

## Izervay (avancincaptad pegol)

### Disclaimer

*Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.*

*Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.*

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### Summary

Age-related macular degeneration (AMD) is a common progressive eye condition and a leading cause of vision loss in those over 65 years old. The most common form is dry AMD, affecting about 70-90% of AMD patients. As dry AMD advances, the risk of geographic atrophy increases. Geographic atrophy (GA), characterized by irreversible loss of retinal cells, leading to progressive vision difficulties like blurred areas or missing spots when reading, accounts for ~15% of all AMD cases. Geographic atrophy impacts daily functioning and can ultimately cause severe central vision loss or blindness.

Despite the significant burden of GA, effective treatment options have been lacking until recently. Current management includes complement therapy (Izervay [avacincaptad pegol] and Syfovre [pegcetacoplan] and retinal implants. FDA granted approval to Izervay (avacincaptad pegol) as the first C5 complement inhibitor for GA secondary to AMD. As an overactive complement system contributes to AMD pathology, inhibiting C5 may reduce this damaging effect.

1. The monthly intravitreal injections of Izervay were studied in two phase 3 trials, GATHER1 and GATHER2, which showed significantly reduced GA lesion growth rates compared to sham injections over 12 months. However, no differences in visual acuity were observed between the treatment and placebo groups.
2. A post-hoc analysis of the GATHER1 and GATHER2 study assessed the impact of Izervay (avancincaptad pegol) 2 mg versus sham on the impact on visual acuity measured by letter loss from baseline. There was a significant difference between Izervay (avancincaptad pegol) and sham for loss of  $\geq 15$  words (3.4% vs. 78%) by 12 months. This difference was consistently seen for  $\geq 10$  word and  $\geq 20$  word loss. This post-hoc analysis also found a reduction in the loss of visual acuity to below driving eligibility threshold, which is a clinically meaningful outcome. However, this study is significantly limited by its post-hoc design, limited statistical analysis and power (despite pooling the GATHER1 and GATHER2 study sample to increase total size).
3. While Izervay (avancincaptad pegol) represents an important advance as the first approved C5 complement inhibitor for GA, concerns exist regarding its benefit-risk profile. Increased adverse events like endophthalmitis and conversion to wet AMD were seen with Izervay (avancincaptad pegol) versus placebo. Additionally, the lack of efficacy on visual acuity, a key goal in managing AMD, raises uncertainty about its clinical value.

## Definitions

"Age-related macular degeneration (AMD)" is a common progressive eye disease that results in damage to the macula and central vision loss. It has two main forms - dry and wet AMD.

"Drusen" is yellow extracellular deposits that accumulate under the retinal pigment epithelium characterizing early AMD.

"Dry AMD" is the most common form of AMD (~90% cases) characterized by drusen deposits and abnormalities in the retinal pigment epithelium in the macula.

"Documentation" refers to written information, including but not limited to:

- Up-to-date chart notes, relevant test results, and/or relevant imaging reports to support diagnoses; or
- Prescription claims records, and/or prescription receipts to support prior trials of formulary alternatives.

“Endophthalmitis” is a serious inflammation of the interior of the eye that can lead to vision loss.

“Geographic atrophy (GA)” is an advanced form of dry AMD defined by irreversible atrophy and loss of retinal cells leading to progressive vision impairment. Also known as atrophic AMD.

“Idiopathic Polypoidal Choroidal Vasculopathy (IPCV)” is a condition characterized by the presence of polypoidal, saccular dilations of blood vessels located beneath the RPE. It can lead to serous and hemorrhagic detachments of the RPE. While IPCV shares some similarities with nAMD, it's a distinct entity.

“Intravitreal injection” refers to injection of a medication into the vitreous humor of the eye to directly deliver the drug to the retina.

“Macula” is the small central area of the retina responsible for sharp, detailed central vision.

“Neovascular Age-Related Macular Degeneration (nAMD)” is the wet form of AMD. It is characterized by the growth of abnormal blood vessels under the retina, which can leak fluid and blood. This leads to rapid and severe central vision loss if not treated.

“No evidence of” indicates that the reviewer has not identified any records of the specified item or condition within the submitted materials or claims history. In the absence of such evidence, the member is considered eligible. If any evidence of the item or condition is present upon review of the request, the member does not qualify.

