or first line drugs: 365 days, Geisinger Health Plan new starts only

SUSVIMO (RANIBIZUMAB)

Affected Drugs
SUSVIMO (IMPLANT 1ST FILL) INTRAVITREAL SOLUTION 10MG/0.1ML VIAL
SUSVIMO OCULAR IMPLANT INTRAVITREAL IMPLANT
SUSVIMO (IMPLANT REFILL) INTRAVITREAL SOLUTION 10MG/0.1ML VIAL

Step Therapy Criteria

- Medical record documentation of a diagnosis of neovascular age-related macular degeneration **AND**
- Medical record documentation patient has previously responded to at least two (2) intravitreal doses of a Vascular Endothelial Growth Factor (VEGF) inhibitor medication **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to intravitreal bevacizumab (Avastin) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to one (1) additional intravitreal VEGF inhibitor (e.g. Eylea, Beovu, or Lucentis)

AND

- Medical record documentation that Susvimo (ranibizumab) will not be given in combination with an intravitreal Vascular Endothelial Growth Factor (VGEF) inhibitor **OR**
- If the request is for use in combination with an intravitreal VEGF inhibitor, all of the following must be met:
    - Medical record documentation Susvimo (ranibizumab) will be given in combination with intravitreal ranibizumab injection (Lucentis) **AND**
    - Medical record documentation intravitreal ranibizumab injection will be administered on an as needed basis, as determined by the prescriber

AUTHORIZATION DURATION: Approval will be given for an **initial duration of two years (2) years** or less if the reviewing provider feels it is medically appropriate. After the initial two (2) year approval, subsequent approvals will be for a **lifetime duration** or less if the reviewing provider feels it is medically appropriate, and will require:

- Medical record documentation that Susvimo (ranibizumab) will not be given in combination with an intravitreal Vascular Endothelial Growth (VGEF) inhibitor

QUANTITY LIMIT: 0.2mL (2 vials) per 24 weeks (to allow 2mg per 24 weeks per treated eye)

LIMITATION: Susvimo (ranibizumab) to be given in combination with intravitreal ranibizumab (Lucentis) injections after 92 weeks from the start of Susvimo therapy has not been studied in clinical trials and will require prior authorization.

Step 1 Drugs
Intravitreal Avastin (bevacizumab)

Step 2 Drugs
Intravitreal Eylea (aflibercept)
Intravitreal Lucentis (ranibizumab)
Intravitreal Beovu (brolucizumab)

Number of days for claims review for select or first line drugs: 365 days, Geisinger Health Plan new starts only

VABYSMO (FARICIMAB)

Affected Drugs
VABYSMO INTRAVITREAL SOLUTION 6MG/0.05ML VIAL

Step Therapy Criteria
- Medical record documentation of a diagnosis of neovascular age-related macular degeneration **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to intravitreal bevacizumab (Avastin) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to one (1) additional intravitreal VEGF inhibitor (e.g. Eylea, Beovu, or Lucentis)

OR
- Medical record documentation of a diagnosis of diabetic macular edema **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to intravitreal bevacizumab (Avastin) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to one (1) additional intravitreal VEGF inhibitor (e.g. Eylea or Lucentis)

AUTHORIZATION DURATION: Approvals will be given for a lifetime duration.

QUANTITY LIMIT: 0.1mL (12mg) per 21 days (6mg per eye per 21 days)

Step 1 Drugs
Neovascular age-related macular degeneration & Diabetic Macular Edema:
Intravitreal Avastin (bevacizumab)

Step 2 Drugs
Neovascular age-related macular degeneration
Intravitreal Eylea (aflibercept)
Intravitreal Lucentis (ranibizumab)
Intravitreal Beovu (brolucizumab)

Diabetic Macular Edema:
Intravitreal Eylea (aflibercept)
Intravitreal Lucentis (ranibizumab)

Number of days for claims review for select or first line drugs: 365 days, Geisinger Health Plan new starts only

Devised: 9/15/20
Revised: 6/18/21 (Renflexis, Inflectra, Remicade), 1/18/22 (Rituxan), 3/15/22 (Susvimo, Vabysmo, Beovu), 5/17/22 (VEGf QL), 7/19/22 (VEGf Best-Corrected VA), 9/13/22 (RTX ITP duration/alts), 10/25/22 (VEGf QL, Beovu DME indication), 12/21/22 (Beovu affected drugs, clarified intravitreal bevacizumab (Avastin), Inflectra/Remicade delete, Renflexis alternatives edit), 1/17/23 (Byooviz, Cimerli)
Reviewed: