

# Ophthalmology

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This section describes program information and billing policies for ophthalmology services.

## Correct Claim Form

Ophthalmological services can be billed on either a *CMS-1500* or *UB-04* (outpatient providers) claim form. The following ophthalmological and eye appliance procedure codes, however, must be billed only on the *CMS-1500*:

CPT® codes: 68761, 92002 thru 92060, 92071 thru 92284, 92310 thru 92353, 92370, 92371 and 92499

HCPCS codes: S0500, S0512, S0514, S0516, V2020 thru V2499, V2500, V2501, V2510, V2511, V2513 thru V2521, V2523, V2531, V2599, V2600 thru V2615, V2623 thru V2629, V2702 thru V2718, V2744 thru V2755, V2760 thru V2770, V2781 thru V2784 and V2799

## Modifiers

Ophthalmological services and eye appliances (frames, lenses, contact lens, etc.) must be billed with the appropriate modifier(s). Vision care modifiers are listed in the *Modifiers for Vision Care Services* section of the Part 2 *Vision Care* manual.

## Unilateral

The following CPT 90000 series of codes for eye procedures are considered unilateral services.

CPT Code	Description
92230	Fluorescein angiography with interpretation and report

When performed on one eye, these procedures must be billed with a quantity of "1" and either modifier LT (left side) or RT (right side) to indicate which eye.

When performed on both eyes, these procedures must be billed on a single line using the modifier 50 (bilateral procedure) with a quantity of "2."

## **Bilateral**

The following CPT 90000 series of codes for eye procedures are considered bilateral services. Therefore, a code should be billed only once, regardless of whether the procedure was performed on one or both eyes. However, in the case of eye surgeries, this does not apply, and the appropriate code should be used to specify whether the procedure was unilateral or bilateral.

When performed as a bilateral procedure, claims must be billed on a single line using modifier 50 (bilateral procedure) with a quantity of "1", for CPT codes 92132 thru 92134, 92202 and 92227 thru 92229. The allowed service is one per day, whether it is unilateral or bilateral. No documentation is required for CPT codes listed above.

### **CPT Codes for Bilateral Service Eye Procedures**

<b>CPT Code</b>	<b>Description</b>
* 92132	Scanning computerized ophthalmic diagnostic imaging, anterior segment, with interpretation and report, unilateral or bilateral
* 92133	Scanning computerized ophthalmic diagnostic imaging, posterior segment, with interpretation and report, unilateral or bilateral; optic nerve
* 92134	Retina
«92137	Computerized ophthalmic diagnostic imaging (eg, optical coherence tomography [OCT]), posterior segment, with interpretation and report, unilateral or bilateral; retina, including OCT angiography»
92201	Ophthalmoscopy, extended; with retinal drawing and scleral depression of peripheral retinal disease, with interpretation and report, unilateral or bilateral
92202	Ophthalmoscopy, extended; with drawing of optic nerve or macula, with interpretation and report, unilateral or bilateral
92227	Imaging of retina for detection or monitoring of disease; with remote clinical staff review and report, unilateral or bilateral
* 92228	Imaging of retina for detection or monitoring of disease; with remote physician or other qualified health care professional interpretation and report, unilateral or bilateral
92229	Imaging of retina for detection or monitoring of disease; point-of-care automated analysis and report, unilateral or bilateral

**«CPT Codes for Bilateral Service Eye Procedures» (continued)**

<b>CPT Code</b>	<b>Description</b>
* 92235	Fluorescein angiography (includes multiframe imaging) with interpretation and report, unilateral or bilateral
* 92240	Indocyanine-green angiography (includes multiframe imaging) with interpretation and report, unilateral or bilateral
* 92242	Fluorescein angiography and indocyanine-green angiography (includes multiframe imaging) performed at the same patient encounter with interpretation and report, unilateral or bilateral

When performed on one eye, these procedures must be billed with a quantity of “1” and either modifier LT (left side) or RT (right side) to indicate which eye. When performed on both eyes, these procedures must be billed on a single line using modifier 50 (bilateral procedure) with a quantity of “1.”

**Note:** CPT codes 92235, 92240 and 92242 are not reimbursable with modifiers LT, RT or 50.

CPT codes 92227, 92228, and 92229 are not reimbursable for the same recipient on the same date of service by any provider in conjunction with codes 92002 thru 92014, 92133, 92134, 92227, 92228, 92250 or Evaluation and Management (E&M) codes 99202 thru 99350 and 99417.

### **Ophthalmic Diagnostic Imaging: Billing Restrictions**

CPT codes 92132 thru 92134 (scanning computerized ophthalmic diagnostic imaging with interpretation and report, unilateral or bilateral) are not reimbursable when billed for the same recipient, by the same rendering provider, for the same date of service as the following codes:

**«CPT Codes for Billing Ophthalmic Diagnostic Imaging»**

<b>CPT Code</b>	<b>Description</b>
76512	Ophthalmic ultrasound, diagnostic; B-scan (with or without superimposed non-quantitative A-scan)
92250	Fundus photography with interpretation and report

### **ICD-10-CM Diagnosis Code Requirements**

Refer to the *Ophthalmology: Diagnosis Codes* section in this manual for ICD-10-CM diagnosis codes that must be billed in conjunction with codes 92132 thru 92134.

## Corneal Pachymetry

CPT code 76514 is payable only once-in-a-lifetime when billed with the glaucoma-related diagnosis codes indicated in the *Professional Services: Diagnosis Code* section in this manual. Refer to the *Radiology: Diagnosis Ultrasound* section for the ICD-10-CM diagnosis codes to bill in conjunction with code 76514 for payment, in the appropriate Part 2 manual.

## Computerized Corneal Topography

Computerized corneal topography (CPT code 92025) is reimbursable to optometrists within their scope of practice. It requires medical review.

When billing for code 92025, providers must document in the *Remarks* field (Box 80)/*Additional Claim Information* field (Box 19) of the claim or on an attachment that the service was performed according to one of the following criteria:

- Pre- or post-operatively for corneal transplant (codes 65710, 65730, 65750, 65755 and 65756)
- Pre- or post-operatively prior to cataract surgery due to irregular corneal curvature or irregular astigmatism
- In the treatment of irregular astigmatism as a result of corneal disease or trauma
- To assist in the fitting of contact lenses for patients with corneal
- Disease or trauma (ICD-10-CM diagnosis codes H17.0 thru H18.9)
- To assist in defining further treatment

This procedure is not covered under the following conditions:

- When performed pre- or post-operatively for non-Medi-Cal covered refractive surgery procedures such as codes 65760 (kerato mileusis), 65765 (keratophakia), 65767 (epikeratoplasty), 65771 (radial keratotomy), 65772 (corneal relaxing incision) and 65775 (corneal wedge resection)
- When performed for routine screening purposes in the absence of associated signs, symptoms, illness or injury

## Billing Requirements

CPT code 92025 must be billed with the appropriate modifiers. When billing for both the professional and technical service components, a modifier is neither required nor allowed. When billing for only the professional component, use modifier 26. When billing for only the technical component, use modifier TC.

**Note:** Do not bill modifier 99 with CPT code 92025. The claim will be denied.

## **«Ophthalmic Exams: Billing Restrictions**

Office visits, hospital visits, consultations and ophthalmological exams (CPT codes 92002 thru 92014) related to a surgery and billed during the follow-up period of the surgery, are not separately reimbursable if billed by the surgeon or assistant surgeon.

These claims will be denied with RAD code 074: "This service is included in the surgical fee." Surgical follow-up periods (referred to as global days) are listed in the relative value (RVU) files of the latest quarterly physician fee schedule on the [Centers for Medicare & Medicaid Services \(CMS\) website](#).

