Draft Revision Policy: Do Not Implement

Ranibizumab (Lucentis®); Ranibizumab-nuna [Byooviz™]; Ranibizumab-eqrn [Cimerli™]; Ranibizumab-leyk [Nufymco™]; Ranibizumab-hkdz [Ranluspec®]

Some agents on this policy may require step therapy See "Step Therapy Requirements for Provider Administered Specialty Medications" Document at:
https://www.bcbst.com/docs/providers/Comm_BC_PAD_Step_Therapy_Guide.pdf

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the medical policy and a health plan or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

The proposal is to add text/statements in red and to delete text/statements with strikethrough:

POLICY

INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications
Lucentis, Byooviz, Cimerli, Nufymco and Ranluspec are indicated for:

- Neovascular (wet) age-related macular degeneration
- Macular edema following retinal vein occlusion
- Myopic choroidal neovascularization

Lucentis, Cimerli, Nufymco and Ranluspec are also indicated for:

- Diabetic macular edema
- Diabetic retinopathy

All other indications are considered experimental/investigational and not medically necessary.

PRESCRIBER SPECIALTIES

This medication must be prescribed by or in consultation with an ophthalmologist.

COVERAGE CRITERIA

Diabetic Macular Edema
Authorization of 12 months may be granted for treatment of diabetic macular edema.

Neovascular (Wet) Age-Related Macular Degeneration
Authorization of 12 months may be granted for treatment of neovascular (wet) age-related macular degeneration.

Macular Edema Following Retinal Vein Occlusion
Authorization of 12 months may be granted for treatment of macular edema following retinal vein occlusion.

Diabetic Retinopathy
Authorization of 12 months may be granted for treatment of diabetic retinopathy.

Myopic Choroidal Neovascularization
Authorization of 12 months may be granted for treatment of myopic choroidal neovascularization.

CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in the criteria coverage section when the member has demonstrated a positive clinical response to therapy (e.g., improvement or maintenance in best corrected visual acuity [BCVA] or visual field, or a reduction in the rate of vision decline or the risk of more severe vision loss).

MEDICATION QUANTITY LIMITS

Drug Name	Diagnosis	Maximum Dosing Regimen
~~Lucentis (Ranibizumab)~~ ~~Cimerli (Ranibizumab-eqrn)~~	~~Diabetic Macular Edema, Diabetic Retinopathy~~	~~Route of Administration: Intravitreal 0.3mg per affected eye every month (approximately 28 days)~~
~~Lucentis (Ranibizumab)~~ ~~Byooviz (Ranibizumab-nuna)~~ ~~Cimerli (Ranibizumab-eqrn)~~	~~Macular Edema following Retinal Vein Occlusion~~	~~Route of Administration: Intravitreal 0.5mg per affected eye every month (approximately 28 days)~~
~~Lucentis (Ranibizumab)~~ ~~Byooviz (Ranibizumab-nuna)~~ ~~Cimerli (Ranibizumab-eqrn)~~	~~Myopic Choroidal Neovascularization~~	~~Route of Administration: Intravitreal 0.5mg per affected eye every month (approximately 28 days) for up to 3 months. Patients may be retreated if needed.~~
~~Lucentis (Ranibizumab)~~ ~~Byooviz (Ranibizumab-nuna)~~ ~~Cimerli (Ranibizumab-eqrn)~~	~~Neovascular (Wet) Age-Related Macular Degeneration~~	~~Route of Administration: Intravitreal 0.5mg per affected eye every month (approximately 28 days). May be dosed less frequently after 3 or 4 monthly doses.~~
Byooviz (Ranibizumab-nuna)	Macular Edema following Retinal Vein Occlusion	Route of Administration: Intravitreal 0.5mg per affected eye every month (approximately 28 days)
Byooviz (Ranibizumab-nuna)	Myopic Choroidal Neovascularization	Route of Administration: Intravitreal 0.5mg per affected eye every month (approximately 28 days) for up to 3 months. Patients may be retreated if needed.
Byooviz (Ranibizumab-nuna)	Neovascular (Wet) Age-Related Macular Degeneration	Route of Administration: Intravitreal 0.5mg per affected eye every month (approximately 28 days). May be dosed less frequently after 3 or 4 monthly doses.
Cimerli (Ranibizumab-eqrn)	Diabetic Macular Edema	Route of Administration: Intravitreal 0.3mg per affected eye every month (approximately 28 days)

