Brand/Trade names are shown for reference purposes only. Criteria apply to the generic product when a generic equivalent has been approved by the FDA. Additional criteria apply to brand name requests (when a generic is available), per PHC Policy #MPRP4033.

Spesolimab-sbzo (Spevigo™)	Ranibizumab-nuna Intravitreal Injection (Byooviz™)	Ranibizumab-eqrn (Cimerli™) Intravitreal Injection	Ranibizumab Intravitreal Injection via Sustained Intravitreal Implant (Susvimo™)
Aflibercept Intravitreal Injection (Eylea™)	Brolucizumab-dbll Intravitreal Injection (Beovu™)	Faricimab Intravitreal Injection (Vabysmo™)	Teplizumab-mzwv (Tzield™)

Requirements for Brolucizumab-dbll Intravitreal Injection (Beovu™)

Unless otherwise specified as having renewal requirements, criteria apply to new starts only. Include documentation of continuation of care if member is not new to treatment.

PA Criteria	Criteria Details
Covered Uses	1) Neovascular (wet) age-related macular degeneration (AMD) 2) Diabetic Macular Edema
Exclusion Criteria	Members with active ocular or periocular infection
Required Medical Information	1) Clinic notes to confirm the diagnosis submitted 2) Baseline visual acuity score
Age Restriction	18 years and older.
Prescriber Restriction	Must be prescribed or recommended by an ophthalmologist.
Coverage Duration	Initial: Up to 8 injections per eye in 12 months Renewal: Up to 7 injections per eye in 12 months
Other Requirements	Renewal will be based on documentation of benefit from therapy (may be indicated on TAR unless clinic notes are specifically requested). Baseline and updated vision status may be requested with evidence of: 1) Improvement or stabilization compared to baseline or 2) Decrease in rate of vision loss compared to baseline Requests for off-label use: See PHC criteria document *Case-by-Case TAR Requirements and Considerations.*

Medical Billing:

Dose limits & billing requirements (approved TAR is required):

HCPCS	Description	Dosing, Units
J0179	Injection, brolucizumab- dbll, 1mg	nAMD: 6mg every 4 weeks for 3 doses, then every 8-12 weeks. DME: 6 mg every 6 weeks for 5 doses, then every 8-12 weeks.

Requirements for Ranibizumab-nuna Intravitreal Injection (Byooviz™)

Unless otherwise specified as having renewal requirements, criteria apply to new starts only. Include documentation of continuation of care if member is not new to treatment.

PA Criteria	Criteria Details
Covered Uses	1) Neovascular (wet) age-related macular degeneration (AMD) 2) Macular edema following retinal vein occlusion (RVO) 3) Myopic Choroidal Neovascularization (mCNV)
Exclusion Criteria	Members with active ocular or periocular infection
Required Medical Information	TAR submissions are to include: 1) Clinic notes confirming the submitted diagnosis 2) Baseline visual acuity score
Age Restriction	18 years and older.
Prescriber Restriction	Must be prescribed or recommended by an Ophthalmologist.
Coverage Duration	Limited to a maximum of 13 injections per 12 months (per eye).
Other Requirements	Renewal authorizations will be based on documentation of benefit from therapy (may be indicated on the TAR unless clinic notes are specifically requested). Baseline and updated vision status maybe requested with evidence of: 1) Improvement or stabilization compared to baseline OR 2) Decrease in rate of vision loss compared to baseline For members on Susvimo intravitreal implant, requiring additional ranibizumab doses: Documentation ~~of~~ supporting the medical necessity of supplemental doses must include at least one of the following: 1) A decrease of 15 ETDRS letters or more from the best recorded visual acuity score (BCV) A at baseline/since starting Susvimo, OR 2) An increase of 150 mm or more in retinal thickness measured by central subfield thickness (CST) on spectral-domain OCT (SD OCT) from the lowest CST measurement since starting Susvimo, OR 3) An increase of 100 mm or more in CST on SD OCT from the lowest CST measurement since starting Susvimo associated with a decrease of 10 ETDRS letters or more from the best recorded BCVA at baseline/since starting Susvimo Requests for off-label use: See PHC criteria document, *Case-by-Case TAR Requirements and Considerations*

Medical Billing:

Dose limits & billing requirements (approved TAR is required):

HCPCS	Description	Dosing, Units
Q5124	Injection, ranibizumab-nuna, 0.1 mg	0.5ml every 28 days nAMD: treatment interval may be extended after the initial 4 doses.