**Tips:** To locate files containing surgical procedure codes and associated follow-up (global) time periods, providers should enter "PPRVU" in the search box on the CMS website home page. PPRVU spreadsheets are released quarterly. Quarter one files end in the letter A, quarter two files end in the letter B and so on. Within the PPRVU spreadsheet, providers should refer to the "Glob Days" column for follow-up (global) time frames.>>

## **Bevacizumab**

Bevacizumab is a recombinant humanized monoclonal IgG1 antibody that binds to and inhibits the biologic activity of human vascular endothelial growth factor (VEGF) in vitro and in vivo assay systems.

### **Required Codes**

C18.0 thru C20	E08.311	E09.3211 thru E09.3213
C21.2	E08.3211 thru E08.3213	E09.3219
C21.8	E08.3219	E09.3311 thru E09.3313
C34.00 thru C34.92	E08.3311 thru E08.3313	E09.3319
C48.1 thru C48.2	E08.3319	E09.3411 thru E09.3413
C50.011 thru C50.929	E08.3411 thru E08.3413	E09.3419
C53.0 thru C53.9	E08.3419	E09.3511 thru E09.3513
C56.1 thru C57.4	E08.3511 thru E08.3513	E09.3519
C64.1 thru C64.9	E08.3519	E10.311
C71.0 thru C71.9	E09.311	

**«Required Codes (continued)»**

E10.3211 thru E10.3213	E11.3419	H34.8130 thru H34.8132
E10.3219	E11.3511 thru E11.3513	H34.8190 thru H34.8192
E10.3311 thru E10.3313	E11.3519	H34.8310 thru H34.8312
E10.3319	E13.311	H34.8320 thru H34.8322
E10.3411 thru E10.3413	E13.3211 thru E13.3213	H34.8330 thru H34.8332
E10.3419	E13.3219	H34.8390 thru H34.8392
E10.3511 thru E10.3513	E13.3311 thru E13.3313	H35.3210 thru H35.3213
E10.3519	E13.3319	H35.3220 thru H35.3223
E11.311	E13.3411 thru E13.3413	H35.3230 thru H35.3233
E11.3211 thru E11.3213	E13.3419	H35.3290 thru H35.3293
E11.3219	E13.3511 thru E13.3513	H35.351 thru H35.353
E11.3311 thru E3313	E13.3519	H35.359
E11.3319	H34.8110 thru H34.8112	H35.81
E11.3411 thru E11.3413	H34.8120 thru H34.8122	

**Dosage**

Dosage is variable depending upon which disease is being treated.

**Billing**

HCPCS code: J9035 (injection, bevacizumab, 10 mg)

Providers may bill for the quantity that is equal to the amount given to the patient plus the amount wasted up to a total dose of 10 mg (one unit). Maximum reimbursement will not exceed 10 mg (one unit), per patient, per date of service when bevacizumab is used as an intravitreal injection. This limitation applies only to the intravitreal use of bevacizumab.

Appropriate site modifiers are LT, RT or 50 (bilateral). CPT code 67028 (intravitreal injection of a pharmacologic agent [separate procedure]) must be billed on the same claim form.

## **«Pegcetacoplan (SYFOVRE™)**

Pegcetacoplan is a complement inhibitor that acts by binding to complement protein C3 and its activation fragment C3b, thereby regulating the cleavage of C3 and the generation of downstream effectors of complement activation.

### **Indications**

All FDA-approved indications

### **Dosage**

FDA-approved dosages

### **TAR Requirement**

An approved *Treatment Authorization Request* (TAR) is required for reimbursement.

### **TAR Criteria**

Syfovre is medically necessary when all of the following criteria are met:

- Must be used for FDA approved indication and dosages.
- Patient must be 60 years of age or older.
- Must be prescribed by or in consultation with an ophthalmologist.
- Patient has a diagnosis of geographic atrophy (GA) secondary to age-related macular degeneration (AMD).
- Diagnosis has been confirmed by geographic atrophy secondary to age-related macular degeneration sensitive tests (for example, optical coherence tomography [OCT], fundus autofluorescence [FAF] imaging).
- The GA is not secondary to any conditions other than AMD (for example, Stargardt disease, cone rod dystrophy, toxic maculopathies).
- Patient does not have ocular or periocular infections; active intraocular inflammation.

Initial authorization is for 6 months.

#### **Continuation of therapy:**

- Patient continues to meet initial coverage criteria.
- Patient has experienced positive response to therapy (for example, disease stabilization or slowing of the rate of disease progression compared to pre-treatment baseline or reduction in total area of GA lesions).

Reauthorization is for 12 months.»

## «Age Limits

Must be 60 years of age or older.

## Billing

HCPCS code J2781 (injection, pegcetacoplan, intravitreal, 1 mg)

## Suggested ICD-10-CM Diagnosis Codes

H35.3113, H35.3114, H35.3123, H25.3124, H35.3133, H35.3134, H35.3193, H35.3194

## Prescribing Restrictions

Frequency of billing equals 15 mg/15 units every 25 to 60 days.

Maximum billing unit(s) equals 15 mg/15 units.»

## Ranibizumab

Ranibizumab is a recombinant humanized IgG1 kappa isotype monoclonal antibody fragment designed for intraocular use. Ranibizumab binds to and inhibits the biologic activity of human vascular endothelial growth factor A (VEGF-A).

## Indications

Ranibizumab is indicated for the treatment of:

- Diabetic macular edema
- Central retinal vein occlusion
- Branch retinal vein occlusion
- Neovascular age-related macular degeneration
- Cystoid macular degeneration
- Retinal/macular edema following retinal vein occlusion

## Authorization

An approved *Treatment Authorization Request* (TAR) is required for reimbursement. The TAR must include medical justification for the use of ranibizumab over bevacizumab.

## Dosage

Dosage is variable depending upon which disease is being treated.

## Billing

HCPCS code: J2778 (injection, ranibizumab, 0.1 mg)

HCPCS code: J2778 (injection, ranibizumab, 0.1 mg)

«One of the following modifiers is required for reimbursement:

- LT (Left side)
- RT (Right side)»

CPT code 67028 (intravitreal injection of a pharmacologic agent [separate procedure]) must be billed on the same claim form.

## **Ranibizumab-eqrn (Cimerli™)**

Ranibizumab products bind to the receptor binding site of active forms of VEGF-A, including the biologically active, cleaved form of this molecule, VEGF110. VEGF-A has been shown to cause neovascularization and leakage in models of ocular angiogenesis and vascular occlusion and is thought to contribute to pathophysiology of neovascular AMD, mCNV, DR, DME and macular edema following RVO. The binding of ranibizumab products to VEGF-A prevents the interaction of VEGF-A with its receptors (VEGFR1 and VEGFR2) on the surface of endothelial cells, reducing endothelial cell proliferation, vascular leakage, and new blood vessel formation.

## Indications

All FDA-approved indications

## Dosage

FDA-approved dosages

## **TAR Requirement**

An approved *Treatment Authorization Request* (TAR) is required for reimbursement.

## **TAR Criteria**

Cimerli is considered medically necessary when all of the following conditions are met:

- Must be used for FDA-approved indications and dosages
- Patient must be 18 years of age or older
- Must be prescribed by or in consultation with an ophthalmologist
- Patient has one of the following diagnoses:
  - Neovascular (Wet) Age-Related Macular Degeneration (AMD)
  - Macular Edema Following Retinal Vein Occlusion (RVO)
  - Myopic Choroidal Neovascularization (mCNV)
  - Diabetic Macular Edema (DME)
  - Diabetic Retinopathy

- Patient does not have ocular or periocular infections
- Patient has tried and failed an intravitreal vascular endothelial growth factor (VEGF) inhibitor (for example, bevacizumab, ranibizumab, aflibercept) unless contraindicated or clinically inappropriate
- Documentation of patient's best corrected visual acuity (BCVA) score at baseline and periodically during treatment

Initial authorization is for six months (three months for mCNV).

