

MEDICATION COVERAGE POLICY

PHARMACY AND THERAPEUTICS ADVISORY COMMITTEE

POLICY	Intravitreal medications	P & T DATE	03/21/2023
THERAPEUTIC CLASS	Topical Anti-Inflammatory Agents	REVIEW HISTORY	03/2023
LOB AFFECTED	Medi-Cal	(MONTH/YEAR)	

This policy has been developed through review of medical literature, consideration of medical necessity, generally accepted medical practice standards, and approved by the HPSJ Pharmacy and Therapeutic Advisory Committee.

Effective 1/1/2022, the Pharmacy Benefit is regulated by Medi-Cal Rx. Please visit <https://med-calrx.dhcs.ca.gov/home/> for portal access, formulary details, pharmacy network information, and updates to the pharmacy benefit.

All medical claims require that an NDC is also submitted with the claim. If a physician administered medication has a specific assigned CPT code, that code must be billed with the correlating NDC. If there is not a specific CPT code available for a physician administered medication, the use of unclassified CPT codes is appropriate when billed with the correlating NDC.

OVERVIEW

Intravitreal administration of medication into the vitreous cavity may be indicated for several ophthalmic disease conditions. This policy discusses the indications and coverage criteria for several intravitreal medications which are indicated for physician administration.

The purpose of this coverage policy is to review the available agents (Table 1) and distinguish where the medications may be billed to. For agents listed for coverage under the medical benefit, this coverage is specific to outpatient coverage only (excludes emergency room and inpatient coverage).

Table 1. Available Intravitreal Agents: (Current as of 12/2022)

CPT code	Generic Name (Brand Name)	Available Strengths	Pharmacy Benefit	Medical Benefit (Restrictions)
CORTICOSTEROIDS				
J1100 (1 mg injection) J7312 (Ozurdex implant)	DEXAMETHASONE (Ozurdex)	0.1% SOLUTION, MAXIDEX 0.1% SUSPENSION, DEXYCU 9% SUSPENSION, OZURDEX 0.7 MG IMPLANT	Yes	Yes (PA, QL)
J7313 (Iluvien, 0.01 mg) J7311 (Retisert 0.01 mg) J7314 (Yutiq 0.01 mg)	FLUOCINOLONE (Iluvien, Retisert, Yutiq)	IMPLANT: 0.19 MG 0.59 MG	Yes	Yes (PA, QL)
J3301 (10 mg injection) J3299 (Xipere 1 mg)	TRIAMCINOLONE (Triesence, Xipere)	40 mg/mL intraocular suspension	Yes	Yes
VEGF- Agents				
J9035	Bevacizumab (Avastin)	100 mg/4mL vial	Yes	Yes (PA, QL)
J2778 (0.1 mg injection) J2779 (Susvimo, 0.1 mg implant)	Ranibizumab (Lucentis, Susvimo)	0.3 mg/0.05 mL solution 0.5 mg/0.05 mL solution Susvimo: 10MG/0.1ML implant	Yes	Yes (PA, QL)
Q5124	Ranibizumab-nuna (Byooviz)	0.5 mg/0.05 mL solution	Yes	Yes (PA, QL)
---	Ranibizumab-eqrn (Cimerli)	0.3 mg/0.05 mL, 0.5 mg/0.05 mL	Yes	Yes (PA, QL)
J0179	Brolucizumab (Beovu)	6 mg/0.05 mL	Yes	Yes (PA, QL)
J0178	Aflibercept (Eylea)	2 mg/0.05 mL solution	Yes	Yes (PA, QL)
J2777	Faricimab (Vabysmo)	6 mg/0.05 mL	Yes	Yes (PA, QL)
PA = Prior Authorization; QL = Quantity Limit				

⊕ EVALUATION CRITERIA FOR APPROVAL/EXCEPTION CONSIDERATION

Below are the coverage criteria and required information for agents with medical benefit restrictions. This coverage criteria has been reviewed and approved by the HPSJ Pharmacy & Therapeutics (P&T) Advisory Committee. For agents that do not have established prior authorization criteria, HPSJ will make the determination based on Medical Necessity criteria as described in HPSJ Medical Review Guidelines (UM06).

