MEDICATION COVERAGE POLICY

PHARMACY AND THERAPEUTICS ADVISORY COMMITTEE

Health Plan of San Joaquin | Mountain Valley Health Plan

POLICY	Intravitreal medications	**P & T DATE**	03/19/2024
THERAPEUTIC CLASS	Topical Anti-Inflammatory Agents	**REVIEW HISTORY** (MONTH/YEAR)	03/2023
LOB AFFECTED	Medi-Cal		

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://medi-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 12/2023)*

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
Vascular Endothelial Growth Factor (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: 10 mg/0.1mL implant	Yes	Yes (PA, QL)
Q5124	Ranibizumab-nuna (Byooviz)	0.5 mg/0.05 mL solution	Yes	Yes (PA, QL)
Q5128	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)
J0177	Aflibercept (Eylea HD)	8 mg/0.07mL solution	Yes	Yes (PA, QL)

J2777	Faricimab (Vabysmo)	6 mg/0.05 mL	Yes	Yes (PA, QL)
Complement Inhibitor				
C9162	Avacincaptad Pegol (Izervay)	2mg/0.1mL solution	Yes	Yes (PA, QL)
J2781	Pegcetacoplan (Syfovre)	15mg/0.1mL solution	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/MVHP Pharmacy & Therapeutics (P&T) Advisory Committee. For agents that do not have established prior authorization criteria, HPSJ/MVHP will make the determination based on Medical Necessity criteria as described in HPSJ/MVHP 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-eqrn (Cimerli), 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, Eylea HD)

- ❒ **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:**
    - For Eylea: Limit to standard dosing of one 2 mg dose per eye every 4 weeks for Eylea.
    - For Eylea HD: Limit to standard dosing of one 8 mg dose every 4 weeks for the first three (3) doses, followed by 8 mg once every 8 to 16 weeks (±1 week).

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
Dexamethasone (Ozurdex), Fluocinolone (Iluvien, Retisert, Yutiq), Triamcinolone (Triescence, Xipire)

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

Complement Inhibitors
Avacincaptad Pegol (Izervay), Pegcetacoplan (Syfovre)

Pegcetacoplan (Syfovre)

- ❒ **Coverage Criteria: Indicated for ALL of the following:**
  - Eye condition appropriate for treatment, including:
    - Geographic atrophy (GA) secondary to age-related macular degeneration (AMD).
    - Indication approved by FDA or society guidelines
  - No concurrent ocular or periocular infection, or active intraocular inflammation.
  - Age 60 years or older
- ❒ **Limits:**
  - Does not exceed standard dosing per FDA package insert, including dosing frequency no more often than every 25 days per affected eye.
- ❒ **Other Notes:** N/A

Avacincaptad Pegol (Izervay)

- ❒ **Coverage Criteria: Indicated for ALL of the following:**
  - Eye condition appropriate for treatment, including:
    - Geographic atrophy (GA) secondary to age-related macular degeneration (AMD).
    - Indication approved by FDA or society guidelines
  - No concurrent ocular or periocular infection, or active intraocular inflammation.
  - Age 50 years or older
- ❒ **Limits:**
  - Does not exceed standard dosing per FDA package insert, including no more than 12 months total duration.
- ❒ **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).

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REVIEW & EDIT HISTORY

Document Changes	Reference	Date	P&T Chairman
Creation of Policy	Intravitreal Medications	03/2023	Matthew Garrett, PharmD
Update to Policy	Intravitreal Medications	03/2024	Matthew Garrett, PharmD

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