#### Continued Therapy

- Patient continues to meet initial approval criteria
- Patient has experienced a clinically significant positive benefit as evidenced by at least one of the following:
  - Improvement in best corrected visual acuity (BCVA) score from baseline
  - Minimal observable CNV lesion growth
  - Detained neovascularization
- Patient has an absence of unacceptable toxicity such as endophthalmitis, retinal detachment, increases in intraocular pressure (IOP) and arterial thromboembolic events

Reauthorization is for six months (three months for mCNV).

#### **Age Limits**

Must be 18 years of age or older

#### **Billing**

HCPCS code: Q5128 (injection, ranibizumab-egrn [cimerli], biosimilar, 0.1 mg)

#### **Prescribing Restriction(s)**

Frequency of billing equals 0.5 mg/5 units once a month (approximately 28 days), each eye

Maximum billing unit(s) equal 0.5 mg/5 units each eye

## **Ranibizumab-nuna for Intravitreal Use (Byooviz)**

Ranibizumab products bind to the receptor binding site of active forms of VEGF-A, including the biologically active, cleaved form of this molecule, VEGF110. VEGF-A has been shown to cause neovascularization and leakage in models of ocular angiogenesis and vascular occlusion and is thought to contribute to pathophysiology of neovascular AMD, mCNV, and macular edema following RVO. The binding of ranibizumab products to VEGF-A prevents the interaction of VEGF-A with its receptors (VEGFR1 and VEGFR2) on the surface of endothelial cells, reducing endothelial cell proliferation, vascular leakage, and new blood vessel formation.

### **Indications**

All FDA-approved indications

### **Dosage**

FDA-approved dosages

### **TAR Requirement**

An approved *Treatment Authorization Request* (TAR) is required for reimbursement

### **TAR Criteria**

Byooviz is considered medically necessary when all of the following conditions are met:

- Must be used for FDA-approved indications and dosages
- Patient must be 18 years of age or older
- Must be prescribed by or in consultation with an ophthalmologist
- Patient has a diagnosis of:
  - Neovascular (Wet) Age-Related Macular Degeneration (AMD)
  - Macular Edema Following Retinal Vein Occlusion (RVO)
  - Myopic Choroidal Neovascularization (mCNV)
- Patient has tried and failed an intravitreal vascular endothelial growth factor (VEGF) inhibitor (for example, bevacizumab, ranibizumab, aflibercept) unless contraindicated or clinically inappropriate
- Documentation of patient's best corrected visual acuity (BCVA) score at baseline and periodically during treatment

Initial authorization is for six months (three months for mCNV)

### Continued therapy

- Patient continues to meet initial approval criteria
- Patient has experienced a clinically significant positive benefit as evidenced by at least one of the following:
  - Improvement in best corrected visual acuity (BCVA) score from baseline
  - Minimal observable CNV lesion growth
  - Detained neovascularization.
- Patient has an absence of unacceptable toxicity such as endophthalmitis, retinal detachment, increases in intraocular pressure (IOP) and arterial thromboembolic events.

Reauthorization is for six months (three months for mCNV)

### **Age Limit**

Must be 18 years of age or older

### **Billing**

HCPCS code: Q5124, (injection, ranibizumab-nuna, biosimilar, (byooviz), 0.1 mg)

### **Prescribing Restriction(s)**

Frequency of billing equals 0.5 mg/5 units in each eye every 28 days  
Maximum billing unit(s) equals 0.5 mg/5 units in each eye

### **Aflibercept**

#### **«Clinical Use Parameters**

Use in accordance with FDA-approved labeling, including indication, dosage, frequency, age, and any prescribing limitation.»

## **TAR Requirement**

An approved *Treatment Authorization Request* (TAR) is required for reimbursement.

## **Billing**

HCPCS codes:

J0177 (injection, aflibercept hd, 1 mg).

J0178 (injection, aflibercept, 1 mg).

«Q5155 (injection, aflibercept-jbvf [yesafili], biosimilar, 1 mg).»

One of the following modifiers is required for reimbursement:

- LT (Left side)
- RT (Right side)

CPT code 67028 (intravitreal injection of a pharmacologic agent [separate procedure]) must be billed on the same claim form.

## **Avacincaptad-pegol (IZERVAY)**

Avacincaptad pegol is an RNA aptamer, a PEGylated oligonucleotide that binds to and inhibits complement protein C5. By inhibiting C5, avacincaptad pegol may prevent its cleavage to C5a and C5b thus decreasing membrane attack complex (MAC) formation.

## **«Aflibercept-ayyh (PAVBLU)**

### **Indications, Dosages and Age**

Refer to FDA-approved labeling.

Must be 18 years of age or older.

### **TAR Requirement**

An approved *Treatment Authorization Request* (TAR) is required for reimbursement.

### **Billing**

HCPCS code Q5147 (injection, aflibercept-ayyh [pavblu], biosimilar, 1 mg).

CPT code 67028 (intravitreal injection of a pharmacologic agent [separate procedure]) must be billed on the same claim form.

One of the following modifiers is required for reimbursement:

- LT (Left side)
- RT (Right side)

### **Prescribing Restriction(s)**

Frequency of billing equals 2 mg/2 units per eye every 4 weeks.

Maximum billing unit(s) equals 2 mg/2 units per eye administered by intravitreal injection every 4 weeks.

## **Aflibercept-abzv (ENZEEVU)**

### **Indications, Dosages and Age**

Refer to FDA-approved labeling.

Must be 18 years of age or older.

### **TAR Requirement**

An approved *Treatment Authorization Request* (TAR) is required for reimbursement.››

## «Billing

HCPCS code Q5149 (injection, aflibercept-abzv [enzeevu], biosimilar, 1 mg).

CPT code 67028 (intravitreal injection of a pharmacologic agent [separate procedure]) must be billed on the same claim form.

One of the following modifiers is required for reimbursement:

- LT (Left side)
- RT (Right side)

## Prescribing Restriction(s)

Frequency of billing equals 2 mg/2 units per eye every 4 weeks.

Maximum billing unit(s) equals 2 mg/2 units per eye administered by intravitreal injection every 4 weeks.

## Aflibercept-mrbb (AHZANTIVE)

### Indications, Dosages and Age

Refer to FDA-approved labeling.

Must be 18 years of age or older

### TAR Requirement

An approved *Treatment Authorization Request* (TAR) is required for reimbursement.»

**«Billing**

HCPCS code Q5150 (injection, aflibercept-mrbb [ahzantive], biosimilar, 1 mg).

CPT code 67028 (intravitreal injection of a pharmacologic agent [separate procedure]) must be billed on the same claim form.

One of the following modifiers is required for reimbursement:

- LT (Left side)
- RT (Right side)

**Prescribing Restriction(s)**

Frequency of billing equals 2 mg/2 units per eye every 4 weeks.

Maximum billing unit(s) equals 2 mg/2 units per eye administered by intravitreal injection every 4 weeks.»

**Avacincaptad-pegol (IZERVAY)**

Avacincaptad pegol is an RNA aptamer, a PEGylated oligonucleotide that binds to and inhibits complement protein C5. By inhibiting C5, avacincaptad pegol may prevent its cleavage to C5a and C5b thus decreasing membrane attack complex (MAC) formation.

## Indications

All FDA-approved indications.

## Dosage

FDA-approved dosages.

## TAR Requirement

A *Treatment Authorization Request* (TAR) is required for reimbursement.