Requirements for Teplizumab-mzwv (Tzield™)

Unless otherwise specified as having renewal requirements, criteria apply to new starts only. Include documentation of continuation of care if member is not new to treatment.

PA Criteria	Criteria Details
Covered Uses	Delay onset of Stage 3 type 1 diabetes (T1D) in adults and pediatric patients 8 years an older with Stage 2 T1D.
Exclusion Criteria	Current diagnosis of Stage 3 T1D
Required Medical Information	Diagnosis of Stage 2 type 1 diabetes confirmed by all of the following: 1) Documentation of at least 2 of the following type 1 diabetes-related autoantibodies within the last 6 months: a. Islet cell autoantibody (ICA) b. Glutamic acid decarboxylase 65 (GAD) autoantibody c. Zinc transporter 8 autoantibody (ZnT8A) d. Insulinoma-associated antigen 2 autoantibody (IA-2A) e. Insulin autoantibody (IAA) 2) Documentation of dysglycemia without overt hyperglycemia within the preceding 2 months defined as one of the following (oral glucose tolerance test preferred): a. Fasting plasma glucose level 100-125 mg/dL; OR b. Two-hour postprandial plasma glucose 140-199 mg/dL; OR c. Postprandial glucose level at 30, 60 or 90 minutes ≥ 200 mg/ dL; OR d. A1C 5.7-6.4% 3) Documentation type 2 diabetes has been ruled out based on clinical history. 4) Body surface area (BSA). 5) Administering facility must be able to accommodate 14 consecutive calendar days of administration.
Age Restriction	8 years and older
Prescriber Restriction	Endocrinologist
Coverage Duration	One-time approval, 14-day treatment course only
Other Requirements	Note, prior to initiating therapy, provider must have awareness of the following: 1) Completion of age-appropriate vaccinations. 2) No evidence of active serious infections (i.e. Epstein-Barr virus or cytomegalovirus infection). 3) Adequate hepatic function at baseline (i.e. ALT/AST, bilirubin) 4) Adequate hematologic function at baseline (i.e. platelets, hemoglobin, absolute neutrophil count, lymphocytes). 5) Member is not pregnant. Note that each 2 ml single dose vial (SDV) contains 2,000 mcg (2 mg), equivalent to 400 HCPCS billing units per vial. Vials are diluted to 100 mcg/ml and must be administered within 4 hours of being diluted, with remainder discarded (see PHC Drug Waste policy for billing waste with JW modifier. TARs must include both the dose and anticipated waste amounts. Waste units must be billed separately from the administered dose units, using the JW modifier as stated in Policy MPRP4062, Drug Wastage Payments. The number of units on the authorized

Requirements for Teplizumab-mzwv (Tzield™)

	TAR will be sufficient for both dose and waste claims. 1 vial per day is sufficient for all doses up to a BSA of 1.94 m^2. Requests for more than 1 vial (400 billing units) per day must include the member's current BSA.

Medical Billing:

Dose limits & billing requirements (approved TAR is required):

HCPCS	Description	Dosing, Units
J9381	Injection, teplizumab-mzwv, 5 mcg	Administer once daily for 14 consecutive days. A single vial (2 ml=2,000 mcg) is 400 HCPCS units (5 mcg/unit). For BSA </= 1.94 m2, maximum reimbursement is for 1 vial, 400 units (includes dose + waste). Day 1: 65 mcg/m2 body surface area (BSA) Day 2: 125 mcg/m2 BSA IV once daily Day 3: 250 mcg/m2 BSA Day 4: 500 mcg/m2 BSA Day 5 to day 14: 1,030 mcg/m2 BSA once daily If a planned infusion dose is missed, resume dosing by administering all remaining doses on consecutive days to complete the 14-day treatment course.

Requirements for Aflibercept Intravitreal Injection (Eylea™)

Unless otherwise specified as having renewal requirements, criteria apply to new starts only. Include documentation of continuation of care if member is not new to treatment.