“[s]” indicates state mandates may apply.

“Stargardt Disease” is an inherited form of juvenile macular degeneration. It typically begins in childhood or adolescence and is caused by mutations in specific genes. Over time, there's a progressive loss of central vision.

## Medical Necessity Criteria for Initial Clinical Review

### Initial Indication-Specific Criteria

#### Geographic Atrophy Secondary to Age-Related Macular Degeneration

The Plan considers Izervay (avacincaptad pegol) medically necessary when ALL of the following criteria are met:

1. The medication is prescribed by or in consultation with an ophthalmologist; *AND*
2. The member is 18 years of age or older; *AND*
3. The member has a diagnosis of geographic atrophy secondary to age-related macular degeneration supported by clinical documentation; *AND*

4. The member meets ALL of the following:
  - a. No evidence of active ocular or periocular infections; *or*
  - b. No evidence of active intraocular inflammation; *AND*
5. Izervay (avacincaptad pegol) is being prescribed at a dose and frequency that is within FDA approved labeling *OR* is supported by compendia or evidence-based published dosing guidelines for the requested indication.

If the above prior authorization criteria are met, Izervay (avacincaptad pegol) will be approved for up to 12-months.<sup>1s</sup>

*Continued Care*

#### [Medical Necessity Criteria for Subsequent Clinical Review](#)

##### Geographic Atrophy Secondary to Age-Related Macular Degeneration

The Plan considers Izervay (avacincaptad pegol) medically necessary when ALL of the following criteria are met:

1. The medication is prescribed by or in consultation with an ophthalmologist; *AND*
2. Clinical documentation is provided showing ALL of the following:
  - a. Continued disease stability or slowing in the growth rate of geographic atrophy lesions; *AND*
  - b. No evidence of unacceptable toxicity or adverse events, such as endophthalmitis, retinal detachment, or conversion to wet AMD; *AND*
  - c. If applicable, clinical rationale and supporting evidence for extended Izervay (avacincaptad pegol) treatment beyond 24 months of total use.

If the above reauthorization criteria are met, the requested product will be authorized for up to 12 months.<sup>1s</sup>

##### [Experimental or Investigational / Not Medically Necessary<sup>1s</sup>](#)

Izervay (avacincaptad pegol) for any other indication or use is considered not medically necessary by the Plan, as it is deemed to be experimental, investigational, or unproven. Non-covered indications include, but are not limited to, the following:

- Neovascular Age-Related Macular Degeneration (nAMD). There have been reports of nAMD in those who have received Izervay (avacincaptad pegol), and thus it is unlikely to provide benefit in those who are already experiencing nAMD.
- Stargardt Disease. There are no high quality human studies to support the safety and efficacy of Izervay (avacincaptad pegol) for the management of Stargardt disease. Animal models have shown promise, but no human studies have supported these findings.

- Idiopathic Polypoidal Choroidal Vasculopathy. There are no high quality studies to support the safety and efficacy of Izervay (avacincaptad pegol) for the management of idiopathic polypoidal choroidal vasculopathy.

#### Applicable Billing Codes

Table 1

CPT/HCPCS codes for geographic atrophy secondary to age-related macular degeneration considered medically necessary if criteria are met:

| <i>Code</i> | <i>Description</i>   |
|-------------|--|
| J2782       | Injection, avacincaptad pegol, 0.1 mg                                |
| 67028       | Intravitreal injection of a pharmacologic agent (separate procedure) |

Table 2

ICD-10 diagnosis codes considered medically necessary for geographic atrophy secondary to age-related macular degeneration with Table 1 (CPT/HCPCS) codes if criteria are met:

| <i>Code</i> | <i>Description</i>  |
|-------------|---|
| E08.311     | Diabetes mellitus due to underlying condition with unspecified diabetic retinopathy with macular edema                            |
| E08.319     | Diabetes mellitus due to underlying condition with unspecified diabetic retinopathy without macular edema                         |
| E08.3211    | Diabetes mellitus due to underlying condition with mild nonproliferative diabetic retinopathy with macular edema, right eye       |
| E08.3212    | Diabetes mellitus due to underlying condition with mild nonproliferative diabetic retinopathy with macular edema, left eye        |
| E08.3213    | Diabetes mellitus due to underlying condition with mild nonproliferative diabetic retinopathy with macular edema, bilateral       |
| E08.3219    | Diabetes mellitus due to underlying condition with mild nonproliferative diabetic retinopathy with macular edema, unspecified eye |
| E08.3291    | Diabetes mellitus due to underlying condition with mild nonproliferative diabetic retinopathy without macular edema, right eye    |
| E08.3292    | Diabetes mellitus due to underlying condition with mild nonproliferative diabetic   |

