Clinical Policy: Ranibizumab (Byooviz, Cimerli, Lucentis, Nufymco, Susvimo)

Reference Number: LA.PHAR.186
Effective Date: 10.05.23
Last Review Date: 04.27.26
Line of Business: Medicaid

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

****Please note: This policy is for medical benefit****

Description
Ranibizumab (Lucentis®, Susvimo®), ranibizumab-nuna (Byooviz®), ranibizumab-eqrn (Cimerli™), and ranibizumab-leyk (Nufymco™) are vascular endothelial growth factor (VEGF) inhibitors.

FDA Approved Indication(s)

Indication	Lucentis	Cimerli	Nufymco	Byooviz	Susvimo
Neovascular (wet) age-related macular degeneration (nAMD)	X	X	X	X	X (who have previously responded to at least two intravitreal injections of a VEGF inhibitor medication)
Macular edema following retinal vein occlusion (RVO)	X	X	X	X	-
Myopic choroidal neovascularization (mCNV)	X	X	X	X	-
Diabetic macular edema (DME)	X	X	X	-	X (who have previously responded to at least two intravitreal injections of a VEGF inhibitor medication)
Diabetic retinopathy (DR)	X	X	X	-	X (who have previously responded to at least two intravitreal injections of a VEGF inhibitor medication)

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of Louisiana Healthcare Connections that Byooviz, Cimerli, Lucentis, Nufymco, and Susvimo are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Ophthalmic Disease Other Than Diabetic Macular Edema and Diabetic Retinopathy (must meet all)**:**

1. Diagnosis of one of the following (a, b, or c):*
   **For DME and DR see section I.B. below*
   a. nAMD;
   b. Macular edema following RVO;
   c. mCNV;
2. Prescribed by or in consultation with an ophthalmologist;
3. Age ≥ 18 years;
4. Failure of bevacizumab intravitreal solution^, unless contraindicated or clinically significant adverse effects are experienced;
   ^Prior authorization may be required for bevacizumab intravitreal solution. Requests for IV formulations of Avastin, Mvasi, and Zirabev will not be approved
5. If request is for Susvimo, member meets both of the following (a and b):
   a. Member has previously responded to at least 2 intravitreal injections of a VEGF inhibitor (e.g., intravitreal bevazicumab);
   b. Request is for the treatment of nAMD;
6. Dose does not exceed one of the following (a or b):
   a. For RVO or mCNV: 0.5 mg (1 vial/syringe) per month;
   b. For nAMD, either i or ii:
      i. If request is for Byooviz, Cimerli, Lucentis, or Nufymco: 0.5 mg (1 vial/syringe) per month;
      ii. If request is for Susvimo: 2 mg (one 100 mg/mL vial) per 6 months.

Approval duration:
mCNV: 3 months
All other indications: 6 months

B. Diabetic Macular Edema, Diabetic Retinopathy (must meet all)**:**

1. Request is for Cimerli, Lucentis, Nufymco, or Susvimo;
2. Diagnosis of one of the following (a or b):
   a. DME;
   b. DR;
3. Prescribed by or in consultation with an ophthalmologist;
4. Age ≥ 18 years;
5. Failure of bevacizumab intravitreal solution^, unless contraindicated or clinically significant adverse effects are experienced;
   ^Prior authorization may be required for bevacizumab intravitreal solution. Requests for IV formulations of Avastin, Mvasi, and Zirabev will not be approved

6. If request is for Susvimo, member has previously responded to at least 2 intravitreal injections of a VEGF inhibitor (e.g., intravitreal bevazicumab);
7. Dose does not exceed one of the following (a or b):
   a. For DME, either i or ii:
      i. If request is for Cimerli, Lucentis, or Nufymco: 0.3 mg (1 vial/syringe) per month;
      ii. If request is for Susvimo: 2 mg (one 100 mg/mL vial) per 6 months;
   b. For DR, either i or ii:
      i. If request is for Cimerli, Lucentis, or Nufymco: 0.3 mg (1 vial/syringe) per month;
      ii. If request is for Susvimo: 2 mg (one 100 mg/mL vial) per 9 months.

Approval duration: 6 months

C. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to LA.PMN.255
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy LA.PMN.53.