PA Criteria	Criteria Details
Covered Uses	1) Diabetic macular edema (DME) 2) Diabetic retinopathy in patients with DME (DR w/ DME); or proliferative DR without DME (PDR, +/- DME) 3) Neovascular (wet) age-related macular degeneration (AMD) 4) Macular edema following retinal vein occlusion (RVO) 5) Retinopathy of prematurity (ROP)
Exclusion Criteria	Members with active ocular or periocular infection
Required Medical Information	<u>Diagnosis of AMD, macular edema following RVO, DME/DR+DME, or PDR:</u> 1) Clinic notes to confirm the diagnosis submitted 2) Baseline visual acuity score <u>Diagnosis of ROP:</u> 1) Must have a or b: a. Gestational age of ≤ 32 weeks b. Maximum birth weight of ≤ 1500 g (3.3 lb) 2) Must have diagnosis of a, b or c: a. ROP Zone I stage 1+, 2+, 3, & 3+ b. ROP Zone II Stage 2+, 3+ c. AP-ROP (aggressive posterior ROP)
Age Restriction	• DME, DR w/ DME, AMD, macular edema w/RVO: 18 years and older. • ROP: ≤ 52 weeks chronological age
Prescriber Restriction	Must be prescribed or recommended by an ophthalmologist
Coverage Duration	• AMD, DME, DR w/ DME, & RVO: Limited to a maximum of 13 injections per 12 months (per eye). • ROP: 1 dose per affected eye per request
Other Requirements	<u>Renewal or retreatment requests:</u> <u>AMD, DME, DR w/ DME, PDR, & RVO:</u> Renewal will be based on documentation of benefit from therapy (may be indicated on the TAR unless clinic notes are specifically requested). Baseline and updated vision status maybe requested with evidence of: 1) Improvement or stabilization compared to baseline OR 2) Decrease in rate of vision loss compared to baseline <u>ROP:</u> 1) Current gestational age 2) Continues to be positive for diagnosis of a, b or c: a. ROP Zone I stage 1+, 2+, 3, & 3+ b. ROP Zone II Stage 2+, 3+ c. AP-ROP (aggressive posterior ROP) 3) Has had ≤ 2 prior treatments with aflibercept Requests for off-label use: See PHC criteria document, *Case-by-Case TAR Requirements and Considerations.*

Requirements for Aflibercept Intravitreal Injection (Eylea™)

Medical Billing:

Dose limits & billing requirements (approved TAR is required):

HCPCS	Description	Dosing, Units
J0178	Intravitreal injection, aflibercept, 1mg	AMD: 2mg every 4 weeks for 3 doses followed by 2 mg every 8 weeks (may be used monthly) DME & DR w/ DME, PDR: 2mg every 4 weeks for 5 doses followed by 2mg every 8 weeks (may be used monthly) RVO: 2mg every 4 weeks ROP: 0.4 mg into the affected eye, may repeat after a minimum interval of 10 days.

Requirements for Ranibizumab (Lucentis™) and Ranibizumab-eqrn (Cimerli™) Intravitreal Injection

Unless otherwise specified as having renewal requirements, criteria apply to new starts only. Include documentation of continuation of care if member is not new to treatment.

