Ophthalmologic Policy: Vascular Endothelial Growth Factor (VEGF) Inhibitors (for Indiana Only)

Policy Number: CSIND0042.10
Effective Date: April 1, 2024

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Related Policies

- Maximum Dosage and Frequency (for Indiana Only)
- Oncology Medication Clinical Coverage (for Indiana Only)

Application

This Medical Benefit Drug Policy only applies to the state of Indiana.

Coverage Rationale

This policy provides information about the use of certain specialty pharmacy medications administered by the intravitreal route for ophthalmologic conditions.

This policy refers to the following vascular endothelial growth factor (VEGF) inhibitors and dual VEGF/angiopoietin-2 (Ang-2) inhibitors:

- Avastin® (bevacizumab)
- Beovu® (brolucizumab-dbll)
- Byooviz™ (ranibizumab-nuna)
- Cimerli™ (ranibizumab-eqrn)
- Eylea™ (aflibercept)
- Eylea® HD (aflibercept)
- Lucentis® (ranibizumab)
- Susvimo™ (ranibizumab)
- Vabysmo™ (faricimab-svoa)

The following information pertains to medical necessity review:

General Requirements

For **initial and continuation of therapy**, intravitreal VEGF inhibitor administration is no more than 12 doses per year per eye, regardless of diagnosis.

Diagnosis-Specific Requirements

Lucentis is proven and medically necessary for the treatment of certain conditions outlined within the InterQual® criteria. For medical necessity clinical coverage criteria for Lucentis, refer to the current release of the InterQual® guideline, CP: Specialty Rx Non-Oncology Ranibizumab (Lucentis).

Click here to view the InterQual® criteria.

Eylea is proven and medically necessary for the treatment of certain conditions outlined within the InterQual® criteria. For medical necessity clinical coverage criteria for Eylea, refer to the current release of the InterQual® guideline, CP: Specialty Rx Non-Oncology Aflibercept (Eylea).

Click here to view the InterQual® criteria.

Beovu is proven and medically necessary for the treatment of certain conditions outlined within the InterQual® criteria. For medical necessity clinical coverage criteria for Beovu, refer to the current release of the InterQual® guideline, CP: Specialty Rx Non-Oncology Brolucizumab (Beovu).

Click here to view the InterQual® criteria.

Avastin (bevacizumab) is proven and medically necessary for the treatment of certain conditions outlined within the InterQual® criteria. For medical necessity clinical coverage criteria for Avastin, refer to the current release of the InterQual® guideline, CP: Specialty Rx Non-Oncology Bevacizumab (Avastin) Intravitreal.

Click here to view the InterQual® criteria.

Byooviz (ranibizumab-nuna) is proven and medically necessary for the treatment of:
- Neovascular age-related macular degeneration (nAMD)
- Macular edema following retinal vein occlusion (RVO)
- Myopic choroidal neovascularization (mCNV)

Cimerli™ (ranibizumab-eqrn) is proven and medically necessary for the treatment of:
- Myopic choroidal neovascularization (mCNV)
- Diabetic macular edema (DME)
- Diabetic retinopathy (DR)
- Macular edema following retinal vein occlusion (RVO)
- Neovascular age-related macular degeneration (nAMD)

Eylea HD (aflibercept) is proven and medically necessary for the treatment of:
- Diabetic macular edema (DME)
- Diabetic retinopathy (DR)
- Neovascular age-related macular degeneration (nAMD)

Susvimo (ranibizumab) is proven and medically necessary for the treatment of:
- Neovascular age-related macular degeneration (nAMD) who have previously responded to ≥ 2 intravitreal injections of a VEGF inhibitor

Vabysmo (faricimab-svoa) is proven and medically necessary for the treatment of:
- Neovascular age-related macular degeneration (nAMD)
- Diabetic macular edema (DME)
- Macular edema following retinal vein occlusion (RVO)

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by federal, state, or contractual requirements and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

HCPCS Code	Description	Brand Name
J0177	Injection, aflibercept hd, 1 mg	Eylea HD
J0178	Injection, aflibercept, 1 mg	Eylea
J0179	Injection, brolucizumab-dbll, 1 mg	Beovu
J2777	Injection, faricimab-svoa, 0.1 mg	Vabysmo
J2778	Injection, ranibizumab, 0.1 mg	Lucentis
J2779	Injection, ranibizumab, 0.1 mg	Susvimo
J9035	Injection, bevacizumab, 10 mg	Avastin
Q5124	Injection, ranibizumab-nuna, biosimilar, (Byooviz), 0.1 mg	Byooviz
Q5128	Injection, ranibizumab-eqrn (cimerli)	Cimerli

Diagnosis Code	Description	Applies to HCPCS Code				
		J0177	J2777	J2779	Q5124	Q5128
B39.5	Histoplasmosis duboisii					
B39.9	Histoplasmosis, unspecified					
E08.311	Diabetes mellitus due to underlying condition with unspecified diabetic retinopathy with macular edema	x	x			x
E08.319	Diabetes mellitus due to underlying condition with unspecified diabetic retinopathy without macular edema	x				x
E08.3211	Diabetes mellitus due to underlying condition with mild nonproliferative diabetic retinopathy with macular edema, right eye	x	x			x
E08.3212	Diabetes mellitus due to underlying condition with mild nonproliferative diabetic retinopathy with macular edema, left eye	x	x			x
E08.3213	Diabetes mellitus due to underlying condition with mild nonproliferative diabetic retinopathy with macular edema, bilateral	x	x			x
E08.3219	Diabetes mellitus due to underlying condition with mild nonproliferative diabetic retinopathy with macular edema, unspecified eye	x	x			x
E08.3291	Diabetes mellitus due to underlying condition with mild non-proliferative diabetic retinopathy without macular edema, right eye	x				x
E08.3292	Diabetes mellitus due to underlying condition with mild non-proliferative diabetic retinopathy without macular edema, left eye	x				x

Diagnosis Code	Description	Applies to HCPCS Code				
		J0177	J2777	J2779	Q5124	Q5128
E08.3293	Diabetes mellitus due to underlying condition with mild non-proliferative diabetic retinopathy without macular edema, bilateral	x				x
E08.3299	Diabetes mellitus due to underlying condition with mild non-proliferative diabetic retinopathy without macular edema, unspecified eye	x				x
E08.3311	Diabetes mellitus due to underlying condition with moderate nonproliferative diabetic retinopathy with macular edema, right eye	x	x			x
E08.3312	Diabetes mellitus due to underlying condition with moderate nonproliferative diabetic retinopathy with macular edema, left eye	x	x			x
E08.3313	Diabetes mellitus due to underlying condition with moderate nonproliferative diabetic retinopathy with macular edema, bilateral	x	x			x
E08.3319	Diabetes mellitus due to underlying condition with moderate nonproliferative diabetic retinopathy with macular edema, unspecified eye	x	x			x
E08.3391	Diabetes mellitus due to underlying condition with moderate non-proliferative diabetic retinopathy without macular edema, right eye	x				x
E08.3392	Diabetes mellitus due to underlying condition with moderate non-proliferative diabetic retinopathy without macular edema, left eye	x				x
E08.3393	Diabetes mellitus due to underlying condition with moderate non-proliferative diabetic retinopathy without macular edema, bilateral	x				x
E08.3399	Diabetes mellitus due to underlying condition with moderate non-proliferative diabetic retinopathy without macular edema, unspecified eye	x				x
E08.3411	Diabetes mellitus due to underlying condition with severe nonproliferative diabetic retinopathy with macular edema, right eye	x	x			x
E08.3412	Diabetes mellitus due to underlying condition with severe nonproliferative diabetic retinopathy with macular edema, left eye	x	x			x
E08.3413	Diabetes mellitus due to underlying condition with severe nonproliferative diabetic retinopathy with macular edema, bilateral	x	x			x
E08.3419	Diabetes mellitus due to underlying condition with severe nonproliferative diabetic retinopathy with macular edema, unspecified eye	x	x			x
E08.3491	Diabetes mellitus due to underlying condition with severe non-proliferative diabetic retinopathy without macular edema, right eye	x				x
E08.3492	Diabetes mellitus due to underlying condition with severe non-proliferative diabetic retinopathy without macular edema, left eye	x				x

