

Ranibizumab Agents (Byooviz, Cimerli, Lucentis)

Override(s)	Approval Duration
Prior Authorization	1 year

Medications	Dosing Limit
Byooviz (ranibizumab-nuna) 0.5 mg vial	0.5 mg per eye; each eye may be treated as frequently as every 4 weeks
Lucentis (ranibizumab) 0.3 mg, 0.5 mg vial & syringe	<p>Diabetic macular edema and diabetic retinopathy: 0.3 mg per eye; each eye may be treated as frequently as every 4 weeks</p> <p>Age related macular degeneration, branch or central retinal vein occlusion, myopic choroidal neovascularization, and radiation retinopathy: 0.5 mg per eye; each eye may be treated as frequently as every 4 weeks</p>
Cimerli (ranibizumab-cqnr) 0.3 mg, 0.5 mg vial	<p>Diabetic macular edema and diabetic retinopathy: 0.3 mg per eye; each eye may be treated as frequently as every 4 weeks</p> <p>Age related macular degeneration, branch or central retinal vein occlusion, myopic choroidal neovascularization, and radiation retinopathy: 0.5 mg per eye; each eye may be treated as frequently as every 4 weeks</p>

APPROVAL CRITERIA

Requests for Lucentis (ranibizumab), Byooviz (ranibizumab-nuna) or Cimerli (ranibizumab-cqnr) may be approved if the following criteria are met:

- I. Individual has a diagnosis of one of the following:
 - A. Choroidal neovascularization associated with myopic degeneration; **OR**
 - B. Diabetic macular edema (DME) (including DME with diabetic retinopathy or any severity); **OR**
 - C. Proliferative or moderate to severe non-proliferative diabetic retinopathy with or without diabetic macular edema; **OR**
 - D. Established neovascular “wet” age-related macular degeneration; **OR**
 - E. Macular edema from branch retinal vein occlusion; **OR**
 - F. Macular edema from central retinal vein occlusion; **OR**

G. Radiation retinopathy (Finger 2016).

Requests for intravitreal injections of Lucentis (ranibizumab), Byooviz (ranibizumab-nuna), or Cimerli (ranibizumab-cqrn) may not be approved when the above criteria are not met and for all other indications.

Key References:

1. American Academy of Ophthalmology. Preferred Practice Pattern Guidelines: Retinal Vein Occlusions. October 2019. Available at: <https://www.aao.org/preferred-practice-pattern/retinal-vein-occlusions-ppp>.
2. American Academy of Ophthalmology. Preferred Practice Pattern Guidelines: Age-Related Macular Degeneration. October 2019. Available at: <https://www.aao.org/preferred-practice-pattern/age-related-macular-degeneration-ppp>.
3. American Academy of Ophthalmology. Preferred Practice Pattern Guidelines: Diabetic Retinopathy. October 2019. Available at: <https://www.aao.org/preferred-practice-pattern/diabetic-retinopathy-ppp>.
4. Costagliola C, Cipollone U, Rinaldi M, et al. Intravitreal bevacizumab (Avastin) injection for neovascular glaucoma: a survey on 23 cases throughout 12-month follow-up. *Br J Clin Pharmacol*. 2008; 66(5):667-673.
5. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2022. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
6. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>.
7. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
8. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022; Updated periodically.
9. Finger PT, Chin KJ, Semenova EA. Intravitreal anti-VEGF therapy for macular radiation retinopathy: a 10-year study. *Eur J Ophthalmol*. 2016; 26(1):60-66.
10. Sankar MJ, Sankar J, Chandra P. Anti-vascular endothelial growth factor (VEGF) drugs for treatment of retinopathy of prematurity. *Cochrane Database Syst Rev* 2018; 1:CD009734.
11. Pulido JS, Flaxel CJ, Adelman RA, Hyman L, Folk JC, Olsen TW. American Academy of Ophthalmology: Retinal Vein Occlusions Preferred Practice Pattern® guidelines. *Ophthalmology*. 2016; 123: 182–208.
12. Cheung, C.M.G.; Arnold, J.J.; Holz, F.G.; Park, K.H.; Lai, T.Y.Y.; Larsen, M.; Mitchell, P.; Ohno-Matsui, K.; Chen, S.J.; Wolf, S.; et al. Myopic Choroidal Neovascularization: Review, Guidance, and Consensus Statement on Management. *Ophthalmology* **2017**, *124*, 1690–1711.
13. Weber, M. L. & Heier, J. S. Choroidal Neovascularization Secondary to Myopia, Infection and Inflammation. *Dev Ophthalmol* **55**: 167–75, 10.1159/000431194, Epub 2015 Oct 26 (2016).

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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