PA Criteria	Criteria Details
Covered Uses	1) Diabetic macular edema (DME) 2) Diabetic retinopathy in patients with DME (DR w/ DME); or proliferative DR without DME (PDR, +/- DME) 3) Neovascular (wet) age-related macular degeneration (AMD) 4) Macular edema following retinal vein occlusion (RVO) 5) Myopic Choroidal Neovascularization (mCNV)
Exclusion Criteria	Members with active ocular or periocular infection
Required Medical Information	Diagnosis of AMD, macular edema following RVO, or mCNV: 1) Clinic notes to confirm the diagnosis submitted 2) Baseline visual acuity score 3) Documentation of trial and failure to, or reason(s) why preferred biosimilar, Byooviz cannot be used Diagnosis of DME, DR w/DME, PDR: 1) Clinic notes to confirm the diagnosis submitted 2) Baseline visual acuity score
Age Restriction	18 years and older.
Prescriber Restriction	Must be prescribed or recommended by an ophthalmologist
Coverage Duration	Limited to a maximum of 13 injections per 12 months (per eye).
Other Requirements	Renewal authorizations will be based on documentation of benefit from therapy (may be indicated on TAR unless clinic notes are specifically requested). Baseline and updated vision status maybe requested with evidence of: 1) Improvement or stabilization compared to baseline or 2) Decrease in rate of vision loss compared to baseline For members on Susvimo intravitreal implant, requiring additional ranibizumab doses: Documentation supporting the medical necessity of supplemental doses must include at least one of the following: 1) A decrease of 15 ETDRS letters or more from the best recorded visual acuity score (BCV) A at baseline/since starting Susvimo, OR 2) An increase of 150 mm or more in retinal thickness measured by central subfield thickness (CST) on spectral-domain OCT (SD OCT) from the lowest CST measurement since starting Susvimo, OR 3) An increase of 100 mm or more in CST on SD OCT from the lowest CST measurement since starting Susvimo associated with a decrease of 10 ETDRS letters or more from the best recorded BCVA at baseline/since starting Susvimo Requests for off-label use: See PHC criteria document, *Case-by-Case TAR Requirements and Considerations.*

Requirements for Ranibizumab (Lucentis™) and Ranibizumab-eqrn (Cimerli™) Intravitreal Injection

Medical Billing:

Dose limits & billing requirements (approved TAR is required):

HCPCS	Description	Dosing, Units
J2778	Intravitreal injection, ranibizumab, per 0.1 mg	AMD, RVO, mCNV: 0.5mg (5units) every 28 days DME/DR w/DME, PDR: 0.3mg (3 units) every 28 days

Requirements for Spesolimab-sbzo (Spevigo™)

Unless otherwise specified as having renewal requirements, criteria apply to new starts only. Include documentation of continuation of care if member is not new to treatment.

PA Criteria	Criteria Details
Covered Uses	Generalized pustular psoriasis (GPP) flares
Exclusion Criteria	• Primary plaque psoriasis vulgaris without presence of pustules • Pustules that are restricted to psoriatic plaques • Diagnosis other than for the treatment of a GPP flare
Required Medical Information	1) Initial dose, *each distinct flare*: a. Awareness of immune-suppression risks specific to latent TB infection, and order exists for TST (Tuberculin Skin Test/PPD) or Interferon Gamma Release Assay (eg, Quanti FERON-TB Gold test). b. Clinical notes confirming a diagnosis of moderate to severe GPP flare, including: i. Skin biopsy results and ii. Presence of fresh or worsening pustules with both a. The mean Generalized Pustular Psoriasis Physician Global Assessment (GPPGA) total score of ≥ 3 (at least moderate severity) b. GPPGA pustulation sub score of at least 2, with pustules & erythema covering an involved body surface area of 5% or greater. 2) Second dose per flare: a. Clinical notes with evaluation having occurred between 7-14 days after the first dose, and which include all of the following to confirm need for second dose: i. GPPGA score ≥ 2 ii. GPPGA pustulation sub score of ≥1 b. The second dose must be administered no sooner than 7 days and no later than 14 days after first dose (ie, with first dose being day 1, 2nd dose should be day 8 to day 15).
Age Restriction	18 years and older
Prescriber Restriction	Prescribed or recommended by a dermatologist
Coverage Duration	One dose (900 mg) per TAR request, with maximum of 1 TAR renewal if needed per flare (a 2nd 900 mg dose per flare when requirements are met).
Other Requirements & Information	

Medical Billing:

Dose limits & billing requirements (approved TAR is required):

HCPCS	Description	Dosing, Units
J1747	Intravitreal injection, spesolimab-sbzo, 1 mg	900 mg IV once; if flare persists, an additional 900 mg IV may be given one week later. Each dose is billed as 900 HCPCS units.

Requirements for Ranibizumab Intravitreal Injection via Sustained Intravitreal Implant (Susvimo™)

Unless otherwise specified as having renewal requirements, criteria apply to new starts only. Include documentation of continuation of care if member is not new to treatment.

