

**Geisinger Medicare
2024
Part B Step Therapy List & Criteria**

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AVASTIN (BEVACIZUMAB)

Affected Drugs

AVASTIN INTRAVENOUS SOLUTION 100MG/4ML VIAL
AVASTIN INTAVENOUS SOLUTION 400MG/16ML VIAL

Step Therapy Criteria

- Medical record documentation of a therapeutic failure of, intolerance to, or contraindication to all of the following: Alymsys (bevacizumab-maly), Mvasi (bevacizumab-awwb), Vegzelma (bevacizumab-adcd), Zirabev (bevacizumab-bvzr).

AUTHORIZATION DURATION:

For adjuvant treatment of Stage III or IV Epithelial Ovarian, Fallopian Tube or Primary Peritoneal Cancer following initial surgical resection:

Authorization will be for one (1) 21 month approval. Authorization of Avastin for adjuvant treatment should not exceed the FDA-approved treatment duration of 21 months (28 cycles). For requests exceeding the above limit, medical record documentation of the following is required:

- Peer-reviewed literature citing well-designed clinical trials to indicate that the member's healthcare outcome will be improved by dosing beyond the FDA-approved treatment duration

For all other indications:

Authorization will be open-ended

Step 1 Drugs

Alymsys (bevacizumab-maly)
Mvasi (bevacizumab-awwb)
Vegzelma (bevacizumab-adcd)
Zirabev (bevacizumab-bvzr)

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

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

OR

- Medical record documentation of a diagnosis of retinopathy of prematurity (ROP)

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

EYLEA HD (AFLIBERCEPT)

Affected Drugs

EYLEA HD INTRAVITREAL SOLUTION 8MG/0.07ML 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 one (1) of the following: Eylea*, Beovu*, Lucentis*, Byooviz*, or Cimerli* **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Vabysmo*

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 one (1) of the following: Eylea*, Beovu*, Lucentis*, Byooviz*, or Cimerli* **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Vabysmo*

*Prior authorization required

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

QUANTITY LIMIT: 0.14mL (16mg) per 21 days (8mg per eye per 21 days)

Step 1 Drugs

Neovascular age-related macular degeneration:

Intravitreal Eylea (aflibercept)
Intravitreal Lucentis (ranibizumab)
Intravitreal Beovu (brolucizumab)
Intravitreal Byooviz (ranibizumab-nuna)
Intravitreal Cimerli (ranibizumab-eqrn)

Diabetic Retinopathy/Diabetic Macular Edema:

Intravitreal Eylea (aflibercept)
Intravitreal Lucentis (ranibizumab)
Intravitreal Byooviz (ranibizumab-nuna)
Intravitreal Cimerli (ranibizumab-eqrn)

Step 2 Drugs

Neovascular age-related macular degeneration/Diabetic Retinopathy/Diabetic Macular Edema:

Vabysmo (faricimab)

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

GEL-ONE (CROSS-LINKED HYALURONATE)

Affected Drugs

GEL-ONE INTRA-ARTICULAR 30MG/3ML PREFILLED SYRINGE

Step Therapy Criteria

- Physician documented symptomatic osteoarthritis of the knee, defined as knee pain associated with radiographic evidence of osteophytes in the knee joint provided the clinical presentation is not that of “bone-on-bone”, morning stiffness of less than or equal to 30 minutes in duration, crepitus on range of motion; **AND**
- Physician documented knee joint pain sufficient to interfere with ambulatory functional activities; **AND**
- Physician documentation of non-pharmacologic modalities, e.g., weight loss, quadriceps muscle strengthening, other physical therapy modalities, or exercises that have not promoted satisfactory symptomatic relief; **AND**
- Physician documentation that there has been no significant improvement following pharmacologic therapy with a full-dose nonsteroidal anti-inflammatory drug (NSAID) regimen, with or without supplemental acetaminophen, over a 10-12 week period of time or if NSAID’s are contraindicated, a failure of daily acetaminophen regimen over a 4 to 6 week period; **AND**
- Physician documentation that there has been no significant improvement following standard dose intra-articular corticosteroid injection(s) e.g., a satisfactory clinical response of greater than or equal to 3 months; this requirement does not apply if the use of corticosteroids might increase the risk of local or systemic bacterial infection, e.g., diabetes mellitus; **AND**
- Physician documentation of failure on, intolerance to or contraindication to two (2) of the following: Durolane, Euflexxa, Gelsyn-3, GenVisc, Hyalgan, Orthovisc, Supartz, Synvisc/Synvisc-One, and Visco-3