## TAR Criteria

Izervay is medically necessary when all of the following criteria are met:

- Must be used for FDA approved indication and dosages.
- Patient must be 50 years of age or older.
- Must be prescribed by or in consultation with an ophthalmologist.
- Patient has a diagnosis of geographic atrophy (GA) secondary to age-related macular degeneration (AMD).
- Diagnosis has been confirmed by geographic atrophy secondary to age-related macular degeneration sensitive tests (for example, optical coherence tomography [OCT], fundus autofluorescence [FAF] imaging, etc.).
- The GA is not secondary to any conditions other than AMD (for example, Stargardt disease, cone rod dystrophy, toxic maculopathies, etc.).
- Patient does not have ocular or periocular infections; active intraocular inflammation.

Initial authorization is for 12 months.

### Continuation of therapy:

- Patient continues to meet initial coverage criteria.
- Patient has experienced positive response to therapy (for example, disease stabilization or slowing of the rate of disease progression compared to pre-treatment baseline or reduction in total area of GA lesions).

**Reauthorization is for 12 months.**

### **Age Limits**

Must be 50 years of age or older.

### **Billing**

HCPCS code J2782 (injection, avacincaptad pegol, 0.1 mg).

Appropriate site modifiers are LT, RT. CPT code 67028 (intravitreal injection of a pharmacologic agent [separate procedure]) must be billed on the same claim form.

### **Suggested ICD-10-CM Diagnosis Codes**

H35.3113, H35.3123, H35.3133, H35.3114, H35.3124, H35.3134

### **Prescribing Restriction(s)**

Frequency of billing equals 2 mg / 20 units monthly (approximately  $28 \pm 7$  days) for up to 12 months per eye.

Maximum billing unit(s) equals 2 mg / 20 units per eye.

### **«Aflibercept-yszy (Opuviz)**

#### **Indications, Dosages and Age**

Refer to the FDA-approved labeling.

Must be 18 years of age or older.

#### **TAR Requirement**

An approved *Treatment Authorization Request* (TAR) is required for reimbursement.»

## «Billing

HCPCS code Q5153 (injection, aflibercept-yszy [opuviz], biosimilar, 1 mg)

One of the following modifiers is required for reimbursement:

- LT (Left side)
- RT (Right side)

CPT code 67028 (intravitreal injection of a pharmacologic agent [separate procedure]) must be billed on the same claim form

## Prescribing Restrictions

Frequency of billing equals every 4 weeks

Maximum billing units: 2 mg/2 units»

## Verteporfin

Verteporfin therapy is a two-stage process requiring administration of both verteporfin for injection and nonthermal red light. Following intravenous administration, verteporfin is transported by lipoproteins to the neovascular endothelium in the affected eye(s), including choroidal neovasculation and the retina. Verteporfin then needs to be activated by nonthermal red light, which results in local damage to the endothelium, leading to temporary choroidal vessel occlusion.

## Indications

Intravenous verteporfin is indicated for the treatment of:

- Age-related macular degeneration in patients with predominantly classic subfoveal choroidal neovascularization
- Pathologic myopia
- Presumed ocular histoplasmosis

## Authorization

An approved *Treatment Authorization Request* (TAR) is required for reimbursement only when the dosage exceeds 16 mg.

## Required Codes

One of the following ICD-10-CM codes is required for reimbursement:

† B39.4, † B39.5, † B39.9, H35.3210 thru H35.3293, H44.20 thru H44.2A9.

## Dosage

The recommended dosage is 6 mg per m<sup>2</sup> body surface area.

## Billing

HCPCS code J3396 (injection, verteporfin, 0.1 mg).

## “By Report” Procedures

In some situations, it may be necessary to bill “By Report” – include a brief report that justifies the procedure.

The following CPT codes require medical justification. Claims for these procedures will suspend for medical review and/or manual pricing. Justification includes but is not limited to the patient’s diagnosis and associated symptoms, a short explanation of why the visit was necessary, a summary of services performed and the outcome and a statement of the treatment plan that indicates whether a referral was made.

### CPT Codes Requiring Medical Justification

CPT Code	Description
65210	Removal of foreign body, external eye; conjunctival embedded
67938	Removal of embedded foreign body, eyelid
68761	Closure of the lacrimal punctum
68801	Dilation of the lacrimal punctum

**CPT Codes Requiring Medical Justification (continued)**

<b>CPT Code</b>	<b>Description</b>
92018	Ophthalmological examination and evaluation, under general anesthesia, with or without manipulation of globe for passive range of motion or other manipulation to facilitate diagnostic examination; complete
92019	limited
92025	Computerized corneal topography, unilateral or bilateral, with interpretation and report
92100	Serial tonometry
92250	Fundus photography with interpretation and report
92310 thru 92312	Contact lens evaluations
92499	Unlisted ophthalmological service or procedure

**Routine Examinations**

Claims by either an ophthalmologist or optometrist for routine comprehensive eye examinations (CPT codes 92004 [new patient] and 92014 [established patient]) are covered once every two years for recipients of any age.

**Determination of Refractive State**

When performed, determination of refractive state (CPT code 92015) must be separately reported when billed in conjunction with CPT code 92004 or 92014.

Code 92015 is considered typical postoperative follow-up care included in the surgical package for cataract extraction surgeries. Therefore, this service is not reimbursable when billed in conjunction with or within the 90-day post follow-up period of CPT codes 66840, 66850, 66852, 66920, 66930, 66940 and 66982 thru 66985.

**Tonometry**

Tonometry services are included in an eye examination and should not be billed as a separate procedure.

**Note:** This is a one-time measurement and not serial tonometry.

**Diagnostic Drugs**

The use of topically applied diagnostic drugs (cycloplegic, mydriatic or anesthetic topical pharmaceutical agents) is included in the reimbursement of ophthalmological procedures.

## **Interim Examinations**

A second eye examination with refraction within 24 months is covered only when a sign or symptom indicates a need for this service. Claims billed with CPT codes 92004 and 92014 must include the appropriate ICD-10-CM code that justifies the examination in (Box 67) of the *UB-04* claim form or *Nature of Illness or Injury* field (Box 21) of the *CMS-1500* claim. This policy applies whether the claim is submitted by the provider of the prior examination or by a different provider. Refer to the *Professional Services: Diagnosis Codes* section in the Part 2 *Vision Care* manual for a list of required ICD-10-CM diagnosis codes when billing for interim comprehensive eye examinations within the 24-month benefit period.

## **E&M Codes Not Reimbursable With Eye Examination Services**

Evaluation and Management (E&M) visit codes (CPT codes 99202 thru 99215 and 99417) should not be billed with eye examination codes (CPT codes 92002, 92004, 92012 and 92014) by the same provider, for the same recipient and date of service. Reimbursement for duplicate services will be reduced or denied.

## **Medicare-Covered Services**

Eye examinations for Medicare/Medi-Cal-eligible recipients must be billed to Medicare prior to billing Medi-Cal for the following claims:

- Examinations performed in conjunction with eye disease (such as glaucoma or cataract) or eye injury
- Interim examinations for recipients with a sign or symptom that justifies the need for an examination (providers must include the principal ICD-10-CM diagnosis code on the claim)

## **Medicare Non-Covered**

Routine examinations for the purpose of prescribing, fitting or changing eyeglasses, as well as eye refractions, are not covered by Medicare. Eye examination claims (CPT codes 92002, 92004, 92012 and 92014) for Medicare/Medi-Cal-eligible recipients with only diagnoses for disorders, refraction, accommodation and color vision deficiencies may be billed directly to Medi-Cal. The recipient's primary ICD-10-CM diagnosis code must be entered in the *Principal Diagnosis Code* field (Box 67) of the *UB-04* claim form or *Diagnosis or Nature of Illness or Injury* field (Box 21) of the *CMS-1500* claim form. Determination of refractive state (CPT code 92015) is not covered by Medicare and may be billed directly to Medi-Cal.