Diagnosis Code	Description	Applies to HCPCS Code				
		J0177	J2777	J2779	Q5124	Q5128
E08.3493	Diabetes mellitus due to underlying condition with severe non-proliferative diabetic retinopathy without macular edema, bilateral	x				x
E08.3499	Diabetes mellitus due to underlying condition with severe non-proliferative diabetic retinopathy without macular edema, unspecified eye	x				x
E08.3511	Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy with macular edema, right eye	x	x			x
E08.3512	Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy with macular edema, left eye	x	x			x
E08.3513	Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy with macular edema, bilateral	x	x			x
E08.3519	Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy with macular edema, unspecified eye	x	x			x
E08.3521	Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy with traction retinal detachment involving the macula, right eye	x				x
E08.3522	Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy with traction retinal detachment involving the macula, left eye	x				x
E08.3523	Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy with traction retinal detachment involving the macula, bilateral	x				x
E08.3529	Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy with traction retinal detachment involving the macula, unspecified eye	x				x
E08.3531	Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, right eye	x				x
E08.3532	Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, left eye	x				x
E08.3533	Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, bilateral	x				x
E08.3539	Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, unspecified eye	x				x

Diagnosis Code	Description	Applies to HCPCS Code				
		J0177	J2777	J2779	Q5124	Q5128
E08.3541	Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, right eye	x				x
E08.3542	Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, left eye	x				x
E08.3543	Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, bilateral	x				x
E08.3549	Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, unspecified eye	x				x
E08.3551	Diabetes mellitus due to underlying condition with stable proliferative diabetic retinopathy, right eye	x				x
E08.3552	Diabetes mellitus due to underlying condition with stable proliferative diabetic retinopathy, left eye	x				x
E08.3553	Diabetes mellitus due to underlying condition with stable proliferative diabetic retinopathy, bilateral	x				x
E08.3559	Diabetes mellitus due to underlying condition with stable proliferative diabetic retinopathy, unspecified eye	x				x
E08.3591	Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy without macular edema, right eye	x				x
E08.3592	Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy without macular edema, left eye	x				x
E08.3593	Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy without macular edema, bilateral	x				x
E08.3599	Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy without macular edema, unspecified eye	x				x
E08.37X1	Diabetes mellitus due to underlying condition with diabetic macular edema, resolved following treatment, right eye	x	x			x
E08.37X2	Diabetes mellitus due to underlying condition with diabetic macular edema, resolved following treatment, left eye	x	x			x
E08.37X3	Diabetes mellitus due to underlying condition with diabetic macular edema, resolved following treatment, bilateral	x	x			x

Diagnosis Code	Description	Applies to HCPCS Code				
		J0177	J2777	J2779	Q5124	Q5128
E08.37X9	Diabetes mellitus due to underlying condition with diabetic macular edema, resolved following treatment, unspecified eye	x	x			x
E09.311	Drug or chemical induced diabetes mellitus with unspecified diabetic retinopathy with macular edema	x	x			x
E09.3211	Drug or chemical induced diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, right eye	x	x			x
E09.3212	Drug or chemical induced diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, left eye	x	x			x
E09.3213	Drug or chemical induced diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, bilateral	x	x			x
E09.3219	Drug or chemical induced diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, unspecified eye	x	x			x
E09.3291	Drug or chemical induced diabetes mellitus with mild non-proliferative diabetic retinopathy without macular edema, right eye	x				x
E09.3292	Drug or chemical induced diabetes mellitus with mild non-proliferative diabetic retinopathy without macular edema, left eye	x				x
E09.3293	Drug or chemical induced diabetes mellitus with mild non-proliferative diabetic retinopathy without macular edema, bilateral	x				x
E09.3299	Drug or chemical induced diabetes mellitus with mild non-proliferative diabetic retinopathy without macular edema, unspecified eye	x				x
E09.3311	Drug or chemical induced diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, right eye	x	x			x
E09.3312	Drug or chemical induced diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, left eye	x	x			x
E09.3313	Drug or chemical induced diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, bilateral	x	x			x
E09.3319	Drug or chemical induced diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, unspecified eye	x	x			x
E09.3391	Drug or chemical induced diabetes mellitus with moderate non-proliferative diabetic retinopathy without macular edema, right eye	x				x
E09.3392	Drug or chemical induced diabetes mellitus with moderate non-proliferative diabetic retinopathy without macular edema, left eye	x				x

Diagnosis Code	Description	Applies to HCPCS Code				
		J0177	J2777	J2779	Q5124	Q5128
E09.3393	Drug or chemical induced diabetes mellitus with moderate non-proliferative diabetic retinopathy without macular edema, bilateral	x				x
E09.3399	Drug or chemical induced diabetes mellitus with moderate non-proliferative diabetic retinopathy without macular edema, unspecified eye	x				x
E09.3411	Drug or chemical induced diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, right eye	x	x			x
E09.3412	Drug or chemical induced diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, left eye	x	x			x
E09.3413	Drug or chemical induced diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, bilateral	x	x			x
E09.3419	Drug or chemical induced diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, unspecified eye	x	x			x
E09.3491	Drug or chemical induced diabetes mellitus with severe non-proliferative diabetic retinopathy without macular edema, right eye	x				x
E09.3492	Drug or chemical induced diabetes mellitus with severe non-proliferative diabetic retinopathy without macular edema, left eye	x				x
E09.3493	Drug or chemical induced diabetes mellitus with severe non-proliferative diabetic retinopathy without macular edema, bilateral	x				x
E09.3499	Drug or chemical induced diabetes mellitus with severe non-proliferative diabetic retinopathy without macular edema, unspecified eye	x				x
E09.3511	Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy with macular edema, right eye	x	x			x
E09.3512	Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy with macular edema, left eye	x	x			x
E09.3513	Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy with macular edema, bilateral	x	x			x
E09.3519	Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy with macular edema, unspecified eye	x	x			x
E09.3521	Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, right eye	x				x
E09.3522	Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, left eye	x				x

Diagnosis Code	Description	Applies to HCPCS Code				
		J0177	J2777	J2779	Q5124	Q5128
E09.3523	Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, bilateral	x				x
E09.3529	Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, unspecified eye	x				x
E09.3531	Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, right eye	x				x
E09.3532	Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, left eye	x				x
E09.3533	Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, bilateral	x				x
E09.3539	Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, unspecified eye	x				x
E09.3541	Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, right eye	x				x
E09.3542	Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, left eye	x				x
E09.3543	Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, bilateral	x				x
E09.3549	Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, unspecified eye	x				x
E09.3551	Drug or chemical induced diabetes mellitus with stable proliferative diabetic retinopathy, right eye	x				x
E09.3552	Drug or chemical induced diabetes mellitus with stable proliferative diabetic retinopathy, left eye	x				x
E09.3553	Drug or chemical induced diabetes mellitus with stable proliferative diabetic retinopathy, bilateral	x				x
E09.3559	Drug or chemical induced diabetes mellitus with stable proliferative diabetic retinopathy, unspecified eye	x				x