PA Criteria	Criteria Details
Covered Uses	Neovascular (wet) age-related macular degeneration (AMD)
Exclusion Criteria	• Members with active ocular or periocular infection • Concurrent use of other ophthalmic VEGF inhibitors, with the exception of supplemental ranibizumab & biosimilars (Byooviz™, Lucentis™, Cimerli™)
Required Medical Information	Diagnosis of AMD: 1) Clinic notes to confirm the diagnosis submitted 2) Documentation of at least 2 prior doses of intravitreal injections of a VEGF inhibitor with demonstrated anatomic and visual response: • Central subfield thickness (CST) reduction • Improvement in visual acuity from baseline
Age Restriction	18 years and older.
Prescriber Restriction	Must be prescribed or recommended by an ophthalmologist.
Coverage Duration	Initial approval and renewal: 6 months (1 implant fill).
Other Requirements	Renewal will be based on documentation of benefit from therapy (may be indicated on TAR unless clinic notes are specifically requested). Baseline and updated vision status may be requested with evidence of: 1) Improvement or stabilization compared to baseline or 2) Decrease in rate of vision loss compared to baseline Requests for off-label use: See PHC criteria document, *Case-by-Case TAR Requirements and Considerations.*

Medical Billing:

Dose limits & billing requirements (approved TAR is required):

HCPCS	Description	Dosing, Units
J2779	Injection, ranibizumab, via intravitreal implant (Susvimo), 0.1 mg	2 mg every 6 months. Maximum treatment dose reimbursed is 20 units (2 mg) per eye every 6 months, and waste should be billed separately per PHC Policy MPRPR4062, Drug Wastage Payments. Maximum authorized TAR units per eye: 100 units, equivalent to 10 mg vials (allowing 2 mg dose + 8 mg waste).

Requirements for Faricimab Intravitreal Injection (Vabysmo™)

Unless otherwise specified as having renewal requirements, criteria apply to new starts only. Include documentation of continuation of care if member is not new to treatment.

PA Criteria	Criteria Details
Covered Uses	1) Diabetic macular edema (DME) 2) Neovascular (wet) age-related macular degeneration (nAMD)
Exclusion Criteria	Members with active ocular or periocular infection
Required Medical Information	1) Clinic notes to confirm the diagnosis submitted 2) Baseline visual acuity score 3) Documentation of trial and failure or contraindication to at least 1 of PHC's preferred ophthalmic VEGF inhibitors: ranibizumab-nuna (Byooviz™), ranibizumab (Lucentis™), ranibizumab-eqrn (Cimerli™), aflibercept (Eylea™), brolucizumab-dbll (Beovu™), or off-label bevacizumab (Avastin™).
Age Restriction	18 years and older
Prescriber Restriction	Must be prescribed or recommended by an ophthalmologist
Coverage Duration	Limited to a maximum of 13 injections per eye in 12 months
Other Requirements	Renewal authorization will be based on documentation of benefit from therapy (may be indicated on TAR unless clinic notes are specifically requested). Baseline and updated vision status maybe requested with evidence of: 1) Improvement or stabilization compared to baseline or 2) Decrease in rate of vision loss compared to baseline Requests for off-label use: See PHC criteria document, *Case-by-Case TAR Requirements and Considerations.*

Requirements for Faricimab Intravitreal Injection (Vabysmo™)

Medical Billing:

Dose limits & billing requirements (approved TAR is required):

HCPCS	Description	Dosing, Units
J2777	Intravitreal injection, faricimab, per 0.1 mg	**nAMD:** • Initial -- 6 mg (60 HCPCS units) every 4 weeks for the first 4 doses (weeks 1-16): Total of 240 units authorized per eye (480 max units for bilateral treatment) for initial TARs. • Continuation – depending on evaluations at 8 & 12 weeks following the initial 4 doses, subsequent doses may be repeated at 4-16 week intervals. **DME:** Two regimens are FDA approved: • 6 mg every 4 weeks for at least 4 doses. Following resolution of edema, doses are continued every 4-8 weeks (intervals modified +/- depending on CST & visual acuity evaluations) through week 52 OR • 6 mg every 4 weeks for the first 6 doses, followed by 6 mg every 8 weeks over the next 28 weeks. Some may need every 4 weeks dosing after the first 4 doses.