Refer to the *Medicare Non-Covered Services: CPT® Codes* section in this manual for a list of ICD-10-CM diagnosis codes that may be submitted directly to Medi-Cal in conjunction with CPT codes 92002, 92004, 92012 and 92014.

## **Hard Copy Billing Crossover Claims**

Claims that do not automatically cross over electronically from Medicare carriers must be hard copy billed to the California MMIS Fiscal Intermediary Crossover Unit on a *CMS-1500* claim form. Refer to *the Medicare/Medi-Cal Crossover Claims: Vision Care* section in the appropriate Part 2 manual for detailed crossover billing information.

Providers must attach a copy of the *Explanation of Medicare Benefits (EOMB)/Medicare Remittance Notice (MRN)* to all crossover claims.

Refractive services (CPT code 92015) may be billed directly to Medi-Cal.

## **Contact Lenses**

Claims billed with CPT codes 92071 (fitting of contact lens for treatment of ocular surface disease), 92072 (fitting of contact lens for management of keratoconus, initial fitting), 92310 (prescription of optical and physical characteristics of and fitting of contact lenses, with medical supervision of adaptation; corneal lens, both eyes, except for aphakia), 92311 (prescription of optical and physical characteristics of and fitting of contact lens, with medical supervision of adaptation; corneal lens for aphakia, one eye) and 92312 (prescription of optical and physical characteristics of and fitting of contact lens, with medical supervision of adaptation; corneal lens for aphakia, both eyes) require authorization (a *Treatment Authorization Request*) from the Department of Health Care Services (DHCS) Vision Services Branch (VSB). Refer to the *Contact Lenses* and *TAR Completion for Vision Care* sections in the Part 2 Vision Care manual for policy and billing instructions.

## **Modifiers 22 and SC**

Providers can only use modifiers 22 and SC when billing for CPT codes 92071, 92072 and 92310 thru 92312.

## **Required Information**

The following information is required in the *Medical Justification* field of the 50-3 *Treatment Authorization Request (TAR)* form or on a separate attachment. For additional information about the authorization process, refer to the *TAR Completion for Vision Care* section in the Part 2 *Vision Care* manual.

- Valid diagnosis or condition that precludes the satisfactory wearing of conventional eyeglasses, including documentation of clinical data when possible
- Best corrected visual acuities through eyeglasses and contact lenses
- Identification of the contact lens to be used by trade or manufacturer's name, base curve, diameter and power

- For a diagnosis of aniseikonia (ICD-10-CM code H52.32), a statement that indicates why eyeglasses cannot be used and supporting clinical data. (Anisometropia greater than three diopters, coupled with the presence of symptoms commonly associated with aniseikonia can qualify contact lenses for authorization. Where a smaller degree of anisometropia is present, detailed justification is required.)
- For conditions where contact lenses are the only option, a statement of the chronic pathology or deformity of the nose, skin or ears that precludes the wearing of conventional eyeglasses
- If extended wear contact lenses are prescribed, justification of why conventional, disposable or plan replacement extended wear lenses rather than daily wear lenses are necessary. (When infirmity is a pertinent factor in the decision, a statement that demonstrates the immediate availability of someone to assist the recipient in lens insertion, centering and removal is required.)
- A statement that indicates whether a recipient has worn contact lenses in the past

## **Cataract Surgery Supplies**

The following HCPCS codes are used to bill cataract surgery supplies and drugs:

<b>HCPCS Code</b>	<b>Description</b>
V2630	Anterior chamber intraocular lens
V2631	Iris supported intraocular lens
V2632	Posterior chamber intraocular lens

Refer to the *Ophthalmology: Diagnosis Codes* section in this manual for ICD-10-CM diagnosis codes that must be billed in conjunction with HCPCS codes V2630 thru V2632. Claims for codes V2630 thru V2632 are manually priced and must include an invoice.

## **Ocular Prosthesis**

Supply of ocular prosthesis is billed with HCPCS codes V2623 thru V2629. Services for prosthetic eyes and modification of prosthetic eyes must be billed on a *CMS-1500* claim form. Codes V2623 and V2627 thru V2629 must be billed with modifier NU or RP.

**Note:** Modifiers NU and RP cannot be billed on the same claim line; separate claims must be used.

Refer to the *Prosthetic Eyes* section in the Part 2 *Vision Care* manual for additional policy and billing information.

## **Fluocinolone Acetonide, Intravitreal Implant (Retisert)**

Fluocinolone acetonide intravitreal implant, 0.59 mg, is a sterile implant designed to release fluocinolone acetonide locally to the posterior segment of the eye at a nominal initial rate of 0.6 µg/day, decreasing over the first month to a steady state between 0.3 thru 0.4 µg/day over approximately 30 months. Corticosteroids inhibit the inflammatory response to a variety of inciting agents and probably delay or slow healing. They inhibit the edema, fibrin deposition, capillary dilation, leukocyte migration, capillary proliferation, fibroblast proliferation, deposition of collagen, and scar formation associated with inflammation. Corticosteroids are capable of producing a rise in intraocular pressure.

### **Indications**

All FDA-approved indications.

### **Dosage**

FDA-approved dosages.

### **TAR Requirement**

An approved *Treatment Authorization Request* (TAR) is required for reimbursement. The TAR must meet the following criteria for approval:

- Prescribed for FDA-approved indications and dosing regimens
- Must have a diagnosis of chronic (equal to or greater than 1 year) of non-infectious uveitis affecting the posterior segment of the eye
- Must be 12 years of age or older
- Must have failed (for example, recurrent uveitis despite use of traditional therapy) or was intolerant to traditional treatment including intravitreal steroid injections, systemic corticosteroids and/or immunosuppressive agents (for example, cyclosporine, azathioprine, methotrexate), or
- Must be experiencing adverse events associated with high dose systemic steroid or immunosuppressive therapy.

### **Age Limits**

Must be 12 years of age or older.

## Billing

HCPCS code J7311 (injection, fluocinolone acetonide, intravitreal implant [Retisert], 0.01 mg).

One of the following modifiers is required for reimbursement:

- ❖ LT (Left side)
- ❖ RT (Right side)

## Prescribing Restrictions

Frequency of billing equals every 30 months.

Maximum billing units equals one implant equals 0.59 mg equals 59 units per eye.

## Fluocinolone Acetonide Intravitreal Implant (Iluvien)

Corticosteroids inhibit phospholipase A2 lipocortin induction. Lipocortins may control biosynthesis of prostaglandins and leukotrienes by inhibiting arachidonic acid. Arachidonic acid is released by membrane phospholipids by phospholipase A2.

## Indications

All FDA-approved indications.

## Dosage

FDA-approved dosages.

## TAR Requirement

An approved *Treatment Authorization Request* (TAR) is required for reimbursement. The TAR must meet the following criteria for approval:

- ❖ FDA-approved indications.
- ❖ Must be 18 years or older.
- ❖ Must not have active an ocular or periocular infection.
- ❖ Must not have glaucoma.
- ❖ Must have a diagnosis of macular edema.
- ❖ Must have previously received a treatment course with corticosteroids and did not have a clinically significant rise in intraocular pressure.

## **Age Limits**

Must be 18 years of age or older.

## **Billing**

HCPCS code J7313 (injection, fluocinolone acetonide, intravitreal implant [Iluvien], 0.01 mg).