Diagnosis Code	Description	Applies to HCPCS Code				
		J0177	J2777	J2779	Q5124	Q5128
E09.3591	Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy without macular edema, right eye	x				x
E09.3592	Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy without macular edema, left eye	x				x
E09.3593	Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy without macular edema, bilateral	x				x
E09.3599	Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy without macular edema, unspecified eye	x				x
E09.37X1	Drug or chemical induced diabetes mellitus with diabetic macular edema, resolved following treatment, right eye	x	x			x
E09.37X2	Drug or chemical induced diabetes mellitus with diabetic macular edema, resolved following treatment, left eye	x	x			x
E09.37X3	Drug or chemical induced diabetes mellitus with diabetic macular edema, resolved following treatment, bilateral	x	x			x
E09.37X9	Drug or chemical induced diabetes mellitus with diabetic macular edema, resolved following treatment, unspecified eye	x	x			x
E10.311	Type 1 diabetes mellitus with unspecified diabetic retinopathy with macular edema	x	x			x
E10.3211	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, right eye	x	x			x
E10.3212	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, left eye	x	x			x
E10.3213	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, bilateral	x	x			x
E10.3219	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, unspecified eye	x	x			x
E10.3291	Type 1 diabetes mellitus with mild non-proliferative diabetic retinopathy without macular edema, right eye	x				x
E10.3292	Type 1 diabetes mellitus with mild non-proliferative diabetic retinopathy without macular edema, left eye	x				x
E10.3293	Type 1 diabetes mellitus with mild non-proliferative diabetic retinopathy without macular edema, bilateral	x				x
E10.3299	Type 1 diabetes mellitus with mild non-proliferative diabetic retinopathy without macular edema, unspecified eye	x				x

Diagnosis Code	Description	Applies to HCPCS Code				
		J0177	J2777	J2779	Q5124	Q5128
E10.3311	Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, right eye	x	x			x
E10.3312	Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, left eye	x	x			x
E10.3313	Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, bilateral	x	x			x
E10.3319	Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, unspecified eye	x	x			x
E10.3391	Type 1 diabetes mellitus with moderate non-proliferative diabetic retinopathy without macular edema, right eye	x				x
E10.3392	Type 1 diabetes mellitus with moderate non-proliferative diabetic retinopathy without macular edema, left eye	x				x
E10.3393	Type 1 diabetes mellitus with moderate non-proliferative diabetic retinopathy without macular edema, bilateral	x				x
E10.3399	Type 1 diabetes mellitus with moderate non-proliferative diabetic retinopathy without macular edema, unspecified eye	x				x
E10.3411	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, right eye	x	x			x
E10.3412	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, left eye	x	x			x
E10.3413	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, bilateral	x	x			x
E10.3419	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, unspecified eye	x	x			x
E10.3491	Type 1 diabetes mellitus with severe non-proliferative diabetic retinopathy without macular edema, right eye	x				x
E10.3492	Type 1 diabetes mellitus with severe non-proliferative diabetic retinopathy without macular edema, left eye	x				x
E10.3493	Type 1 diabetes mellitus with severe non-proliferative diabetic retinopathy without macular edema, bilateral	x				x
E10.3499	Type 1 diabetes mellitus with severe non-proliferative diabetic retinopathy without macular edema, unspecified eye	x				x

Diagnosis Code	Description	Applies to HCPCS Code				
		J0177	J2777	J2779	Q5124	Q5128
E10.3511	Type 1 diabetes mellitus with proliferative diabetic retinopathy with macular edema, right eye	x	x			x
E10.3512	Type 1 diabetes mellitus with proliferative diabetic retinopathy with macular edema, left eye	x	x			x
E10.3513	Type 1 diabetes mellitus with proliferative diabetic retinopathy with macular edema, bilateral	x	x			x
E10.3519	Type 1 diabetes mellitus with proliferative diabetic retinopathy with macular edema, unspecified eye	x	x			x
E10.3521	Type 1 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, right eye	x				x
E10.3522	Type 1 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, left eye	x				x
E10.3523	Type 1 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, bilateral	x				x
E10.3529	Type 1 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, unspecified eye	x				x
E10.3531	Type 1 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, right eye	x				x
E10.3532	Type 1 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, left eye	x				x
E10.3533	Type 1 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, bilateral	x				x
E10.3539	Type 1 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, unspecified eye	x				x
E10.3541	Type 1 diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, right eye	x				x
E10.3542	Type 1 diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, left eye	x				x
E10.3543	Type 1 diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, bilateral	x				x
E10.3549	Type 1 diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, unspecified eye	x				x

Diagnosis Code	Description	Applies to HCPCS Code				
		J0177	J2777	J2779	Q5124	Q5128
E10.3551	Type 1 diabetes mellitus with stable proliferative diabetic retinopathy, right eye	x				x
E10.3552	Type 1 diabetes mellitus with stable proliferative diabetic retinopathy, left eye	x				x
E10.3553	Type 1 diabetes mellitus with stable proliferative diabetic retinopathy, bilateral	x				x
E10.3559	Type 1 diabetes mellitus with stable proliferative diabetic retinopathy, unspecified eye	x				x
E10.3591	Type 1 diabetes mellitus with proliferative diabetic retinopathy without macular edema, right eye	x				x
E10.3592	Type 1 diabetes mellitus with proliferative diabetic retinopathy without macular edema, left eye	x				x
E10.3593	Type 1 diabetes mellitus with proliferative diabetic retinopathy without macular edema, bilateral	x				x
E10.3599	Type 1 diabetes mellitus with proliferative diabetic retinopathy without macular edema, unspecified eye	x				x
E10.37X1	Type 1 diabetes mellitus with diabetic macular edema, resolved following treatment, right eye	x	x			x
E10.37X2	Type 1 diabetes mellitus with diabetic macular edema, resolved following treatment, left eye	x	x			x
E10.37X3	Type 1 diabetes mellitus with diabetic macular edema, resolved following treatment, bilateral	x	x			x
E10.37X9	Type 1 diabetes mellitus with diabetic macular edema, resolved following treatment, unspecified eye	x	x			x
E11.311	Type 2 diabetes mellitus with unspecified diabetic retinopathy with macular edema	x	x			x
E11.3211	Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, right eye	x	x			x
E11.3212	Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, left eye	x	x			x
E11.3213	Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, bilateral	x	x			x
E11.3219	Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, unspecified eye	x	x			x
E11.3291	Type 2 diabetes mellitus with mild non-proliferative diabetic retinopathy without macular edema, right eye	x				x
E11.3292	Type 2 diabetes mellitus with mild non-proliferative diabetic retinopathy without macular edema, left eye	x				x
E11.3293	Type 2 diabetes mellitus with mild non-proliferative diabetic retinopathy without macular edema, bilateral	x				x