AUTHORIZATION DURATION: Initial approval will be for six (6) months. Subsequent approvals will be for six (6) months when members meet the following criteria:

- Medical record documentation of significant improvement in pain and function following the previous injection; **AND**
- Documented reduction of the doses of nonsteroidals or analgesics during the six-month period following the last injection in the previous series as well as no need for accompanying intra-articular steroid injections; **AND**
- Six months or longer have elapsed since the last injection in the previous series.

QUANTITY LIMIT: One (1) treatment course to the affected knee(s) (bilateral injections may be allowed if both knees meet the required coverage criteria)

LIMITATIONS:

- Gel-One treatment course is limited to 1 injection in a 6-month period.

CONTRAINDICATIONS:

- The use of these products for injection into any joint other than the knee.
- Injection of these products for indications other than the diagnosis of osteoarthritis
- Documented allergy to chickens or eggs.
- Knee joint infection, skin disease or infection around the area where the injection will be given.
- The insured individual has known sensitivity or contraindication to the use of either sodium hyaluronate or hylan G-F 20, e.g., crystal synovitis or hypersensitivity to hyaluronan preparations

Step 1 Drugs

Durolane, Euflexxa, Gelsyn-3, GenVisc, Hyalgan, Orthovisc, Supartz, Synvisc/Synvisc-One, Visco-3

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

HERCEPTIN (TRASTUZUMAB)

Affected Drugs

HERCEPTIN INTRAVENOUS SOLUTION 440MG VIAL
HERCEPTIN INTRAVENOUS SOLUTION 150MG VIAL

Step Therapy Criteria

- Medical record documentation of a therapeutic failure of, intolerance to, or contraindication to at least two (2) of the following: trastuzumab-anns (Kanjinti), trastuzumab-dkst (Ogivri), trastuzumab-dttb (Ontruzant), trastuzumab-qyyp (Trazimera), and/or trastuzumab-pkrb (Herzuma)

AUTHORIZATION DURATION:

For adjuvant treatment:

Authorization will be for one (1) 12-month approval. Authorization of Herceptin for adjuvant treatment should not exceed the FDA-approved treatment duration of 1 year (12 months). For requests exceeding the above limit, medical record documentation of the following is required:

- Peer-reviewed literature citing well-designed clinical trials to indicate that the member's healthcare outcome will be improved by dosing beyond the FDA-approved treatment duration

For all other indications:

Authorization will be open-ended

Step 1 Drugs

Herzuma (trastuzumab-pkrb), Kanjinti (trastuzumab-anns), Ogivri (trastuzumab-dkst), Ontruzant (trastuzumab-dttb), Trazimera (trastuzumab-qyyp)

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

HYMOVIS (HIGH MOLECULAR WEIGHT VISCOELASTIC HYALURONAN)