One of the following modifiers is required for reimbursement:

- LT (Left side)
- RT (Right side)

## **Prescribing Restrictions**

Frequency of billing equals every 36 months

Maximum billing units equals one implant equals 0.19 mg equals 19 units per eye

## **Fluocinolone Acetonide Intravitreal Implant (Yutiq)**

Fluocinolone acetonide intravitreal implant is a corticosteroid and inhibits phospholipase A2 via lipocortin induction. Lipocortins may control biosynthesis of prostaglandins and leukotrienes by inhibiting arachidonic acid. Arachidonic acid is released by membrane phospholipids by phospholipase A2.

## **Indications**

All FDA-approved indications.

## **Dosage**

FDA-approved dosages.

## TAR Requirement

An approved *Treatment Authorization Request* (TAR) is required for reimbursement. The TAR must meet the following criteria for approval:

- Prescribed for FDA-approved indication and dosage.
- Patient has a diagnosis of chronic (duration of one year or more) non-infectious uveitis affecting the posterior segment of the eye.
- Patient is 18 years of age or older.
- At least one of the following two options has been met for the affected eye(s):
  - Individual has experienced a treatment failure or intolerance of at least two administrations of intra- or peri-ocular injections of corticosteroids, or one conventional therapy, for example:

Systemic or topical corticosteroids such as prednisone or prednisolone acetate respectively

- ❖ Immunosuppressive agents (for example, azathioprine, cyclosporine, methotrexate or mycophenolate)
- ❖ Tumor Necrosis Factor (TNF) inhibitors (for example Humira®)
- ❖ Individual has experienced at least two separate recurrences of uveitis requiring treatment with systemic corticosteroids or ocular injections of corticosteroids

## Age Limits

Must be 18 years of age or older.

## Billing

HCPCS code J7314 (injection, fluocinolone acetonide, intravitreal implant [Yutiq], 0.01 mg)

One of the following modifiers is required for reimbursement:

- LT (Left side)
- RT (Right side)

## Prescribing Restrictions

Frequency of billing equals every 36 months.

Maximum billing units equals one implant equals 0.18 mg equals 18 units per eye.

## **Date Appliance Delivered**

*Welfare and Institutions Code*, Section 14043.341 requires providers to obtain and keep a record of Medi-Cal recipients' signatures when dispensing a product or prescription or when obtaining a laboratory specimen.

Therefore, dispensing optical providers (ophthalmologists, optometrists and dispensing opticians) who dispense a device (eye appliances) requiring a written order or prescription must maintain the following items in their files to qualify for Medi-Cal reimbursement:

- Signature of the person receiving the eye appliance
- Medi-Cal recipient's printed name and signature
- Date signed
- Prescription number or item description of the eye appliance dispensed
- Relationship of the recipient to the person receiving the prescription if the recipient is not picking up the eye appliance

## **Dexamethasone 9% Intraocular**

Dexamethasone 9% Intraocular is a corticosteroid suspension for intraocular administration.

### **Indications**

Dexamethasone 9% Intraocular is used to manage post-operative inflammation of the eye.

### **Age**

18 years of age and older.

### **Dosage**

A single dose of 0.005 mL dexamethasone 9% suspension (equivalent to 517 micrograms) is injected into the posterior chamber inferiorly behind the iris at the end of eye surgery.

## Authorization

No *Treatment Authorization Request* (TAR) is generally required for reimbursement.

## Required Codes

One of the following modifiers is required for reimbursement:

LT (Left side)

RT (Right side)

## Billing

HCPCS code J1095 (injection, dexamethasone 9% intraocular, 1 mcg).

One (1) unit of J1095 equals 1 mcg of dexamethasone 9% intraocular suspension.

## Dexamethasone Intravitreal Implant

Dexamethasone, a potent corticosteroid, has been shown to suppress inflammation by inhibiting multiple inflammatory cytokines resulting in decreased edema, fibrin deposition, capillary leakage and migration of inflammatory cells. The intravitreal implant contains dexamethasone in a solid polymer drug delivery system. The drug is preloaded into a single-use, specially designed applicator to facilitate injection of the rod-shaped implant directly into the vitreous.

## Indications

Intravitreal dexamethasone is indicated for the treatment of:

- Macular edema following branch retinal vein occlusion or central retinal vein occlusion.
- Non-infectious uveitis affecting the posterior segment of the eye.
- Diabetic macular edema.
- Recipients must be 18 years of age or older.

## Authorization

An approved *Treatment Authorization Request* (TAR) is required for reimbursement.

## Dosing

The recommended dose is 0.7 mg utilizing the pre-loaded single use applicator.

## Billing

HCPCS code J7312 (injection, dexamethasone intravitreal implant, 0.1 mg).

Use modifiers LT (left side) and RT (right side) for bilateral procedures. Providers must document use of modifiers LT and RT on separate claim lines.

## **Triamcinolone Acetonide, for Suprachoroidal Use (Xipere™)**

Triamcinolone acetonide is a synthetic glucocorticoid (glucocorticoids are often referred to as corticosteroids) with immunosuppressive and anti-inflammatory activity. The primary mechanism of action for triamcinolone acetonide is as a corticosteroid hormone receptor agonist.

## Indications

All FDA-approved indications.

## Dosage

FDA-approved dosages.

## TAR Requirement

An approved *Treatment Authorization Request* (TAR) is required for reimbursement.

## TAR Criteria

Must submit clinical documentation to substantiate the following:

- Must be used for FDA-approved indications and dosages.
- Patient must be 18 years of age or older.
- Must be prescribed by or in consultation with an ophthalmologist.
- Patient has a diagnosis of macular edema associated with non-infectious uveitis.
- Patient does not have uveitis due to infections such as herpes simplex or herpes zoster.

- Documentation of patients' best corrected visual acuity (BCVA) at baseline and periodically during treatment.
- Patient will not concomitantly use intravitreal corticosteroid injections or intravitreal corticosteroid implant.
- Patient does not have untreated intraocular pressure or uncontrolled glaucoma.
- Patient has tried and failed topical and oral corticosteroids unless contraindicated or clinically inappropriate.
- Dose does not exceed 4 mg (one vial) per eye every 12 weeks.

Initial authorization is for six months (two injections per eye)

#### Continued therapy

- Patient continues to meet initial approval criteria
- Patient has absence of unacceptable toxicity from the drug such as glaucoma, increase in intraocular pressure, cataracts, etc.
- Patient has experienced clinical response as evidenced improvement or stabilization in best corrected visual acuity from baseline

Reauthorization is for six months (two injections per eye).

#### **Age Limit**

Must be 18 years of age or older.

#### **Billing**

HCPSC code: J3299 (injection, triamcinolone acetonide (xipere), 1 mg).

#### **Prescribing Restriction(s)**

Frequency of billing equals 4 mg/4 units each eye as a single dose every three months.

Maximum billing unit(s) equals 4 mg/4 units each eye as a single dose.

## **Dexamethasone Ophthalmic Insert (Dextenza)**

Dexamethasone ophthalmic insert, a corticosteroid, is a resorbable, intracanalicular insert. It is intended to be inserted in the lower lacrimal punctum into the canaliculus and does not require removal. It decreases inflammation by suppression of neutrophil migration, decreased production of inflammatory mediators, and reversal of increased capillary permeability; suppresses normal immune response.

### **Indications**

All FDA-approved indications.

### **Dosage**

FDA-approved dosages.

### **TAR Requirement**

An approved *Treatment Authorization Request* (TAR) is required for reimbursement. The TAR must meet the following criteria for approval:

- Prescribed for FDA-approved indications and dosing regimens.
- Must be 18 years of age or older.
- Must verify that Dextenza will be placed by a provider immediately following ophthalmic surgery.
- Must provide date of ophthalmic surgery.
- Must provide clinical reasons why a corticosteroid ophthalmic solution or suspension is inadequate.
- Must limit quantity to two inserts in a 30-day period.