Diagnosis Code	Description	Applies to HCPCS Code				
		J0177	J2777	J2779	Q5124	Q5128
E11.3299	Type 2 diabetes mellitus with mild non-proliferative diabetic retinopathy without macular edema, unspecified eye	x				x
E11.3311	Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, right eye	x	x			x
E11.3312	Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, left eye	x	x			x
E11.3313	Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, bilateral	x	x			x
E11.3319	Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, unspecified eye	x	x			x
E11.3391	Type 2 diabetes mellitus with moderate non-proliferative diabetic retinopathy without macular edema, right eye	x				x
E11.3392	Type 2 diabetes mellitus with moderate non-proliferative diabetic retinopathy without macular edema, left eye	x				x
E11.3393	Type 2 diabetes mellitus with moderate non-proliferative diabetic retinopathy without macular edema, bilateral	x				x
E11.3399	Type 2 diabetes mellitus with moderate non-proliferative diabetic retinopathy without macular edema, unspecified eye	x				x
E11.3411	Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, right eye	x	x			x
E11.3412	Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, left eye	x	x			x
E11.3413	Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, bilateral	x	x			x
E11.3419	Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, unspecified eye	x	x			x
E11.3491	Type 2 diabetes mellitus with severe non-proliferative diabetic retinopathy without macular edema, right eye	x				x
E11.3492	Type 2 diabetes mellitus with severe non-proliferative diabetic retinopathy without macular edema, left eye	x				x
E11.3493	Type 2 diabetes mellitus with severe non-proliferative diabetic retinopathy without macular edema, bilateral	x				x

Diagnosis Code	Description	Applies to HCPCS Code				
		J0177	J2777	J2779	Q5124	Q5128
E11.3499	Type 2 diabetes mellitus with severe non-proliferative diabetic retinopathy without macular edema, unspecified eye	x				x
E11.3511	Type 2 diabetes mellitus with proliferative diabetic retinopathy with macular edema, right eye	x	x			x
E11.3512	Type 2 diabetes mellitus with proliferative diabetic retinopathy with macular edema, left eye	x	x			x
E11.3513	Type 2 diabetes mellitus with proliferative diabetic retinopathy with macular edema, bilateral	x	x			x
E11.3519	Type 2 diabetes mellitus with proliferative diabetic retinopathy with macular edema, unspecified eye	x	x			x
E11.3521	Type 2 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, right eye	x				x
E11.3522	Type 2 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, left eye	x				x
E11.3523	Type 2 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, bilateral	x				x
E11.3529	Type 2 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, unspecified eye	x				x
E11.3531	Type 2 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, right eye	x				x
E11.3532	Type 2 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, left eye	x				x
E11.3533	Type 2 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, bilateral	x				x
E11.3539	Type 2 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, unspecified eye	x				x
E11.3541	Type 2 diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, right eye	x				x
E11.3542	Type 2 diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, left eye	x				x
E11.3543	Type 2 diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, bilateral	x				x

Diagnosis Code	Description	Applies to HCPCS Code				
		J0177	J2777	J2779	Q5124	Q5128
E11.3549	Type 2 diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, unspecified eye	x				x
E11.3551	Type 2 diabetes mellitus with stable proliferative diabetic retinopathy, right eye	x				x
E11.3552	Type 2 diabetes mellitus with stable proliferative diabetic retinopathy, left eye	x				x
E11.3553	Type 2 diabetes mellitus with stable proliferative diabetic retinopathy, bilateral	x				x
E11.3559	Type 2 diabetes mellitus with stable proliferative diabetic retinopathy, unspecified eye	x				x
E11.3591	Type 2 diabetes mellitus with proliferative diabetic retinopathy without macular edema, right eye	x				x
E11.3592	Type 2 diabetes mellitus with proliferative diabetic retinopathy without macular edema, left eye	x				x
E11.3593	Type 2 diabetes mellitus with proliferative diabetic retinopathy without macular edema, bilateral	x				x
E11.3599	Type 2 diabetes mellitus with proliferative diabetic retinopathy without macular edema, unspecified eye	x				x
E11.37X1	Type 2 diabetes mellitus with diabetic macular edema, resolved following treatment, right eye	x	x			x
E11.37X2	Type 2 diabetes mellitus with diabetic macular edema, resolved following treatment, left eye	x	x			x
E11.37X3	Type 2 diabetes mellitus with diabetic macular edema, resolved following treatment, bilateral	x	x			x
E11.37X9	Type 2 diabetes mellitus with diabetic macular edema, resolved following treatment, unspecified eye	x	x			x
E13.311	Other specified diabetes mellitus with unspecified diabetic retinopathy with macular edema	x	x			x
E13.3211	Other specified diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, right eye	x	x			x
E13.3212	Other specified diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, left eye	x	x			x
E13.3213	Other specified diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, bilateral	x	x			x
E13.3219	Other specified diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, unspecified eye	x	x			x
E13.3291	Other specified diabetes mellitus with mild non-proliferative diabetic retinopathy without macular edema, right eye	x				x

Diagnosis Code	Description	Applies to HCPCS Code				
		J0177	J2777	J2779	Q5124	Q5128
E13.3292	Other specified diabetes mellitus with mild non-proliferative diabetic retinopathy without macular edema, left eye	x				x
E13.3293	Other specified diabetes mellitus with mild non-proliferative diabetic retinopathy without macular edema, bilateral	x				x
E13.3299	Other specified diabetes mellitus with mild non-proliferative diabetic retinopathy without macular edema, unspecified eye	x				x
E13.3311	Other specified diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, right eye	x	x			x
E13.3312	Other specified diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, left eye	x	x			x
E13.3313	Other specified diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, bilateral	x	x			x
E13.3319	Other specified diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, unspecified eye	x	x			x
E13.3391	Other specified diabetes mellitus with moderate non-proliferative diabetic retinopathy without macular edema, right eye	x				x
E13.3392	Other specified diabetes mellitus with moderate non-proliferative diabetic retinopathy without macular edema, left eye	x				x
E13.3393	Other specified diabetes mellitus with moderate non-proliferative diabetic retinopathy without macular edema, bilateral	x				x
E13.3399	Other specified diabetes mellitus with moderate non-proliferative diabetic retinopathy without macular edema, unspecified eye	x				x
E13.3411	Other specified diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, right eye	x	x			x
E13.3412	Other specified diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, left eye	x	x			x
E13.3413	Other specified diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, bilateral	x	x			x
E13.3419	Other specified diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, unspecified eye	x	x			x
E13.3491	Other specified diabetes mellitus with severe non-proliferative diabetic retinopathy without macular edema, right eye	x				x

Diagnosis Code	Description	Applies to HCPCS Code				
		J0177	J2777	J2779	Q5124	Q5128
E13.3492	Other specified diabetes mellitus with severe non-proliferative diabetic retinopathy without macular edema, left eye	x				x
E13.3493	Other specified diabetes mellitus with severe non-proliferative diabetic retinopathy without macular edema, bilateral	x				x
E13.3499	Other specified diabetes mellitus with severe non-proliferative diabetic retinopathy without macular edema, unspecified eye	x				x
E13.3511	Other specified diabetes mellitus with proliferative diabetic retinopathy with macular edema, right eye	x	x			x
E13.3512	Other specified diabetes mellitus with proliferative diabetic retinopathy with macular edema, left eye	x	x			x
E13.3513	Other specified diabetes mellitus with proliferative diabetic retinopathy with macular edema, bilateral	x	x			x
E13.3519	Other specified diabetes mellitus with proliferative diabetic retinopathy with macular edema, unspecified eye	x	x			x
E13.3521	Other specified diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, right eye	x				x
E13.3522	Other specified diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, left eye	x				x
E13.3523	Other specified diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, bilateral	x				x
E13.3529	Other specified diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, unspecified eye	x				x
E13.3531	Other specified diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, right eye	x				x
E13.3532	Other specified diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, left eye	x				x
E13.3533	Other specified diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, bilateral	x				x
E13.3539	Other specified diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, unspecified eye	x				x
E13.3541	Other specified diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, right eye	x				x