|          |  |
|----------|--|
|          | retinopathy without macular edema, left eye  |
| E08.3293 | Diabetes mellitus due to underlying condition with mild nonproliferative diabetic retinopathy without macular edema, bilateral           |
| E08.3299 | Diabetes mellitus due to underlying condition with mild nonproliferative diabetic retinopathy without macular edema, unspecified eye     |
| E08.3311 | Diabetes mellitus due to underlying condition with moderate nonproliferative diabetic retinopathy with macular edema, right eye          |
| E08.3312 | Diabetes mellitus due to underlying condition with moderate nonproliferative diabetic retinopathy with macular edema, left eye           |
| E08.3313 | Diabetes mellitus due to underlying condition with moderate nonproliferative diabetic retinopathy with macular edema, bilateral          |
| E08.3319 | Diabetes mellitus due to underlying condition with moderate nonproliferative diabetic retinopathy with macular edema, unspecified eye    |
| E08.3391 | Diabetes mellitus due to underlying condition with moderate nonproliferative diabetic retinopathy without macular edema, right eye       |
| E08.3392 | Diabetes mellitus due to underlying condition with moderate nonproliferative diabetic retinopathy without macular edema, left eye        |
| E08.3393 | Diabetes mellitus due to underlying condition with moderate nonproliferative diabetic retinopathy without macular edema, bilateral       |
| E08.3399 | Diabetes mellitus due to underlying condition with moderate nonproliferative diabetic retinopathy without macular edema, unspecified eye |
| E08.3411 | Diabetes mellitus due to underlying condition with severe nonproliferative diabetic retinopathy with macular edema, right eye            |
| E08.3412 | Diabetes mellitus due to underlying condition with severe nonproliferative diabetic retinopathy with macular edema, left eye             |
| E08.3413 | Diabetes mellitus due to underlying condition with severe nonproliferative diabetic retinopathy with macular edema, bilateral            |
| E08.3419 | Diabetes mellitus due to underlying condition with severe nonproliferative diabetic retinopathy with macular edema, unspecified eye      |
| E08.3491 | Diabetes mellitus due to underlying condition with severe nonproliferative diabetic retinopathy without macular edema, right eye         |
| E08.3492 | Diabetes mellitus due to underlying condition with severe nonproliferative diabetic retinopathy without macular edema, left eye          |

|          |  |
|----------|--|
| E08.3493 | Diabetes mellitus due to underlying condition with severe nonproliferative diabetic retinopathy without macular edema, bilateral   |
| E08.3499 | Diabetes mellitus due to underlying condition with severe nonproliferative diabetic retinopathy without macular edema, unspecified eye   |
| E08.3511 | Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy with macular edema, right eye  |
| E08.3512 | Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy with macular edema, left eye   |
| E08.3513 | Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy with macular edema, bilateral  |
| E08.3519 | Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy with macular edema, unspecified eye  |
| E08.3521 | Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy with traction retinal detachment involving the macula, right eye                           |
| E08.3522 | Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy with traction retinal detachment involving the macula, left eye                            |
| E08.3523 | Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy with traction retinal detachment involving the macula, bilateral                           |
| E08.3529 | Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy with traction retinal detachment involving the macula, unspecified eye                     |
| E08.3531 | Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, right eye                       |
| E08.3532 | Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, left eye                        |
| E08.3533 | Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, bilateral                       |
| E08.3539 | Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, unspecified eye                 |
| E08.3541 | Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, right eye |
| E08.3542 | Diabetes mellitus due to underlying condition with proliferative diabetic  |