### **Age Limits**

Must be 18 years of age or older.

### **Billing**

HCPCS code J1096 (dexamethasone, lacrimal ophthalmic insert, 0.1 mg).

## **Prescribing Restrictions**

Frequency of billing equals every 30 days.

Maximum billing units equals 1 insert equals 0.4 mg equals 4 units per eye.

## **Phenylephrine and Ketorolac Ophthalmic Solution (Omidria)**

Phenylephrine and ketorolac ophthalmic solution is an alpha1-adrenergic receptor agonist and nonselective cyclooxygenase inhibitor.

Ketorolac: Anti-inflammatory; nonsteroidal anti-inflammatory agent (NSAID); inhibits COX-1 and COX-2 which results in decreased tissue concentrations of prostaglandins to reduce pain caused by surgical trauma.

Phenylephrine:  $\alpha$ 1-adrenergic receptor agonist; acts as a mydriatic agent by contracting the radial muscle of the iris.

## Indications

All FDA-approved indications.

## Dosage

FDA-approved dosages.

## TAR Requirement

No *Treatment Authorization Request* (TAR) is required for reimbursement.

## Billing

HCPCS code J1097 (phenylephrine 10.16 mg/ml and ketorolac 2.88 mg/ml ophthalmic irrigation solution, 1 ml).

## Prescribing Restrictions

Maximum billing units equals 4 ml equals four units.

## Ocriplasmin

Ocriplasmin is a truncated form of human plasmin produced by recombinant DNA technology in a *Pichia pastoris* expression system. Ocriplasmin has proteolytic activity against protein components of the vitreous body and the vitreoretinal interface, thereby dissolving the protein matrix responsible for the vitreomacular adhesion.

## Indications

Ocriplasmin is indicated for the treatment of symptomatic vitreomacular adhesion.

## Required Code

One or more of the following ICD-10-CM diagnosis codes are required for reimbursement: H43.821 thru H43.829.

## Dosage

The recommended dose is 0.125 mg administered by intravitreal injection to the affected eye once as a single dose. If both eyes require treatment, a second vial is to be used for the second eye.

## Billing

HCPCS code J7316 (injection, ocriplasmin, 0.125 mg).

Four (4) units of ocriplasmin for each eye with one administration fee is allowed.

Unit 1 must be administered and documentation that units 2, 3 and 4 have been discarded is required. If treatment for both eyes is needed (justification required), unit 5 must be used for treatment of the second eye with a second vial and documentation that units 6, 7 and 8 have been discarded.

## **Bimatoprost (Durysta™) and Travoprost (iDose® TR)**

Bimatoprost, a prostaglandin analog, is a synthetic structural analog of prostaglandin with ocular hypotensive activity. Bimatoprost is believed to lower interocular pressure (IOP) in humans by increasing outflow of aqueous humor through both the trabecular meshwork (conventional) and uveoscleral routes (unconventional). Elevated IOP presents a major risk factor for glaucomatous field loss. The higher the level of IOP, the greater the likelihood of optic nerve damage and visual field loss.

Travoprost free acid, a prostaglandin analog is a selective FP prostanoid receptor agonist, which is believed to reduce IOP by increasing uveoscleral outflow. The exact mechanism of action is unknown at this time.

## Indications

All FDA-approved indications.

## Dosage

FDA-approved dosages.

## TAR Requirement

An approved *Treatment Authorization Request* (TAR) is required for reimbursement.

## TAR Criteria

Durysta and iDose are considered medically necessary when the following criteria are met:

- Must be used for FDA-labelled indications and dosages.
- Patient must be 18 years of age or older.
- Patient must have a diagnosis of Open Angle Glaucoma or Ocular Hypertension.
- Must be prescribed by or in consultation with an ophthalmologist.
- The affected eye has not received prior treatment with Durysta or iDose TR.

- Patient has had a trial of at least one prostaglandin analog (as monotherapy or combination therapy) with insufficient response, intolerance or adverse effects (for example, bimatoprost, latanoprost, travoprost or tafluprost).
- Patient does not have any of the following contraindications:
  - Ocular or periocular infections
  - Corneal endothelial cell dystrophy
  - Prior corneal transplantation
  - Absent or ruptured posterior lens capsule

Approval duration: one implant per eye per lifetime.

### Continued Therapy

Reauthorization is not allowed.

### **Age Limits**

Must be 18 years of age or older.

### **Billing**

HCPCS codes:

J7351 (injection, bimatoprost, intracameral implant, 1 microgram).

J7355 (injection, travoprost, intracameral implant, 1 microgram).

### **Prescribing Restrictions**

Durysta:

Frequency of billing equals 1 implant (10 mcg) /10 units per eye per lifetime.

Maximum billing unit(s) equals 1 implant (10 mcg) /10 units per eye.

iDose TR:

Frequency of billing equals 1 implant (75 mcg) /75 units per eye per lifetime.

Maximum billing unit(s) equals 1 implant (75 mcg) /75 units per eye.

## **Brolucizumab-dbll (Beovu)**

Brolucizumab is a recombinant humanized monoclonal antibody vascular endothelial growth factor (VEGF) inhibitor that binds to the three major isoforms of VEGF-A, thereby suppressing endothelial cell proliferation, neovascularization, and vascular permeability to slow vision loss.

### **Indications**

All FDA-approved indications.

### **Dosage**

FDA-approved dosages.

### **Authorization**

An approved *Treatment Authorization Request* (TAR) is required for reimbursement.

## **TAR Criteria**

For TAR approval, must submit clinical documentation that demonstrates the following:

- Must be for FDA-approved indications and dosing regimens
- Must be 18 years of age or older
- Must have a diagnosis of Neovascular (wet) Age-Related Macular Degeneration (AMD)
- Patient has tried and failed or is intolerant to treatment with an intravitreal VEGF inhibitor (for example Bevacizumab or ranibizumab)
- Patient must not have ocular or periocular infections
- Patient must not have an active intraocular inflammation

Initial approval is for 12 months

### Continued therapy

- Patient continues to meet initial approval criteria
- Patient has shown positive clinical response as evidenced by improvement/stabilization in visual acuity or therapy is for maintenance of corrected visual acuity from previous therapy.
- Absence of unacceptable toxicity such as endophthalmitis, retinal detachments, increase in intraocular pressure, retinal vasculitis/retinal vascular occlusion, or arterial thromboembolic events

Reauthorization is for 12 months

## **Age Limits**

Must be 18 years of age or older

## **Billing**

HPCS code J0179 (injection, brolocizumab-dbl, 1 mg)

## **Prescribing Restrictions**

Frequency of billing equals every 25 thru 31 days for the first three doses, then every 8 thru 12 weeks. Maximum billing unit(s) equals 6 mg equals 6 units.

## **Faricimab-svoa (Vabysmo™)**

Faricimab is a humanized bispecific antibody that acts through inhibition of two pathways by binding to vascular endothelial growth factor (VEGF)-A and angiopoietin-2 (Ang-2). By inhibiting VEGF-A, faricimab suppresses endothelial cell proliferation, neovascularization and vascular permeability. By inhibiting Ang-2, faricimab is thought to promote vascular stability and desensitize blood vessels to the effects of VEGF-A. Ang-2 levels are increased in some patients with nAMD and DME. The contribution of Ang-2 inhibition to the treatment effect and clinical response for nAMD and DME has yet to be established.