Diagnosis Code	Description	Applies to HCPCS Code				
		J0177	J2777	J2779	Q5124	Q5128
E13.3542	Other specified diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, left eye	x				x
E13.3543	Other specified diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, bilateral	x				x
E13.3549	Other specified diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, unspecified eye	x				x
E13.3551	Other specified diabetes mellitus with stable proliferative diabetic retinopathy, right eye	x				x
E13.3552	Other specified diabetes mellitus with stable proliferative diabetic retinopathy, left eye	x				x
E13.3553	Other specified diabetes mellitus with stable proliferative diabetic retinopathy, bilateral	x				x
E13.3559	Other specified diabetes mellitus with stable proliferative diabetic retinopathy, unspecified eye	x				x
E13.3591	Other specified diabetes mellitus with proliferative diabetic retinopathy without macular edema, right eye	x				x
E13.3592	Other specified diabetes mellitus with proliferative diabetic retinopathy without macular edema, left eye	x				x
E13.3593	Other specified diabetes mellitus with proliferative diabetic retinopathy without macular edema, bilateral	x				x
E13.3599	Other specified diabetes mellitus with proliferative diabetic retinopathy without macular edema, unspecified eye	x				x
E13.37X1	Other specified diabetes mellitus with diabetic macular edema, resolved following treatment, right eye	x	x			x
E13.37X2	Other specified diabetes mellitus with diabetic macular edema, resolved following treatment, left eye	x	x			x
E13.37X3	Other specified diabetes mellitus with diabetic macular edema, resolved following treatment, bilateral	x	x			x
E13.37X9	Other specified diabetes mellitus with diabetic macular edema, resolved following treatment, unspecified eye	x	x			x
H34.8110	Central retinal vein occlusion, right eye, with macular edema		x		x	x
H34.8111	Central retinal vein occlusion, right eye, with retinal neovascularization		x		x	x

Diagnosis Code	Description	Applies to HCPCS Code				
		J0177	J2777	J2779	Q5124	Q5128
H34.8112	Central retinal vein occlusion, right eye, stable		x		x	x
H34.8120	Central retinal vein occlusion, left eye, with macular edema		x		x	x
H34.8121	Central retinal vein occlusion, left eye, with retinal neovascularization		x		x	x
H34.8122	Central retinal vein occlusion, left eye, stable		x		x	x
H34.8130	Central retinal vein occlusion, bilateral, with macular edema		x		x	x
H34.8131	Central retinal vein occlusion, bilateral, with retinal neovascularization		x		x	x
H34.8132	Central retinal vein occlusion, bilateral, stable		x		x	x
H34.8190	Central retinal vein occlusion, unspecified eye, with macular edema		x		x	x
H34.8191	Central retinal vein occlusion, unspecified eye, with retinal neovascularization		x		x	x
H34.8192	Central retinal vein occlusion, unspecified eye, stable		x		x	x
H34.821	Venous engorgement, right eye		x		x	x
H34.822	Venous engorgement, left eye		x		x	x
H34.823	Venous engorgement, bilateral		x		x	x
H34.829	Venous engorgement, unspecified eye		x		x	x
H34.8310	Tributary (branch) retinal vein occlusion, right eye, with macular edema		x		x	x
H34.8311	Tributary (branch) retinal vein occlusion, right eye, with retinal neovascularization		x		x	x
H34.8312	Tributary (branch) retinal vein occlusion, right eye, stable		x		x	x
H34.8320	Tributary (branch) retinal vein occlusion, left eye, with macular edema		x		x	x
H34.8321	Tributary (branch) retinal vein occlusion, left eye, with retinal neovascularization		x		x	x
H34.8322	Tributary (branch) retinal vein occlusion, left eye, stable		x		x	x
H34.8330	Tributary (branch) retinal vein occlusion, bilateral, with macular edema		x		x	x
H34.8331	Tributary (branch) retinal vein occlusion, bilateral, with retinal neovascularization		x		x	x
H34.8332	Tributary (branch) retinal vein occlusion, bilateral, stable		x		x	x
H34.8390	Tributary (branch) retinal vein occlusion, unspecified eye, with macular edema		x		x	x
H34.8391	Tributary (branch) retinal vein occlusion, unspecified eye, with retinal neovascularization		x		x	x
H34.8392	Tributary (branch) retinal vein occlusion, unspecified eye, stable		x		x	x

Diagnosis Code	Description	Applies to HCPCS Code				
		J0177	J2777	J2779	Q5124	Q5128
H35.051	Retinal neovascularization, unspecified, right eye				x	x
H35.052	Retinal neovascularization, unspecified, left eye				x	x
H35.053	Retinal neovascularization, unspecified, bilateral				x	x
H35.059	Retinal neovascularization, unspecified, unspecified eye				x	x
H35.3210	Exudative age-related macular degeneration, right eye, stage unspecified	x	x	x	x	x
H35.3211	Exudative age-related macular degeneration, right eye, with active choroidal neovascularization	x	x	x	x	x
H35.3212	Exudative age-related macular degeneration, right eye, with inactive choroidal neovascularization	x	x	x	x	x
H35.3213	Exudative age-related macular degeneration, right eye, with inactive scar	x	x		x	x
H35.3220	Exudative age-related macular degeneration, left eye, stage unspecified	x	x	x	x	x
H35.3221	Exudative age-related macular degeneration, left eye, with active choroidal neovascularization	x	x	x	x	x
H35.3222	Exudative age-related macular degeneration, left eye, with inactive choroidal neovascularization	x	x	x	x	x
H35.3223	Exudative age-related macular degeneration, left eye, with inactive scar	x	x		x	x
H35.3230	Exudative age-related macular degeneration, bilateral, stage unspecified	x	x	x	x	x
H35.3231	Exudative age-related macular degeneration, bilateral, with active choroidal neovascularization	x	x	x	x	x
H35.3232	Exudative age-related macular degeneration, bilateral, with inactive choroidal neovascularization	x	x	x	x	x
H35.3233	Exudative age-related macular degeneration, bilateral, with inactive scar	x			x	x
H35.3290	Exudative age-related macular degeneration, unspecified eye, stage unspecified	x	x	x	x	x
H35.3291	Exudative age-related macular degeneration, unspecified eye, with active choroidal neovascularization	x	x	x	x	x
H35.3292	Exudative age-related macular degeneration, unspecified eye, with inactive choroidal neovascularization	x	x	x	x	x
H35.3293	Exudative age-related macular degeneration, unspecified eye, with inactive scar	x	x	x	x	x
H35.351	Cystoid macular degeneration, right eye	x	x	x	x	x
H35.352	Cystoid macular degeneration, left eye	x	x	x	x	x
H35.353	Cystoid macular degeneration, bilateral	x	x	x	x	x
H40.89	Other specified glaucoma					x
H44.2A1	Degenerative myopia with choroidal neovascularization, right eye				x	x

Diagnosis Code	Description	Applies to HCPCS Code				
		J0177	J2777	J2779	Q5124	Q5128
H44.2A2	Degenerative myopia with choroidal neovascularization, left eye				x	x
H44.2A3	Degenerative myopia with choroidal neovascularization, bilateral eye				x	x
H44.2A9	Degenerative myopia with choroidal neovascularization, unspecified eye				x	x

Maximum Allowed Frequencies

The allowed frequencies in this section are based upon the FDA approved prescribing information for the applicable medications. For indications without FDA approved dosing, the frequencies are derived from available clinical evidence. This list may not be inclusive of all medications listed and is subject to change.