VEGF-inhibitors

Bevacizumab (Avastin), Ranibizumab (Lucentis), Ranibizumab-nuna (Byooviz), Aflibercept (Eylea), Faricimab (Vabysmo), Brolucizumab (Beovu)

Bevacizumab (Avastin)

- Coverage Criteria: Must meet ALL of the following:**
 - Eye condition appropriate for treatment, including:
 - Diabetic macular edema
 - Macular edema following retinal vein occlusion
 - Myopic choroidal neovascularization
 - Neovascular age-related macular degeneration
 - Indication approved by FDA or society guidelines
 - No concurrent ocular or periocular infection
 - Age 18 years or older
- Limits:** Limit one dose per eye every four weeks.
- Other Notes:** No authorization required when J9035 billed with CPT 67028 on the same date of service when submitted by an ophthalmologist.

Ranibizumab (Lucentis), Ranibizumab-nuna (Byooviz), Ranibizumab (Susvimo)

- Coverage Criteria: Must meet ALL of the following:**
 - Eye condition appropriate for treatment, including:
 - Diabetic macular edema
 - Diabetic retinopathy
 - Macular edema following retinal vein occlusion
 - Myopic choroidal neovascularization
 - Neovascular wet or exudative age-related macular degeneration
 - Polypoid choroidal vasculopathy with active juxtafoveal or subfoveal lesions
 - Indication approved by FDA or society guidelines
 - No concurrent ocular or periocular infection
 - Age 18 years or older
 - **AND** must have failed or had clinically significant adverse effects to bevacizumab
- Limits:** Limit one dose per eye every four weeks for ranibizumab injection and every 24 weeks (6 months) for Susvimo implant.

Aflibercept (Eylea)

- Coverage Criteria: Must meet ALL of the following:**
 - Eye condition appropriate for treatment, including:
 - Diabetic macular edema, with or without diabetic retinopathy
 - Macular edema following central or branch vein occlusion
 - Neovascular (wet or exudative) age-related macular degeneration
 - Indication approved by FDA or society guidelines
 - No concurrent ocular or periocular infection
 - Age 18 years or older
 - **AND** must have failed or had clinically significant adverse effects to bevacizumab unless patient's baseline visual acuity is 20/50 or worse
- Limits:** Limit one dose per eye every 4 weeks.

Faricimab (Vabysmo)

- Coverage Criteria: Must meet ALL of the following:**
 - Eye condition appropriate for treatment, including
 - Neovascular (wet or exudative) age-related macular degeneration
 - Diabetic macular edema, with or without diabetic retinopathy
 - Indication approved by FDA or society guidelines
 - No concurrent ocular or periocular infection
 - Age 18 years or older
 - **AND** must have failed or had clinically significant adverse effects to bevacizumab
- Limits:** Does not exceed standard dosing per FDA package insert.

Brolucizumab (Beovu)

- Coverage Criteria: Must meet ALL of the following:**
 - Eye condition appropriate for treatment, including
 - Neovascular (wet or exudative) age-related macular degeneration
 - Diabetic macular edema, with or without diabetic retinopathy
 - Indication approved by FDA or society guidelines
 - No concurrent ocular or periocular infection
 - Age 18 years or older
 - **AND** must have failed or had clinically significant adverse effects to bevacizumab
- Limits:** Does not exceed standard dosing per FDA package insert.

Intravitreal Corticosteroids

<i>Dexamethasone (Ozurdex), Fluocinolone (Iluvien, Retisert, Yutiq), Triamcinolone (Triescence, Xipire)</i>

Triamcinolone (Triescence, Xipire)

- Coverage Criteria:** None.
- Limits:** n/a
- Required Information for Approval:** N/A

Dexamethasone (Ozurdex)

- Coverage Criteria: Indicated for ALL of the following:**
 - Eye condition appropriate for treatment, including:
 - Diabetic macular edema
 - Macular edema following retinal vein occlusion
 - Non-infectious uveitis affecting posterior segment of the eye
 - Indication approved by FDA or society guidelines
 - No concurrent ocular or periocular infection
 - Age 18 years or older
- Limits:** Does not exceed more than one dose per eye every four (4) months.
- Other Notes:** N/A

Fluocinolone (Iluvien, Yutiq)

- Coverage Criteria: Indicated for ALL of the following:**
 - Eye condition appropriate for treatment, including:
 - Macular edema
 - Diabetic macular edema
 - Uveitis
 - Indication approved by FDA or society guidelines
 - No concurrent ocular or periocular infection
 - Age 18 years or older for Yutiq and Iluvien.
- Limits:** Does not exceed more than one dose per eye every 12 months for Iluvien, and 36 months for Yutiq.