Affected Drugs

HYMOVIS INTRA-ARTICULAR SOLUTION 24MG/3ML PREFILLED SYRINGE

Step Therapy Criteria

- Physician documented symptomatic osteoarthritis of the knee, defined as knee pain associated with radiographic evidence of osteophytes in the knee joint provided the clinical presentation is not that of “bone-on-bone”, morning stiffness of less than or equal to 30 minutes in duration, crepitus on range of motion; **AND**
- Physician documented knee joint pain sufficient to interfere with ambulatory functional activities; **AND**
- Physician documentation of non-pharmacologic modalities, e.g., weight loss, quadriceps muscle strengthening, other physical therapy modalities, or exercises that have not promoted satisfactory symptomatic relief; **AND**
- Physician documentation that there has been no significant improvement following pharmacologic therapy with a full-dose nonsteroidal anti-inflammatory drug (NSAID) regimen, with or without supplemental acetaminophen, over a 10-12 week period of time or if NSAID’s are contraindicated, a failure of daily acetaminophen regimen over a 4 to 6 week period; **AND**
- Physician documentation that there has been no significant improvement following standard dose intra-articular corticosteroid injection(s) e.g., a satisfactory clinical response of greater than or equal to 3 months; this requirement does not apply if the use of corticosteroids might increase the risk of local or systemic bacterial infection, e.g., diabetes mellitus; **AND**
- Physician documentation of failure on, intolerance to or contraindication to two (2) of the following: Durolane, Euflexxa, Gelsyn-3, GenVisc, Hyalgan, Orthovisc, Supartz, Synvisc/Synvisc-One, and Visco-3

AUTHORIZATION DURATION: Initial approval will be for six (6) months. Subsequent approvals will be for six (6) months when members meet the following criteria:

- Medical record documentation of significant improvement in pain and function following the previous injection; **AND**
- Documented reduction of the doses of nonsteroidals or analgesics during the six-month period following the last injection in the previous series as well as no need for accompanying intra-articular steroid injections; **AND**
- Six months or longer have elapsed since the last injection in the previous series.

QUANTITY LIMIT: One (1) treatment course to the affected knee(s) (bilateral injections may be allowed if both knees meet the required coverage criteria)

LIMITATIONS:

- Hymovis treatment course is limited to 2 injections in a 6-month period.

CONTRAINDICATIONS:

- The use of these products for injection into any joint other than the knee.
- Injection of these products for indications other than the diagnosis of osteoarthritis
- Documented allergy to chickens or eggs.
- Knee joint infection, skin disease or infection around the area where the injection will be given.
- The insured individual has known sensitivity or contraindication to the use of either sodium hyaluronate or hylan G-F 20, e.g., crystal synovitis or hypersensitivity to hyaluronan preparations

Step 1 Drugs

Durolane, Euflexxa, Gelsyn-3, GenVisc, Hyalgan, Orthovisc, Supartz, Synvisc/Synvisc-One, Visco-3

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

INFLIXIMAB (REMICADE OR UNBRANDED INFLIXIMAB)

Affected Drugs

REMICADE INTRAVENOUS SOLUTION RECONSTITUTED 100 MG VIAL
INFLIXIMAB INTRAVENOUS SOLUTION RECONSTITUTED 100MG 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) and 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) and 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) and 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) and 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) and 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) and 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)

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

MONOVISC (HIGH MOLECULAR WEIGHT HYALURONON)

Affected Drugs

MONOVISC INTRA-ARTICULAR SOLUTION 88MG/4ML PREFILLED SYRINGE

Step Therapy Criteria

- Physician documented symptomatic osteoarthritis of the knee, defined as knee pain associated with radiographic evidence of osteophytes in the knee joint provided the clinical presentation is not that of “bone-on-bone”, morning stiffness of less than or equal to 30 minutes in duration, crepitus on range of motion; **AND**
- Physician documented knee joint pain sufficient to interfere with ambulatory functional activities; **AND**
- Physician documentation of non-pharmacologic modalities, e.g., weight loss, quadriceps muscle strengthening, other physical therapy modalities, or exercises that have not promoted satisfactory symptomatic relief; **AND**
- Physician documentation that there has been no significant improvement following pharmacologic therapy with a full-dose nonsteroidal anti-inflammatory drug (NSAID) regimen, with or without supplemental acetaminophen, over a 10-12 week period of time or if NSAID’s are contraindicated, a failure of daily acetaminophen regimen over a 4 to 6 week period; **AND**
- Physician documentation that there has been no significant improvement following standard dose intra-articular corticosteroid injection(s) e.g., a satisfactory clinical response of greater than or equal to 3 months; this requirement does not apply if the use of corticosteroids might increase the risk of local or systemic bacterial infection, e.g., diabetes mellitus; **AND**
- Physician documentation of failure on, intolerance to or contraindication to two (2) of the following: Durolane, Euflexxa, Gelsyn-3, GenVisc, Hyalgan, Orthovisc, Supartz, Synvisc/Synvisc-One, and Visco-3