|          |  |
|----------|--|
|          | retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, left eye  |
| E08.3543 | Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, bilateral       |
| E08.3549 | Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, unspecified eye |
| E08.3551 | Diabetes mellitus due to underlying condition with stable proliferative diabetic retinopathy, right eye  |
| E08.3552 | Diabetes mellitus due to underlying condition with stable proliferative diabetic retinopathy, left eye   |
| E08.3553 | Diabetes mellitus due to underlying condition with stable proliferative diabetic retinopathy, bilateral  |
| E08.3559 | Diabetes mellitus due to underlying condition with stable proliferative diabetic retinopathy, unspecified eye  |
| E08.3591 | Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy without macular edema, right eye   |
| E08.3592 | Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy without macular edema, left eye  |
| E08.3593 | Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy without macular edema, bilateral   |
| E08.3599 | Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy without macular edema, unspecified eye   |
| E09.311  | Drug or chemical induced diabetes mellitus with unspecified diabetic retinopathy with macular edema  |
| E09.319  | Drug or chemical induced diabetes mellitus with unspecified diabetic retinopathy without macular edema   |
| E09.3211 | Drug or chemical induced diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, right eye   |
| E09.3212 | Drug or chemical induced diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, left eye  |
| E09.3213 | Drug or chemical induced diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, bilateral   |

|          |   |
|----------|---|
| E09.3219 | Drug or chemical induced diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, unspecified eye        |
| E09.3291 | Drug or chemical induced diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, right eye           |
| E09.3292 | Drug or chemical induced diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, left eye            |
| E09.3293 | Drug or chemical induced diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, bilateral           |
| E09.3299 | Drug or chemical induced diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, unspecified eye     |
| E09.3311 | Drug or chemical induced diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, right eye          |
| E09.3312 | Drug or chemical induced diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, left eye           |
| E09.3313 | Drug or chemical induced diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, bilateral          |
| E09.3319 | Drug or chemical induced diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, unspecified eye    |
| E09.3391 | Drug or chemical induced diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, right eye       |
| E09.3392 | Drug or chemical induced diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, left eye        |
| E09.3393 | Drug or chemical induced diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, bilateral       |
| E09.3399 | Drug or chemical induced diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, unspecified eye |
| E09.3411 | Drug or chemical induced diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, right eye            |
| E09.3412 | Drug or chemical induced diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, left eye             |
| E09.3413 | Drug or chemical induced diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, bilateral            |
| E09.3419 | Drug or chemical induced diabetes mellitus with severe nonproliferative diabetic  |

|          |   |
|----------|---|
|          | retinopathy with macular edema, unspecified eye   |
| E09.3491 | Drug or chemical induced diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, right eye                             |
| E09.3492 | Drug or chemical induced diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, left eye                              |
| E09.3493 | Drug or chemical induced diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, bilateral                             |
| E09.3499 | Drug or chemical induced diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, unspecified eye                       |
| E09.3511 | Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy with macular edema, right eye  |
| E09.3512 | Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy with macular edema, left eye   |
| E09.3513 | Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy with macular edema, bilateral  |
| E09.3519 | Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy with macular edema, unspecified eye                                    |
| E09.3521 | Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, right eye       |
| E09.3522 | Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, left eye        |
| E09.3523 | Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, bilateral       |
| E09.3529 | Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, unspecified eye |
| E09.3531 | Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, right eye   |
| E09.3532 | Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, left eye    |
| E09.3533 | Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, bilateral   |
| E09.3539 | Drug or chemical induced diabetes mellitus with proliferative diabetic  |

|          |   |
|----------|---|
|          | retinopathy with traction retinal detachment not involving the macula, unspecified eye  |
| E09.3541 | Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, right eye       |
| E09.3542 | Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, left eye        |
| E09.3543 | Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, bilateral       |
| E09.3549 | Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, unspecified eye |
| E09.3551 | Drug or chemical induced diabetes mellitus with stable proliferative diabetic retinopathy, right eye  |
| E09.3552 | Drug or chemical induced diabetes mellitus with stable proliferative diabetic retinopathy, left eye   |
| E09.3553 | Drug or chemical induced diabetes mellitus with stable proliferative diabetic retinopathy, bilateral  |
| E09.3559 | Drug or chemical induced diabetes mellitus with stable proliferative diabetic retinopathy, unspecified eye  |
| E09.3591 | Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy without macular edema, right eye   |
| E09.3592 | Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy without macular edema, left eye  |
| E09.3593 | Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy without macular edema, bilateral   |
| E09.3599 | Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy without macular edema, unspecified eye   |
| E10.319  | Type 1 diabetes mellitus with unspecified diabetic retinopathy without macular edema  |
| E10.3211 | Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, right eye  |