Medication Name		Diagnosis	Maximum Frequency
Brand	Generic		
Byooviz	ranibizumab-nuna	Neovascular age-related macular degeneration (nAMD)	The recommended dose is 0.5 mg (0.05 ML) administered by intravitreal injection once a month (approximately 28 days). Patients may be treated with 3 monthly doses followed by less frequent dosing. Patients may also be treated with one dose every 3 months after 4 monthly doses. Maximum of 12 doses per year per eye.
		Macular edema following retinal vein occlusion (RVO)	The recommended dose is 0.5 mg (0.05 ML) administered by intravitreal injection once a month (approximately 28 days). Maximum of 12 doses per year per eye.
		Myopic choroidal neovascularization (mCNV)	The recommended dose is 0.5 mg (0.05 ML) administered by intravitreal injection once a month (approximately 28 days) for up to 3 months. May be retreated if necessary. Maximum of 12 doses per year per eye.
Cimerli	ranibizumab-eqrn	Myopic choroidal neovascularization (mCNV)	The recommended dose is 0.5 mg (0.05 mL) to affected eye(s) once a month (approximately every 28 days) for up to 3 months. May be retreated if necessary. Maximum of 12 doses per year per eye.
		Diabetic macular edema (DME)	The recommended dose is 0.3 mg (0.05 mL) to affected eye(s) once a month (approximately every 28 days). Maximum of 12 doses per year per eye.
		Diabetic retinopathy (DR)	
		Macular edema following retinal vein occlusion (RVO)	The recommended dose is 0.5 mg (0.05 mL) to affected eye(s) once a month (approximately every 28 days). Maximum of 12 doses per year per eye.
		Neovascular (wet) age-related macular degeneration (nAMD)	The recommended dose is 0.5 mg (0.05 mL) to affected eye(s) once a month (approximately every 28 days). Treatment may be reduced to 3 once monthly doses, followed by an average of 4 to 5 injections over the subsequent 9 months. Maximum of 12 doses per year per eye.

Medication Name		Diagnosis	Maximum Frequency
Brand	Generic		
Eylea HD	aflibercept	Diabetic macular edema (DME)	The recommended dose is 8 mg (0.07 mL) into affected eye(s) every 4 weeks (approximately every 28 days +/- 7 days) for the first 3 doses, then 8 mg every 8 to 16 weeks +/- 1 week. Maximum of 12 doses per year per eye.
		Neovascular age-related macular degeneration (nAMD)	
		Diabetic retinopathy (DR)	The recommended dose is 8 mg (0.7 mL) into affected eye(s) every 4 weeks (approximately every 28 days +/- 7 days) for the first 3 doses, followed by 8 mg once every 8 to 12 weeks +/- 1 week. Maximum of 12 doses per year per eye.
Susvimo	ranibizumab	Neovascular age-related macular degeneration (nAMD)	The recommended dose is 2 mg to affected eye(s) continuously delivered via ocular implant every 24 weeks (approximately 6 months). If clinically necessary, supplemental treatment with 0.5 mg intravitreal injection may be administered in the affected eye(s) while the implant is in place.
Vabysmo	faricimab	Diabetic macular edema (DME)	The recommended dose is one of the following regimens: 1) 6 mg administered by intravitreal injection every 4 weeks for at least 4 doses, followed by extensions of up to 4 week interval increments or reductions of up to 8 week interval increments based on response; or 2) 6 mg administered every 4 weeks for the first 6 doses, followed by 6 mg dose via intravitreal injections at intervals of every 8 weeks over the next 28 weeks. Although most patients require dosing every 8 weeks, some patients may need dosing every 4 weeks. Maximum of 12 doses per year per eye.
		Neovascular age-related macular degeneration (nAMD)	The recommended dose is 6 mg (0.05 mL) by intravitreal injection every 4 weeks for the first 4 doses, followed by one of the following three regimens: 1) Weeks 28 and 44; 2) Weeks 24, 36, and 48; or 3) Weeks 20, 28, 36 and 44. Although most patients require dosing every 8 weeks, some patients may need dosing every 4 weeks. Maximum of 12 doses per year per eye.
		Macular edema following retinal vein occlusion (RVO)	The recommended dose is 6 mg (0.05 mL) by intravitreal injection every 4 weeks (approximately every 28 +/- 7 days, monthly) for 6 months.

Background

Vascular endothelial growth factor (VEGF) is a protein that stimulates the growth, proliferation, and survival of vascular endothelial cells. VEGF plays a critical role in the development of new blood vessels (angiogenesis), increases vascular permeability in small blood vessels and prevents apoptosis of vascular endothelial cells in immature blood vessels. VEGF has been implicated in blood retinal barrier breakdown and pathological ocular neovascularization.[4]

Proven

Neovascular Age-Related Macular Degeneration (AMD)

Ranibizumab-nuna, ranibizumab-eqrn, and faricimab are indicated for the treatment of neovascular age-related macular degeneration.

Two identically designed, randomized, multi-center, double-masked, active comparator-controlled, 2-year studies (TENAYA – NCT03823287 and LUCERNE – NCT03823300) assessed the safety and efficacy of faricimab in patients with nAMD. Patients (n = 1,329) were newly diagnosed and treatment-naïve with ages ranging from 50 to 99 (mean = 75.9 years). Patients were randomized in a 1:1 ratio to one of two treatment arms: 1) aflibercept 2 mg administered fixed every 8 weeks after three initial monthly doses; and faricimab 6 mg administered by intravitreal injection every 4 weeks for the first 4 doses, followed by optical coherence tomography and visual acuity evaluations 8 and 12 weeks later to determine whether to give a 6 mg dose via intravitreal injection on one of the following three regimens: 1) weeks 28 and 44 (Q16W dosing); 2) weeks 24, 36, and 48 (Q12W dosing); or 3) weeks 20, 28, 36, and 44 (Q8W dosing). At week 48, after 4 initial monthly doses in the faricimab arm, 45% of patients received Q16W dosing, 33% of patients received Q12W dosing, and the remaining 22% of patients received Q8W dosing. Both studies demonstrated non-inferiority to the comparator control (aflibercept) at the primary endpoint, defined as the mean change from baseline in Best Corrected Visual Acuity (BCVA) when averaged over the week 40, 44, and 48 visits and measured by the Early Treatment Diabetic Retinopathy Study (ETDRS) letter chart. The primary endpoint analysis was a non-inferiority comparison for the mean change in BCVA between the aflibercept and the faricimab arm. In both studies, faricimab-treated patients had a non-inferior mean change from baseline in BCVA compared to patients treated with aflibercept. The clinical efficacy for the second year of the study has not been reviewed.[3]

Woo et al. evaluated the equivalence of efficacy, similar safety, and similar immunogenicity of a ranibizumab biosimilar product (SB11) compared with the reference ranibizumab with neovascular age-related macular degeneration in a randomized, double-masked, parallel-group phase 3 equivalence study. The study was conducted in 75 centers in 9 countries from March 14, 2018, to December 9, 2019, among 705 participants 50 years or older with neovascular age-related macular degeneration with active subfoveal choroidal neovascularization lesions. Patients were randomized in a 1:1 ratio to receive intravitreous injection of either SB11 or ranibizumab, 0.5 mg, every 4 weeks through week 48. Preplanned interim analysis after all participants completed the week 24 assessment of primary efficacy end points at week 8 for change from baseline in best-corrected visual acuity (BCVA) and week 4 for central subfield thickness (CST), with predefined equivalence margins for adjusted treatment differences of −3 letters to 3 letters for BCVA and −36 μm to 36 μm for CST. Least-squares mean (SE) changes in BCVA from baseline at week 8 were 6.2 (0.5) letters in the SB11 group vs. 7.0 (0.5) letters in the ranibizumab group. Least-squares mean (SE) changes in CST from baseline at week 4 were −108 (5) μm in the SB11 group vs, −100 (5)μm in the ranibizumab group. Incidences of treatment-emergent adverse events [231 of 350 (66.0%) vs. 237 of 354 (66.9%)], including serious treatment-emergent adverse events [44 of 350 (12.6%) vs. 44 of 354 (12.4%)] and treatment-emergent adverse events leading to study drug discontinuation [8 of 350 (2.3%) vs. 5 of 354 (1.4%)], were similar in the SB11 and ranibizumab groups. Immunogenicity was low, with a cumulative incidence of antidrug antibodies up to week 24 of 3.0% (10 of 330) in the SB11 group and 3.1% (10 of 327) in the ranibizumab group. These findings of equivalent efficacy and similar safety and immunogenicity profiles compared with ranibizumab support the use of SB11 for patients with neovascular age-related macular degeneration.[5]