AUTHORIZATION DURATION: Initial approval will be for six (6) months. Subsequent approvals will be for six (6) months when members meet the following criteria:

- Medical record documentation of significant improvement in pain and function following the previous injection; **AND**
- Documented reduction of the doses of nonsteroidals or analgesics during the six-month period following the last injection in the previous series as well as no need for accompanying intra-articular steroid injections; **AND**
- Six months or longer have elapsed since the last injection in the previous series.

QUANTITY LIMIT: One (1) treatment course to the affected knee(s) (bilateral injections may be allowed if both knees meet the required coverage criteria)

LIMITATIONS:

Monovisc treatment course is limited to 1 injection in a 6-month period.

CONTRAINDICATIONS:

- The use of these products for injection into any joint other than the knee.
- Injection of these products for indications other than the diagnosis of osteoarthritis
- Documented allergy to chickens or eggs.
- Knee joint infection, skin disease or infection around the area where the injection will be given.
- The insured individual has known sensitivity or contraindication to the use of either sodium hyaluronate or hylan G-F 20, e.g., crystal synovitis or hypersensitivity to hyaluronan preparations

Step 1 Drugs

Durolane, Euflexxa, Gelsyn-3, GenVisc, Hyalgan, Orthovisc, Supartz, Synvisc/Synvisc-One, Visco-3

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) and 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) and 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) and 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) and 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) and 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) and 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)

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 Acute Lymphoblastic Leukemia, Hairy Cell Leukemia, and 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 Hodgkin Lymphoma

- Medical record documentation of a diagnosis of Hodgkin Lymphoma
AND
- For rituximab reference product requests (i.e. Rituxan), medical record documentation of a therapeutic failure on, intolerance to, or contraindication to rituximab-pvvr (Ruxience) **AND** rituximab-arrx (Riabni) **AND** 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 (VEGF) 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 (VEGF) 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 Beovu (brolucizumab)

Intravitreal Byooviz (ranibizumab-nuna)

Intravitreal Cimerli (ranibizumab-eqrn)
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

SYNOJOYNT (SODIUM HYALURONATE)

Affected Drugs

SYNOJOYNT INTRA-ARTICULAR SOLUTION 20MG/2ML PREFILLED SYRINGE

Step Therapy Criteria

- Physician documented symptomatic osteoarthritis of the knee, defined as knee pain associated with radiographic evidence of osteophytes in the knee joint provided the clinical presentation is not that of “bone-on-bone”, morning stiffness of less than or equal to 30 minutes in duration, crepitus on range of motion; **AND**
- Physician documented knee joint pain sufficient to interfere with ambulatory functional activities; **AND**
- Physician documentation of non-pharmacologic modalities, e.g., weight loss, quadriceps muscle strengthening, other physical therapy modalities, or exercises that have not promoted satisfactory symptomatic relief; **AND**
- Physician documentation that there has been no significant improvement following pharmacologic therapy with a full-dose nonsteroidal anti-inflammatory drug (NSAID) regimen, with or without supplemental acetaminophen, over a 10-12 week period of time or if NSAID’s are contraindicated, a failure of daily acetaminophen regimen over a 4 to 6 week period; **AND**
- Physician documentation that there has been no significant improvement following standard dose intra-articular corticosteroid injection(s) e.g., a satisfactory clinical response of greater than or equal to 3 months; this requirement does not apply if the use of corticosteroids might increase the risk of local or systemic bacterial infection, e.g., diabetes mellitus; **AND**
- Physician documentation of failure on, intolerance to or contraindication to two (2) of the following: Durolane, Euflexxa, Gelsyn-3, GenVisc, Hyalgan, Orthovisc, Supartz, Synvisc/Synvisc-One, and Visco-3

AUTHORIZATION DURATION: Initial approval will be for six (6) months. Subsequent approvals will be for six (6) months when members meet the following criteria:

- Medical record documentation of significant improvement in pain and function following the previous injection; **AND**
- Documented reduction of the doses of nonsteroidals or analgesics during the six-month period following the last injection in the previous series as well as no need for accompanying intra-articular steroid injections; **AND**
- Six months or longer have elapsed since the last injection in the previous series.