### **Indications**

All FDA-approved indications

### **Dosage**

FDA-approved dosages

### **TAR Requirement**

An approved *Treatment Authorization Request* (TAR) is required for reimbursement

### **TAR Criteria**

Must submit clinical documentation to substantiate the following:

#### Universal Criteria

- Must be used for FDA-approved indications and dosages
- Must be prescribed by or in consultation with an ophthalmologist
- Patient must have a diagnosis of Neovascular (Wet) Age-Related Macular Degeneration (nAMD) or Diabetic Macular Edema (DME)
- Documentation of patient's best corrected visual acuity (BCVA) at baseline and periodically during treatment
- Patient does not have active ocular inflammation or suspected or active ocular or periocular infection in either eye
- Patient does not have untreated intraocular pressure or uncontrolled glaucoma
- Patient has tried and failed an intravitreal vascular endothelial growth factor (VEGF) inhibitor (for example, bevacizumab, aflibercept or ranibizumab) unless contraindicated or clinically inappropriate

### Neovascular (Wet) Age-Related Macular Degeneration (nAMD)

- Patient must be 50 years of age or older
- Patient has a diagnosis of choroidal neovascularization (CNV) secondary to age-related macular degeneration (nAMD)
- Patient does not have CNV due to causes other than AMD, such as ocular histoplasmosis, trauma, pathological myopia, angioid streaks, choroidal rupture, or uveitis
- Patient is not on any concomitant treatment for CNV or vitreomacular-interface abnormalities

### Diabetic Macular Edema (DME)

- Patient must be 18 years of age or older
- Patient has a diagnosis of DME and decreased visual acuity attributable primarily to DME
- Macular thickening secondary to diabetic macular edema (DME) involving the center of the fovea

### **Initial authorization is for six months**

#### Continued therapy:

- Patient continues to meet initial approval criteria
- Patient has experienced a clinical response as evidenced by improvement in best corrected visual acuity (BCVA) score from baseline
- Patient has absence of unacceptable toxicity from the drug such as endophthalmitis or retinal detachment, increase in intraocular pressure, arterial thromboembolic events (ATEs), etc.

### **Reauthorization is for 12 months**

### **Billing**

HCPCS code: J2777 (injection, faricimab-svoa, 0.1 mg)

### **Prescribing Restriction(s)**

Frequency of billing equals six mg /60 units each eye every four weeks

Maximum billing unit(s) equals six mg /60 units each eye

## **Ranibizumab for Intravitreal Use via Susvimo Ocular Implant (Susvimo™)**

Ranibizumab binds to the receptor binding site of multiple biologically active forms of VEGF-A, including VEGF. VEGF-A has been shown to cause neovascularization and leakage in models of ocular angiogenesis and vascular occlusion and is thought to contribute to pathophysiology of neovascular AMD. The binding of ranibizumab to VEGF-A prevents the interaction of VEGF-A with its receptors (VEGFR1 and VEGFR2) on the surface of endothelial cells, reducing endothelial cell proliferation, vascular leakage, and new blood vessel formation.

### **Indications**

All FDA-approved indications

### **Dosage**

FDA-approved dosages

### **TAR Requirements**

An approved *Treatment Authorization Request* (TAR) is required for reimbursement.

### **TAR Criteria**

Susvimo is considered medically necessary when all of the following conditions are met:

- Must be used for FDA approved indications and dosages
- Patient must be 18 years of age or older
- Must be prescribed by or in consultation with an ophthalmologist
- Patient has a diagnosis of Neovascular (wet) Age-related Macular Degeneration (AMD) within the prior 9 months
- Patient has received 3 or more doses of anti-VEGF intravitreal agents in the affected eye within the prior 6 months and demonstrated a response to an anti-VEGF intravitreal agent (for example, aflibercept, bevacizumab, brolucizumab, etc.)
- Documentation of distance Best Corrected Visual Acuity (BCVA) score at baseline and periodically during treatment
- Supplemental treatment with 0.5 mg intravitreal ranibizumab injection may be administered in the affected eye if clinically necessary
- Patient does not have active ocular or periocular infections
- Patient does not have active intraocular inflammation

Initial authorization is for six months.

#### Continued therapy

- Patient continues to meet initial approval criteria
- Patient has shown clinical response as evidenced by an improvement from baseline in distance Best Corrected Visual Acuity (BCVA) score
- Patient does not have unacceptable toxicity such as endophthalmitis, rhegmatogenous retinal detachment, implant dislocation, vitreous hemorrhage, conjunctival retraction, conjunctival erosion, and conjunctival bleb

Reauthorization is for six months.

#### **Age Limit**

Must be 18 years of age or older.

#### **Billing**

HCPCS code: J2779, (injection, ranibizumab, via intravitreal implant [susvimo] 0.1 mg)

#### **Prescribing Restriction(s)**

Frequency of billing equals 2 mg/20 units each eye every 24 weeks.

Maximum billing unit(s) equals 2 mg/20 units each eye.

## **Revakinagene taroretcel-lwey (ENCELTO)**

### **Clinical Use Parameters**

Use in accordance with FDA-approved labeling, including indication, dosage, frequency, age and any prescribing limitation.

### **TAR Requirement**

An approved *Treatment Authorization Request* (TAR) is required for reimbursement

### **Billing**

HCPCS code J3403 (revakinagene taroretcel-lwey, per implant)

#### **Important Billing Instructions**

Due to systems limitations, providers must take the following steps when billing J3403 for appropriate reimbursement:

#### **TAR/SAR Submission**

1. Submit and receive back an approved *Treatment Authorization Request* (TAR) or approved product specific *Service Authorization Request* (SAR).
2. The TAR/SAR is not negotiated.
3. Provider must submit one (1) service line on the TAR/SAR request and enter “3” in the Units box.

#### **Claim Submission**

1. Bill using J3403 (revakinagene taroretcel-lwey, per implant).
2. Completion of claim forms:
  - «Outpatient claims may be billed electronically or by paper claim using the 837I/UB04 (Institutional) or 837P/CMS1500 (Professional) Medi-Cal claim forms with the following conditions:
    - On the 837I/UB-04 claim form, the provider may submit up to three (3) units on one claim line to represent a total of one (1) service (for example, one implant).»

- «Each claim line represents 3 units with a charge amount up to \$999,999.99.
  - On the 837P/CMS 1500 claim form, the provider may submit one unit each on up to three (3) claim lines to represent a total of one (1) service (for example, one implant).
    - Each claim line represents 1 unit with a charge amount up to \$99,999.99.
    - The sum of the three claim lines (3 units) shall equal the total amount billed “*per implant.*”»
  - Providers must submit an invoice for reimbursement.
  - This process will ensure that the total reimbursement paid for the submitted claim lines is no more than provider submitted invoice paid price.
  - Encelto must be billed on its own with no other drug or biologics.
3. Providers are advised to take the following steps to ensure that Encelto claims are identified and processed expeditiously:
- «Paper claims: drug product may be identified by the notation of “Encelto” in Box 80 (Remarks) of the *UB-04* claim form or Box 19 (Additional Claim Information) on the *CMS 1500* claim form and submitted to:»
    - Attention: Claims Manager
    - Medi-Cal Fiscal Intermediary
    - P.O. Box 526006
    - Sacramento, CA 95852-6006
  - «Electronic claims: drug product may be identified by the notation of “Encelto” on the cover sheet, submitted with the 837I/837P claim form, addressed to “Attention: Claims Manager.” »

## **Legend**

Symbols used in the document above are explained in the following table.

<b>Symbol</b>	<b>Description</b>
«	This is a change mark symbol. It is used to indicate where on the page the most recent change begins.
»	This is a change mark symbol. It is used to indicate where on the page the most recent change ends.
*	This code is split-billable. When billing for both the professional and technical service components, a modifier is neither required nor allowed. When billing for only the professional component, use modifier 26. When billing for only the technical component, use modifier TC.
†	Please refer to ICD-10-CM coding guidelines for use of additional code for retinitis (H32) and proper sequencing.