- Other Notes:** N/A

Fluocinolone (Retisert)

- Coverage Criteria: Indicated for ALL of the following:**
 - Eye condition appropriate for treatment, including:
 - Macular edema
 - Diabetic macular edema
 - Uveitis
 - Indication approved by FDA or society guidelines
 - No concurrent ocular or periocular infection
 - Age 12 years or older
 - **AND** must have failed or had clinically significant adverse effects to Ozurdex, Iluvien, or Yutiq **unless** patient is younger than 18 years of age.
- Limits:** Does not exceed more than one dose per eye every 30 months for Retisert.
- Other Notes:** N/A

CLINICAL JUSTIFICATION

Guidelines from the American Academy of Ophthalmology indicate that multiple, high quality trials have demonstrated that anti-VEGF therapy is more effective in improving vision in CI-DME than monotherapy with focal laser treatment, supplanting it as the first-line therapy.¹ The guidelines indicate the use of intravitreal administration of short- and long-acting corticosteroids for the treatment of DME generally as second-line agents, especially for phakic patients, because of their side-effect profile, including cataract progression and elevated IOP. Clinical trials comparing the efficacy between bevacizumab, ranibizumab, and aflibercept have demonstrated superior visual acuity outcomes for aflibercept in specific patient populations, including patients with worse baseline visual acuity (VA).⁶

The American Academy of Ophthalmology guidelines for Age-Related Macular Degeneration. Indicate intravitreal injection therapy using anti-vascular endothelial growth factor (VEGF) agents (e.g., aflibercept, bevacizumab, and ranibizumab) is the most effective way to manage the disease and represents the first line of treatment.²

The American Academy of Ophthalmology guidelines for treatment of Retinal Vein Occlusions indicate Anti-VEGF agents, laser and intravitreal steroids are cost-effective for the management of RVOs. For macular edema associated with CRVOs and BRVOs, the first line of treatment is anti-vascular endothelial growth factors (anti-VEGFs).

REFERENCES

1. Flaxel CJ, Adelman RA, Bailey ST, et al. Diabetic Retinopathy Preferred Practice Pattern®. *Ophthalmology*. 2020;127(1):P66-P145. doi:10.1016/j.ophtha.2019.09.025
2. Flaxel CJ, Adelman RA, Bailey ST, et al. Age-Related Macular Degeneration Preferred Practice Pattern®. *Ophthalmology*. 2020;127(1):P1-P65. doi:10.1016/j.ophtha.2019.09.024
3. Flaxel CJ, Adelman RA, Bailey ST, et al. Retinal Vein Occlusions Preferred Practice Pattern®. *Ophthalmology*. 2020;127(2):P288-P320. doi:10.1016/j.ophtha.2019.09.029
4. Jhaveri CD, Glassman AR, Ferris FL, et al; DRCR Retina Network. Aflibercept monotherapy or bevacizumab first for diabetic macular edema. *N Engl J Med* 2022;387:692-703. doi:10.1056/NEJMoa2204225
5. Cheung C, Arnold JJ, Holz FG, et al. American Academy of Ophthalmology: Myopic choroidal neovascularization: review, guidance, and consensus statement on management. *Ophthalmology* 2017; 124:1690:1711. <http://dx.doi.org/10.1016/j.ophtha.2017.04.028>
6. 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.