QUANTITY LIMIT: One (1) treatment course to the affected knee(s) (bilateral injections may be allowed if both knees meet the required coverage criteria)

LIMITATIONS:

Synojynt treatment course is limited to 3 injections in a 6-month period.

CONTRAINDICATIONS:

- The use of these products for injection into any joint other than the knee.
- Injection of these products for indications other than the diagnosis of osteoarthritis
- Documented allergy to chickens or eggs.
- Knee joint infection, skin disease or infection around the area where the injection will be given.
- The insured individual has known sensitivity or contraindication to the use of either sodium hyaluronate or hylan G-F 20, e.g., crystal synovitis or hypersensitivity to hyaluronan preparations

Step 1 Drugs

Durolane, Euflexxa, Gelsyn-3, GenVisc, Hyalgan, Orthovisc, Supartz, Synvisc/Synvisc-One, Visco-3

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

TRILURON (SODIUM HYALURONATE)

Affected Drugs

TRILURON INTRA-ARTICULAR SOLUTION 20MG/2ML PREFILLED SYRINGE

Step Therapy Criteria

- Physician documented symptomatic osteoarthritis of the knee, defined as knee pain associated with radiographic evidence of osteophytes in the knee joint provided the clinical presentation is not that of “bone-on-bone”, morning stiffness of less than or equal to 30 minutes in duration, crepitus on range of motion; **AND**
- Physician documented knee joint pain sufficient to interfere with ambulatory functional activities; **AND**
- Physician documentation of non-pharmacologic modalities, e.g., weight loss, quadriceps muscle strengthening, other physical therapy modalities, or exercises that have not promoted satisfactory symptomatic relief; **AND**
- Physician documentation that there has been no significant improvement following pharmacologic therapy with a full-dose nonsteroidal anti-inflammatory drug (NSAID) regimen, with or without supplemental acetaminophen, over a 10-12 week period of time or if NSAID’s are contraindicated, a failure of daily acetaminophen regimen over a 4 to 6 week period; **AND**
- Physician documentation that there has been no significant improvement following standard dose intra-articular corticosteroid injection(s) e.g., a satisfactory clinical response of greater than or equal to 3 months; this requirement does not apply if the use of corticosteroids might increase the risk of local or systemic bacterial infection, e.g., diabetes mellitus; **AND**
- Physician documentation of failure on, intolerance to or contraindication to two (2) of the following: Durolane, Euflexxa, Gelsyn-3, GenVisc, Hyalgan, Orthovisc, Supartz, Synvisc/Synvisc-One, and Visco-3

AUTHORIZATION DURATION: Initial approval will be for six (6) months. Subsequent approvals will be for six (6) months when members meet the following criteria:

- Medical record documentation of significant improvement in pain and function following the previous injection; **AND**
- Documented reduction of the doses of nonsteroidals or analgesics during the six-month period following the last injection in the previous series as well as no need for accompanying intra-articular steroid injections; **AND**
- Six months or longer have elapsed since the last injection in the previous series.

QUANTITY LIMIT: One (1) treatment course to the affected knee(s) (bilateral injections may be allowed if both knees meet the required coverage criteria)

LIMITATIONS:

Triluron treatment course is limited to 3 injections in a 6-month period.