The clinical equivalence of ranibizumab-eqrn and reference ranibizumab was evaluated in a prospective, evaluation-masked, parallel-group, 48-week, phase 3 randomized study in patients with treatment-naïve, subfoveal choroidal neovascularization caused by neovascular age-related macular degeneration (nAMD). A total of 477 patients were randomly assigned to receive ranibizumab-eqrn (n = 238) or reference ranibizumab (n = 239) 0.5mg by intravitreal (IVT) injection in the study eye every 4 weeks. The primary end point was change from baseline in best-corrected visual acuity (BCVA) by Early Treatment Diabetic Retinopathy Study (ETDRS) letters at 8 weeks before the third IVT injection. Biosimilarity of ranibizumab-eqrn to its originator was assess via a 2-sided equivalence test, with an equivalence margin in BCVA of 3 ETDRS letters. The BCVA improved in both groups, with a mean improvement of +5.1 (FYB201) and +5.6 (reference ranibizumab) ETDRS letters at week 8. The analysis of covariance (ANCOVA) least squares mean difference for the change from baseline between ranibizumab-eqrn and reference ranibizumab was -0.4 ETDRS letters with a 90% confidence interval (CI) of -1.6 to 0.9. Primary end point was met as the 90% CI was within the predefined equivalence margin of -3.5 to 3.5. In the post hoc analysis, the ANCOVA least squares mean difference for the change from baseline in BCVA at week 8 between ranibizumab-eqrn and reference ranibizumab was −0.4 ETDRS letters, with a 95% CI of −1.9 to 1.1, again meeting the criteria for equivalence between drugs. In the per-protocol

sensitivity analysis, the ANCOVA least squares mean difference for change in BCVA between ranibizumab-eqrn and reference ranibizumab at week 8 was −0.4 ETDRS letters, with a 90% CI of −1.7 to 0.9, also contained within the predefined equivalence margin. The frequency and type of ocular adverse events were comparable between treatment groups. Most adverse events were of mild or moderate intensity, and no clinically relevant differences were identified. The most frequent study drug-related adverse events in the ranibizumab-eqrn and reference ranibizumab groups, respectively, were cataract (0.0% and 2.1%), retinal pigment epithelium tear (0.4% and 1.3%), reduced visual acuity (0.0% and 1.3%), punctate keratitis (0.0% and 0.8%), vitreous hemorrhage (0.4% and 0.4%), eye pain (0.8% and 0.0%), increased gamma-glutamyl transferase level (0.4% and 0.4%), and increased intraocular pressure (1.3% and 0.8%). A total of 21.4% (ranibizumab-eqrn) and 27.6% (reference ranibizumab) of patients experienced adverse events related to the IVT injection procedure. The prevalence of treatment-emergent AEs associated with MedDRA preferred terms for intraocular inflammation was similar between FYB201 and reference ranibizumab groups. Of the patients treated with FYB201, 8.4% (20/238) experienced treatment-emergent AEs associated with intraocular inflammation terms, compared with 8.4% (20/239) of patients treated with reference ranibizumab. In both treatment groups, 0.8% of patients experienced treatment-emergent AEs possibly related to the investigational medicinal product, specifically iridocyclitis (n = 1) and conjunctivitis (n = 1) in the FYB201 group, and punctate keratitis (n = 2) in the reference ranibizumab group. Frequency and type of systemic AEs were also similar between FYB201 and reference ranibizumab groups, with the most frequent, respectively, being nAMD in the fellow eye (7.6% and 8.8%), nasopharyngitis (5.0% and 6.7%), hypertension (1.3% and 5.9%), and increased C-reactive protein level (4.2% and 2.1%). A slightly higher incidence of systemic serious AEs was observed in the reference ranibizumab arm (12.1%) compared with the FYB201 arm (7.1%). Three patients discontinued the study because of AEs, 1 in the FYB201 group (worsening of nAMD) and 2 in the reference ranibizumab group (unrelated benign pancreatic neoplasm and malignant tongue neoplasm of unspecified stage). In addition, AEs led to permanent or temporary withdrawal of study drug in an additional 9 patients, 5 in the FYB201 group and 4 in the reference ranibizumab group. In the FYB201 group, 3 patients had interruption of treatment due to mild nonserious AEs (1 with upper respiratory tract infection and 2 with conjunctivitis), and 2 patients had moderate AEs; 1 had a chalazion for which treatment was resumed at the subsequent visit without omitting an injection, and 1 had conjunctivitis for which the patient did not receive the last planned injection. In the reference ranibizumab group, mild nonserious AEs resulted in interruption of treatment in 3 patients (1 each of blepharospasm and visual acuity reduced, vascular anastomosis, and complications associated with device and viral infection), and 1 patient had severe endophthalmitis. Three patients died during the study (n = 2 in FYB201 group and n = 1 in the reference ranibizumab group), but none of the deaths were considered related to the study drug.

The clinical efficacy and safety of Susvimo (ranibizumab ocular implant) was established in a randomized, visual assessor-masked, active treatment-controlled study (Archway-NCT03677934) in 415 patients with AMD. Patients were diagnosed with nAMD within the 9 months prior to screening and received ≥ 3 doses of anti-VEGF intravitreal agents in the study eye within the last 6 months prior to screening. Each patient was required to have demonstrated a response to an anti-VEGF intravitreal agent prior to randomization. Patients were randomized to receive continuous delivery of ranibizumab via the Susvimo implant every 24 weeks or 0.5 mg intravitreal ranibizumab injections every 4 weeks. For patients in the Susvimo arm, supplemental treatment with 0.5 mg intravitreal ranibizumab injections were available at Weeks 16, 20, 40, 44, 64, 68, 88 and 92, if needed. The primary endpoint was the change from baseline in distance best corrected visual acuity (BCVA) score averaged over week 36 and week 40. Ranibizumab ocular implant was equivalent to the intravitreal ranibizumab injections. The adjusted mean change from baseline in BCVA score was 0.2 and 0.5, for ranibizumab implant and ranibizumab injections, respectively (difference -0.3, 95% CI: -1.7, 1.1).[9]

The efficacy of Eylea HD (aflibercept) for the treatment of nAMD was established in PULSAR, a randomized, double-masked, active-controlled study in 1,009 treatment-naïve patients with nAMD.[84] Patients were randomly assigned to 1 of 3 treatment groups: 1) Eylea HD every 12 weeks following 3 initial monthly doses; 2) Eylea HD every 16 weeks following 3 initial monthly doses; or 3) Eylea 2 mg every 8 weeks following 3 initial monthly doses. The primary endpoint was the change from baseline in Best Corrected Visual Acuity (BCVA) at week 48 as measured by the Early Treatment Diabetic Retinopathy Study (ETDRS) letter score. Both Eylea HD treatment arms were shown to be non-inferior and clinically equivalent to Eylea treatment with respect to the change in BCVA score at week 48 using the pre-specified non-inferiority margin of 4 letters.