7. Wells J.A., Glassman A.R., Ayala A.R., Jampol L.M., Bressler N.M., Bressler S.B., Diabetic Retinopathy Clinical Research Network Aflibercept, bevacizumab, or ranibizumab for diabetic macular edema: Two-year results from a comparative effectiveness randomized clinical trial. *Ophthalmology*. 2016;123:1351–1359.
8. Avastin Prescribing Information. South San Francisco, CA: Genentech, Inc. May 2020. Available at: www.avastin.com. Accessed February 8, 2023.
9. Lucentis Prescribing Information. South San Francisco, CA: Genentech, Inc.; March 2018. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/125156s117lbl.pdf. Accessed February 4, 2023.
10. Byooviz Prescribing Information. Cambridge, MA: Biogen Inc.; September 2021. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/761202s000lbl.pdf. Accessed February 20, 2023.
11. Susvimo Prescribing Information. South San Francisco, CA: Genentech, Inc.; October 2021. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/761197s000lbl.pdf. Accessed February 22, 2023.
12. Eylea Prescribing Information. Tarrytown, NY: Regeneron Pharmaceuticals, Inc.; August 2019. Available at: www.eylea.com. Accessed February 24, 2023.
13. Vabysmo Prescribing Information. South San Francisco, CA: Genentech, Inc.; January 2022. Available at: www.vabysmo.com. Accessed February 28, 2023.
14. Ozurdex Prescribing Information. Irvine, CA: Allergan, Inc.; October 2020. Available at: www.ozurdex.com. Accessed March 1, 2023.
15. Iluvien Prescribing Information. Alpharetta, GA: Alimera Sciences, Inc.; November 2016. Available at: www.iluvien.com. Accessed March 1, 2023.
16. Retisert Prescribing Information. Bridgewater, NJ: Valeant Pharmaceuticals; January 2021. Available at: www.retersert.com. Accessed March 1, 2023.
17. Yutiq Prescribing Information. Watertown, MA: EyePoint Pharmaceuticals US, Inc.; February 2022. Available at: www.yutiq.com. Accessed March 1, 2023.
18. Xipere Prescribing Information. Alpharetta, GA: Clearside Biomedical, Inc.; October 2021. Available at: www.xipere.com. Accessed March 30, 2022.
19. Maturi R. K., Glassman A. R., Liu D., et al. Effect of adding dexamethasone to continued ranibizumab treatment in patients with persistent diabetic macular edema: a DRCC network phase 2 randomized clinical trial. *JAMA Ophthalmol*. 2018;136(1):29–38. doi: 10.1001/jamaophthalmol.2017.4914.
20. Jhaveri CD, Glassman AR, Ferris FL, et al; DRCC Retina Network. Aflibercept monotherapy or bevacizumab first for diabetic macular edema. *N Engl J Med* 2022;387:692-703. doi:10.1056/NEJMoa2204225
21. Cai S, Bressler N. M. (2017). Aflibercept, bevacizumab or ranibizumab for diabetic macular oedema: Recent clinically relevant findings from DRCC.net protocol T. *Curr. Opin. Ophthalmol*. 28, 636–643. 10.1097/ICU.0000000000000424
22. Gillies MC, Lim LL, Campain A, et al. A randomized clinical trial of intravitreal bevacizumab versus intravitreal dexamethasone for diabetic macular edema: the BEVORDEX study. *Ophthalmology*. 2014;121(12):247-324.
23. Wykoff CC, Abreu F, Adamis AP, et al. Efficacy, durability, and safety of intravitreal faricimab with extended dosing up to every 16 weeks in patients with diabetic macular oedema (YOSEMITE and RHINE): two randomized, double-masked, phase 3 trials. *Lancet*. 2022.
24. Beovu Prescribing Information. East Hanover, NJ: Novartis Pharmaceuticals, Inc.; December 2022. Available at: https://www.novartis.com/us-en/sites/novartis_us/files/beovu.pdf. Accessed March 2, 2023.
25. Susvimo (ranibizumab) [prescribing information]. South San Francisco, CA: Genentech Inc; April 2022.

REVIEW & EDIT HISTORY

Document Changes	Reference	Date	P&T Chairman
Creation of Policy	Intravitreal Medications	03/2023	Matthew Garrett, PharmD

Note: All changes are approved by the HPSJ P&T Committee before incorporation into the utilization policy