II. Continued Therapy

A. All Indications in Section I (must meet all)**:**

1. Currently receiving medication via Louisiana Healthcare Connections benefit or member has previously met initial approval criteria;

2. Member is responding positively to therapy as evidenced by one of the following (a, b, c, or d):
   a. Detained neovascularization;
   b. Improvement in visual acuity;
   c. Maintenance of corrected visual acuity from prior treatment;
   d. Supportive findings from optical coherence tomography or fluorescein angiography;

3. If request is for a dose increase, new dose does not exceed one of the following (a, b, c, or d):

   a. For DME, either i or ii:
      i. If request is for Cimerli, Lucentis, or Nufymco: 0.3 (1 vial/syringe) mg per month;
      ii. If request is for Susvimo: 100 mg (1 vial) per 6 months;
   b. For DR, either i or ii:
      i. If request is for Cimerli, Lucentis, or Nufymco: 0.3 (1 vial/syringe) mg per month;
      ii. If request is for Susvimo: 100 mg (1 vial) per 9 months;
   c. For RVO or mCNV: 0.5 mg (1 vial/syringe) per month;
   d. For nAMD, either i or ii:
      i. If request is for Byooviz, Cimerli, Lucentis, or Nufymco: 0.5 mg (1 vial/syringe) per month;

ii. If request is for Susvimo: 2 mg (one 100 mg/mL vial) per 6 months.

Approval duration:
mCNV: 3 months
All other indications: **12 months**

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to LA.PMN.255

2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy LA.PMN.53

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy LA.PMN.53

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

DME: diabetic macular edema
DR: diabetic retinopathy
FDA: Food and Drug Administration
mCNV: myopic choroidal neovascularization
nAMD: neovascular (wet) age-related macular degeneration
RVO: retinal vein occlusion
VEGF: vascular endothelial growth factor

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
bevacizumab (Avastin®)	**Neovascular (wet) AMD†:** 1.25 mg administered by intravitreal injection every 4 weeks	1.25 mg/month
	Macular edema secondary to RVO†: 1.25 mg administered by intravitreal injection every 4 weeks	1.25 mg/month
	DR†: 1.25 mg administered by intravitreal injection every 6 weeks	1.25 mg/6 weeks
	DME†: 1.25 to 1.5 mg administered by intravitreal injection every 4 weeks	1.5 mg/month

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	mCNV†: 1.25 mg initial intravitreal injection, followed by monthly evaluation for additional injections as needed	1.25 mg/month

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.
†Off-label

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s):
  - Byooviz, Cimerli, Lucentis, Nufymco, Susvimo: ocular or periocular infections; hypersensitivity
  - Susvimo: active intraocular inflammation
- Boxed warning(s):
  - Byooviz, Cimerli, Lucentis, Nufymco: none reported
  - Susvimo: associated with a 3-fold higher rate of endophthalmitis than monthly intravitreal injections of ranibizumab

Appendix D: General Information

- In the Comparison of AMD Treatments Trials study, the difference in mean visual acuity improvement for patients treated with Avastin compared to Lucentis was -1.4 letters (95% [CI],- 3.7 to 0.8) at two years. The proportion of patients with arteriothrombotic events was similar in the Lucentis-treated patients (4.7%) compared to the Avastin-treated patients (5.0%; p=0.89). The proportion of patients with one or more systemic serious adverse events was higher with Avastin (39.9%) than Lucentis (31.7%; adjusted risk ratio, 1.30; 95% CI, 1.07-1.57; p = 0.009). Serious systemic adverse events included all-cause mortality, non-fatal stroke, non-fatal myocardial infarction, vascular death, venous thrombotic events, and hypertension.
- In the ANti-VEGF Antibody for the Treatment of Predominantly Classic CHORoidal Neovascularisation in AMD (ANCHOR) trial, the number of patients that lost fewer than 15 letters at 12 months was achieved by 96.4% of patients treated with Lucentis 0.5 mg compared to 64.3% of patients treated with Visudyne ($p < 0.001$). Rate of intraocular inflammation was higher for patients treated with Lucentis 0.5 mg at 15% compared to Visudyne at 2.8%.
- In the VEGF Trap-Eye: Investigation of Efficacy and Safety in Wet Age-Related Macular Degeneration (VIEW)-1 trial, the difference in the number of patients who lost fewer than 15 letters at 52 weeks between Eylea every 8 weeks compared to Lucentis was 0.6% (95.1% CI -0.32, 4.4). In terms of the number of patients who gained at least 15 letters, the mean difference between Eylea every 8 weeks was 6.6% (95.1% CI -1.0, 14.1). There were no adverse events that were found to be significant from the Lucentis arm.
- In a trial comparing Eylea, Avastin and Lucentis, the Diabetic Retinopathy Clinical Research Network found in patients with diabetic macular edema that when the initial visual-acuity letter score was 78 to 69 (equivalent to approximately 20/32 to 20/40) (51% of participants), the mean improvement was 8.0 with Eylea, 7.5 with Avastin, and 8.3

with Lucentis (p > 0.50 for each pair wise comparison). When the initial letter score was less than 69 (approximately 20/50 or worse), the mean improvement was 18.9 with Eylea, 11.8 with Avastin, and 14.2 with Lucentis (p < 0.001 for Eylea vs. Avastin, p = 0.003 for Eylea vs. Lucentis, and p = 0.21 for Lucentis vs. Avastin).