Diabetic Macular Edema

Raricimab and ranibizumab-eqrn are indicated for the treatment of diabetic macular edema (DME).

Two randomized, multi-center, double-masked, active comparator-controlled 2-year studies (YOSEMITE – NCT03622580 and RHINE – NCT03622593) assessed the safety and efficacy of faricimab in patients with DME. Patients (n = 1,891) with diabetes were enrolled in the two studies with a total of 1,262 patients treated with at least one dose of faricimab. Patient ages ranged

from 24 to 91 years old (mean = 62.2 years). The overall population included both anti-VEGF naïve patients (78%) and patients who had been previously treated with a VEGF inhibitor prior to study participation (22%). The studies were identically designed, 2-year studies. Patients were randomized in a 1:1:1 ratio to one of three treatment regimens: 1) aflibercept Q8W, patients received fixed aflibercept 2 mg administered every 8 weeks (Q8W) after the first five monthly doses; 2) faricimab Q8W, patients received fixed faricimab 6 mg administered Q8W after the first six monthly doses; and 3) faricimab-variable, patients received faricimab 6 mg administered every 4 weeks for at least four doses and until the central subfield thickness (CST) of the macula measured by optical coherence tomography was less than approximately 325 microns, then the interval of dosing was modified by up to 4 week interval extensions or reductions in up to 8 week interval increments based on CST and visual acuity disease activity criteria at study drug dosing visits. After 4 initial monthly doses, the patients in the faricimab-variable arm could have received between the minimum of three and the maximum of eleven total injections through week 56 inclusive. At week 56, 32% of patients had completed at least one Q12W interval followed by one full Q16W interval. Seventeen percent (17%) of patients were treated on Q8W and/or Q4W dosing intervals through week 56 (7% only on Q4W). These percentages are reflective of what happened within the conduct of these trials, but the percentages are not generalizable to a broader DME population due to the inclusion/exclusion criteria limited enrollment to a select subset of DME patients and that there is no empirical data that a similar magnitude would be observed if eligibility criteria allowed for broader enrollment. Both studies demonstrated non-inferiority to the comparator control (aflibercept) at the primary endpoint, defined as the mean change from baseline in BCVA at year 1 (average of the week 48, 52, and 56 visits), measured by the ETDRS Letter Score. The primary endpoint analysis was a non-inferiority comparison for the mean change in BCVA between the aflibercept and faricimab groups. In both studies, faricimab Q8W and faricimab-variable treated patients had a mean change from baseline in BCVA that was non-inferior to the patients treated with aflibercept Q8W. Clinical efficacy for the second-year study has not been reviewed.[4]

The efficacy of Eylea HD was established in PHOTON, a randomized, double-masked, active-controlled study in 658 patients with DME involving the center of the macula.[84] Patients were randomly assigned to 1 of 3 treatment groups: 1) Eylea HD every 12 weeks following 3 initial monthly doses; 2) Eylea HD every 16 weeks following 3 initial monthly doses; or 3) Eylea 2 mg every 8 weeks following 5 initial monthly doses. The primary endpoint was the change from baseline in BCVA at week 48 as measured by the ETDRS letter score. Both Eylea HD treatment arms were shown to be non-inferior and clinically equivalent to Eylea treatment with respect to the change in BCVA score at week 48 using the pre-specified non-inferiority margin of 4 letters.

Macular Edema Secondary to BRVO/CRVO

Faricimab-svoa is indicated for the treatment of macular edema following retinal vein occlusion (RVO).[76]

The (efficacy of faricimab-svoa were evaluated in two randomized, double-masked studies (BALATON – in patients with macular edema following branch retinal vein occlusion, and COMINO – in patients with macular edema following central retinal vein occlusion/hemiretinal vein occlusion). A total of 1,282 newly diagnosed, treatment-naive patients were enrolled in these studies. In both studies, patients were randomized to either faricimab-svoa 6 mg administered every 4 weeks or the control arm receiving aflibercept 2 mg administered every 4 weeks. The primary endpoint was the change from baseline in Best Corrected Visual Acuity (BCVA) at week 24, measured by the Early Treatment Diabetic Retinopathy Study (ETDRS) Letter Score. In both studies, Vabysmo demonstrated non-inferiority to Eylea for the primary endpoint. In BALATON, vision gains were +16.9 (CI 15.7, 18.1) eye chart letters in the faricimab-svoa arm and +17.5 letters (CI 16.3, 18.6) in the aflibercept arm at 24 weeks. In COMINO, vision gains were +16.9 letters (CI 15.4, 18.3) in the faricimab-svoa arm and +17.3 letters (CI 15.9, 18.8) in the aflibercept arm at 24 weeks.

Proliferative Diabetic Retinopathy

Efficacy and safety data of Eylea HD in DR are derived from the PHOTON study. In the PHOTON study, a key efficacy outcome was the change in the ETDRS Diabetic Retinopathy Severity Scale (ETDRS-DRSS). The proportion of patients achieving ≥ 2-step improvement on ETDRS-DRSS was similar between the Eylea HD every 12 weeks and Eylea every 8 weeks. The Eylea HD every 16-week treatment arm did not meet the non-inferiority criteria for the proportion of patients with a ≥ 2-step improvement on ETDRS-DRSS and is not considered clinically equivalent to Eylea administered every 8 weeks.

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

Byooviz (Ranibizumab-Nuna)

Byooviz (ranibizumab-nuna) is indicated for the treatment of patients with neovascular (wet) age-related macular degeneration (AMD), macular edema following vein occlusion (RVO, and myoptic choroidal neovascularization (mCNV).[2]

Cimerli (Ranibizumab-Eqrn)

Cimerli (ranibizumab-eqrn) is indicated for the treatment of patients with neovascular (wet) age-related macular degeneration (AMD), macular edema following retinal vein occlusion (RVO), diabetic macular edema (DME), diabetic retinopathy (DR), and myopic choroidal neovascularization (mCNV).

Eylea HD (Aflibercept)

Eylea HD (aflibercept) is indicated for the treatment of patients with neovascular (wet) age-related macular degeneration (AMD), diabetic macular edema (DME), and diabetic retinopathy (DR).[10]

Susvimo (Ranibizumab)

Susvimo (ranibizumab) is indicated for the treatment of patients with Neovascular (wet) Age-related Macular Degeneration (AMD) who have previously responded to at least two intravitreal injections of a Vascular Endothelial Growth Factor (VEGF) inhibitor medication.

Vabysmo (Faricimab)

Vabysmo (faricimab) is indicated for the treatment of patients with neovascular (wet) age-related macular degeneration (AMD), diabetic macular edema (DME) and macular edema following retinal vein occlusion (RVO).[1]

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Policy History/Revision Information

Date	Summary of Changes
04/01/2024	**Applicable Codes** • Updated list of applicable HCPCS codes to reflect quarterly edits: o Added J0177 o Removed C9161 **Supporting Information** • Archived previous policy version CSIND0042.09

Instructions for Use

This Medical Benefit Drug Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state, or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state, or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state, or contractual requirements for benefit plan coverage govern. Before using this policy, please check the federal, state, or contractual requirements for benefit plan coverage. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Benefit Drug Policy is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare may also use tools developed by third parties, such as the InterQual® criteria, to assist us in administering health benefits. The UnitedHealthcare Medical Benefit Drug Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.