Cimerli (Ranibizumab-eqrn)	Diabetic Retinopathy	Route of Administration: Intravitreal 0.3mg per affected eye every month (approximately 28 days)
Cimerli (Ranibizumab-eqrn)	Macular Edema following Retinal Vein Occlusion	Route of Administration: Intravitreal 0.5mg per affected eye every month (approximately 28 days)
Cimerli (Ranibizumab-eqrn)	Myopic Choroidal Neovascularization	Route of Administration: Intravitreal 0.5mg per affected eye every month (approximately 28 days) for up to 3 months. Patients may be retreated if needed.
Cimerli (Ranibizumab-eqrn)	Neovascular (Wet) Age-Related Macular Degeneration	Route of Administration: Intravitreal 0.5mg per affected eye every month (approximately 28 days). May be dosed less frequently after 3 or 4 monthly doses.
Lucentis (Ranibizumab)	Diabetic Macular Edema	Route of Administration: Intravitreal 0.3mg per affected eye every month (approximately 28 days)
Lucentis (Ranibizumab)	Diabetic Retinopathy	Route of Administration: Intravitreal 0.3mg per affected eye every month (approximately 28 days)
Lucentis (Ranibizumab)	Macular Edema following Retinal Vein Occlusion	Route of Administration: Intravitreal 0.5mg per affected eye every month (approximately 28 days)
Lucentis (Ranibizumab)	Myopic Choroidal Neovascularization	Route of Administration: Intravitreal 0.5mg per affected eye every month (approximately 28 days) for up to 3 months. Patients may be retreated if needed.
Lucentis (Ranibizumab)	Neovascular (Wet) Age-Related Macular Degeneration	Route of Administration: Intravitreal 0.5mg per affected eye every month (approximately 28 days). May be dosed less frequently after 3 or 4 monthly doses.
Nufymco (Ranibizumab-leyk)	Diabetic Macular Edema	Route of Administration: Intravitreal 0.3mg per affected eye every month (approximately 28 days)
Nufymco (Ranibizumab-leyk)	Diabetic Retinopathy	Route of Administration: Intravitreal 0.3mg per affected eye every month (approximately 28 days)
Nufymco (Ranibizumab-leyk)	Macular Edema following Retinal Vein Occlusion	Route of Administration: Intravitreal 0.5mg per affected eye every month (approximately 28 days)
Nufymco (Ranibizumab-leyk)	Myopic Choroidal Neovascularization	Route of Administration: Intravitreal 0.5mg per affected eye every month (approximately 28 days) for up to 3 months. Patients may be retreated if needed.
Nufymco (Ranibizumab-leyk)	Neovascular (Wet) Age-Related Macular Degeneration	Route of Administration: Intravitreal 0.5mg per affected eye every month

		(approximately 28 days). May be dosed less frequently after 3 or 4 monthly doses.
Ranluspec (Ranibizumab-hkdz)	Diabetic Macular Edema	Route of Administration: Intravitreal 0.3mg per affected eye every month (approximately 28 days)
Ranluspec (Ranibizumab-hkdz)	Diabetic Retinopathy	Route of Administration: Intravitreal 0.3mg per affected eye every month (approximately 28 days)
Ranluspec (Ranibizumab-hkdz)	Macular Edema following Retinal Vein Occlusion	Route of Administration: Intravitreal 0.5mg per affected eye every month (approximately 28 days)
Ranluspec (Ranibizumab-hkdz)	Myopic Choroidal Neovascularization	Route of Administration: Intravitreal 0.5mg per affected eye every month (approximately 28 days) for up to 3 months. Patients may be retreated if needed.
Ranluspec (Ranibizumab-hkdz)	Neovascular (Wet) Age-Related Macular Degeneration	Route of Administration: Intravitreal 0.5mg per affected eye every month (approximately 28 days). May be dosed less frequently after 3 or 4 monthly doses.

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

REFERENCES

1. Lucentis [package insert]. South San Francisco, CA: Genentech, Inc.; February 2024.
2. American Academy of Ophthalmology Retinal/Vitreous Panel. Preferred Practice Pattern® Guidelines. Age-Related Macular Degeneration. San Francisco, CA: American Academy of Ophthalmology; 2024. Available at: https://www.aao.org/preferred-practice-pattern/age-related-macular-degeneration-ppp.
3. American Academy of Ophthalmology Retinal/Vitreous Panel. Preferred Practice Pattern® Guidelines. Diabetic Retinopathy. San Francisco, CA: American Academy of Ophthalmology; 2024. Available at: https://www.aao.org/preferred-practice-pattern/diabetic-retinopathy-ppp.

4. American Academy of Ophthalmology Retinal/Vitreous Panel. Preferred Practice Pattern® Guidelines. Retinal Vein Occlusions. San Francisco, CA: American Academy of Ophthalmology; 2024. Available at: https://www.aao.org/preferred-practice-pattern/retinal-vein-occlusions-ppp.
5. Byooviz [package insert]. Cambridge, MA: Biogen, Inc.; August 2025.
6. Cimerli [package insert].]. Princeton, NJ: Sandoz, Inc..; June 2024.
7. Ranluspec [package insert]. Naples, FL: Lupin Pharmaceutical, Inc.; June 2026.
8. Nufymco [package insert]. Pennington, NJ: Zydus Pharmaceuticals Inc.; June 2026.

EFFECTIVE DATE

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