CONTRAINDICATIONS:

- The use of these products for injection into any joint other than the knee.
- Injection of these products for indications other than the diagnosis of osteoarthritis
- Documented allergy to chickens or eggs.
- Knee joint infection, skin disease or infection around the area where the injection will be given.
- The insured individual has known sensitivity or contraindication to the use of either sodium hyaluronate or hylan G-F 20, e.g., crystal synovitis or hypersensitivity to hyaluronan preparations

Step 1 Drugs

Durolane, Euflexxa, Gelsyn-3, GenVisc, Hyalgan, Orthovisc, Supartz, Synvisc/Synvisc-One, Visco-3

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

TRIVISC (SODIUM HYALURONATE)

Affected Drugs

TRIVISC INTRA-ARTICULAR SOLUTION 25MG/2.5ML PREFILLED SYRINGE

Step Therapy Criteria

- Physician documented symptomatic osteoarthritis of the knee, defined as knee pain associated with radiographic evidence of osteophytes in the knee joint provided the clinical presentation is not that of “bone-on-bone”, morning stiffness of less than or equal to 30 minutes in duration, crepitus on range of motion; **AND**
- Physician documented knee joint pain sufficient to interfere with ambulatory functional activities; **AND**
- Physician documentation of non-pharmacologic modalities, e.g., weight loss, quadriceps muscle strengthening, other physical therapy modalities, or exercises that have not promoted satisfactory symptomatic relief; **AND**
- Physician documentation that there has been no significant improvement following pharmacologic therapy with a full-dose nonsteroidal anti-inflammatory drug (NSAID) regimen, with or without supplemental acetaminophen, over a 10-12 week period of time or if NSAID’s are contraindicated, a failure of daily acetaminophen regimen over a 4 to 6 week period; **AND**
- Physician documentation that there has been no significant improvement following standard dose intra-articular corticosteroid injection(s) e.g., a satisfactory clinical response of greater than or equal to 3 months; this requirement does not apply if the use of corticosteroids might increase the risk of local or systemic bacterial infection, e.g., diabetes mellitus; **AND**
- Physician documentation of failure on, intolerance to or contraindication to two (2) of the following: Durolane, Euflexxa, Gelsyn-3, GenVisc, Hyalgan, Orthovisc, Supartz, Synvisc/Synvisc-One, and Visco-3

AUTHORIZATION DURATION: Initial approval will be for six (6) months. Subsequent approvals will be for six (6) months when members meet the following criteria:

- Medical record documentation of significant improvement in pain and function following the previous injection; **AND**
- Documented reduction of the doses of nonsteroidals or analgesics during the six-month period following the last injection in the previous series as well as no need for accompanying intra-articular steroid injections; **AND**
- Six months or longer have elapsed since the last injection in the previous series.

QUANTITY LIMIT: One (1) treatment course to the affected knee(s) (bilateral injections may be allowed if both knees meet the required coverage criteria)

LIMITATIONS:

TriVisc treatment course is limited to 3 injections in a 6-month period..

CONTRAINDICATIONS:

- The use of these products for injection into any joint other than the knee.
- Injection of these products for indications other than the diagnosis of osteoarthritis
- Documented allergy to chickens or eggs.
- Knee joint infection, skin disease or infection around the area where the injection will be given.
- The insured individual has known sensitivity or contraindication to the use of either sodium hyaluronate or hylan G-F 20, e.g., crystal synovitis or hypersensitivity to hyaluronan preparations

Step 1 Drugs

Durolane, Euflexxa, Gelsyn-3, GenVisc, Hyalgan, Orthovisc, Supartz, Synvisc/Synvisc-One, Visco-3

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 Beovu (brolucizumab)

Intravitreal Byooviz (ranibizumab-nuna)

Intravitreal Cimerli (ranibizumab-eqrn)

Intravitreal Eylea (aflibercept)

Intravitreal Lucentis (ranibizumab)

Diabetic Macular Edema:

Intravitreal Byooviz (ranibizumab-nuna)

Intravitreal Cimerli (ranibizumab-eqrn)

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), 6/23/23 (Eylea ROP), 7/18/23 (Herceptin), 8/25/23 (Gel-One, Hymovis, Monovisc, Synjoynt, Triluron, TriVisc), 11/21/23 (added infliximab/Remicade, Renflexis alternatives edit, Susvimo/Vabysmo step drugs), 4/19/24 (added Avastin [per 1/16/24 P&T], RTX indications)

Reviewed:

MA UM Committee approval: 12/31/23, 5/22/24