V. Dosage and Administration

Drug Name	Indication	Dosing Regimen	Maximum Dose
Ranibizumab (Lucentis), ranibizumab-nuna (Byooviz), ranibizumab-eqrn (Cimerli), ranibizumab-leyk (Nufymco)	nAMD	0.5 mg (0.05 mL) administered by intravitreal injection once a month. <u>Alternative dosing:</u> Once monthly injections for three months followed by 4-5 doses dispersed among the following 9 months; or treatment may be reduced to one injection every 3 months after the first four injections if monthly injections are not feasible.	0.5 mg/month
	Macular edema following RVO	0.5 mg (0.05 mL) administered by intravitreal injection once a month.	0.5 mg/month
	mCNV	0.5 mg (0.05 mL) administered by intravitreal injection once a month for up to 3 months. Patients may be retreated if needed.	0.5 mg/month
Ranibizumab (Lucentis), ranibizumab-eqrn (Cimerli), ranibizumab-leyk (Nufymco)	DME and DR with or without DME	0.3 mg (0.05 mL) administered by intravitreal injection once a month	0.3 mg/month
Ranibizumab (Susvimo)	nAMD and DME	2 mg (0.02 mL of 100 mg/mL solution) continuously delivered via the Susvimo implant with refills every 24 weeks (approximately 6 months)	2 mg/6 months
	DR	2 mg (0.02 mL of 100 mg/mL solution) continuously delivered via the Susvimo implant with refills every 36 weeks (approximately 9 months)	2 mg/9 months

VI. Product Availability

Drug Name	Availability
Ranibizumab-nuna (Byooviz)	Single-dose glass vial: 0.5 mg/0.05 mL
Ranibizumab-eqrn (Cimerli)	Single-dose glass vials: 0.3 mg/0.05 mL, 0.5 mg/0.05 mL
Ranibizumab (Lucentis)	Single-use prefilled syringes: 0.3 mg/0.05 mL, 0.5 mg/0.05 mL
Ranibizumab-leyk (Nufymco)	Single-dose glass vials: 0.3 mg/0.05 mL, 0.5 mg/0.05 mL
Ranibizumab (Susvimo)	Single-dose glass vial: 100 mg/mL

VII. References

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11. Wells JA, Glassman AR, Ayala AR, et al. Aflibercept, bevacizumab, or ranibizumab for diabetic macular edema. *N Engl J Med*. 2015 Mar 26;372(13):1193-203. doi: 10.1056/NEJMoa1414264.

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Coding Implications
Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J2778	Injection, ranibizumab, 0.1 mg
J2779	Injection, ranibizumab, via intravitreal implant (susvimo), 0.1 mg
Q5124	Injection, ranibizumab-nuna, biosimilar, (byooviz), 0.1 mg
Q5128	Injection, ranibizumab-eqrn, biosimilar (cimerli), 0.1 mg

Reviews, Revisions, and Approvals	Date	LDH Approval Date
Converted corporate to local policy.	05.21	09.18.21
Converted redirection language from "must use" to "Failure of" bevacizumab intravitreal solution; added Byooviz and Susvimo to policy; references reviewed and updated.	07.22	08.18.22
Added Cimerli to to policy; added HCPCS codes for Susvimo, Byooviz, and Cimerli. Template changes applied to other diagnoses/indications and continued therapy section. References reviewed and updated. Added verbiage this policy is for medical benefit only.	06.02.23	10.05.23
No significant changes; references reviewed and updated.	05.26.24	07.29.24
Ad hoc: in intial approval criteria, separated DME and DR into a new section and clarified request is for Cimerli or Lucentis.	10.10.24	01.27.25
Annual review: simplified FDA approved indications to show Lucentis and Cimerli are additionally indicated from Byooviz for DME and DR; added quantity limit of 1 vial/syringe for Lucentis and biosimilars; revised Susvimo maximum dose to 100 mg (1 vial) per 6 months per PI; in Appendix B per Clinical Pharmacology, removed dosing for neovascular glaucoma, updated dosing regimens, clarified off-label indications; removed Lucentis single-use glass vials in Section VI per PI, references reviewed and updated.	04.28.25	07.04.25
Updated FDA indication to include DR for Susvimo.	08.19.25	11.12.25
Annual review: for DME, DR, RVO, and nAMD, extended continued therapy duration from 6 months to 12 months; references reviewed and updated. Added Nufymco to policy.	04.27.26	

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. LHCC makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved.

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