|          |   |
|----------|---|
| E10.3212 | Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, left eye               |
| E10.3213 | Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, bilateral              |
| E10.3219 | Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, unspecified eye        |
| E10.3291 | Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, right eye           |
| E10.3292 | Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, left eye            |
| E10.3293 | Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, bilateral           |
| E10.3299 | Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, unspecified eye     |
| E10.3311 | Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, right eye          |
| E10.3312 | Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, left eye           |
| E10.3313 | Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, bilateral          |
| E10.3319 | Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, unspecified eye    |
| E10.3391 | Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, right eye       |
| E10.3392 | Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, left eye        |
| E10.3393 | Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, bilateral       |
| E10.3399 | Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, unspecified eye |
| E10.3411 | Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, right eye            |
| E10.3412 | Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy with                                     |

|          |   |
|----------|---|
|          | macular edema, left eye   |
| E10.3413 | Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, bilateral                                |
| E10.3419 | Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, unspecified eye                          |
| E10.3491 | Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, right eye                             |
| E10.3492 | Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, left eye                              |
| E10.3493 | Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, bilateral                             |
| E10.3499 | Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, unspecified eye                       |
| E10.3511 | Type 1 diabetes mellitus with proliferative diabetic retinopathy with macular edema, right eye  |
| E10.3512 | Type 1 diabetes mellitus with proliferative diabetic retinopathy with macular edema, left eye   |
| E10.3513 | Type 1 diabetes mellitus with proliferative diabetic retinopathy with macular edema, bilateral  |
| E10.3519 | Type 1 diabetes mellitus with proliferative diabetic retinopathy with macular edema, unspecified eye                                    |
| E10.3521 | Type 1 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, right eye       |
| E10.3522 | Type 1 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, left eye        |
| E10.3523 | Type 1 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, bilateral       |
| E10.3529 | Type 1 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, unspecified eye |
| E10.3531 | Type 1 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, right eye   |
| E10.3532 | Type 1 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, left eye    |

|          |   |
|----------|---|
| E10.3533 | Type 1 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, bilateral                             |
| E10.3539 | Type 1 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, unspecified eye                       |
| E10.3541 | Type 1 diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, right eye       |
| E10.3542 | Type 1 diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, left eye        |
| E10.3543 | Type 1 diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, bilateral       |
| E10.3549 | Type 1 diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, unspecified eye |
| E10.3551 | Type 1 diabetes mellitus with stable proliferative diabetic retinopathy, right eye  |
| E10.3552 | Type 1 diabetes mellitus with stable proliferative diabetic retinopathy, left eye   |
| E10.3553 | Type 1 diabetes mellitus with stable proliferative diabetic retinopathy, bilateral  |
| E10.3559 | Type 1 diabetes mellitus with stable proliferative diabetic retinopathy, unspecified eye  |
| E10.3591 | Type 1 diabetes mellitus with proliferative diabetic retinopathy without macular edema, right eye   |
| E10.3592 | Type 1 diabetes mellitus with proliferative diabetic retinopathy without macular edema, left eye  |
| E10.3593 | Type 1 diabetes mellitus with proliferative diabetic retinopathy without macular edema, bilateral   |
| E10.3599 | Type 1 diabetes mellitus with proliferative diabetic retinopathy without macular edema, unspecified eye   |
| E11.311  | Type 2 diabetes mellitus with unspecified diabetic retinopathy with macular edema   |
| E11.319  | Type 2 diabetes mellitus with unspecified diabetic retinopathy without macular edema  |
| E11.3211 | Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, right eye  |

|          |   |
|----------|---|
| E11.3212 | Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, left eye               |
| E11.3213 | Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, bilateral              |
| E11.3219 | Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, unspecified eye        |
| E11.3291 | Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, right eye           |
| E11.3292 | Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, left eye            |
| E11.3293 | Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, bilateral           |
| E11.3299 | Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, unspecified eye     |
| E11.3311 | Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, right eye          |
| E11.3312 | Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, left eye           |
| E11.3313 | Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, bilateral          |
| E11.3319 | Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, unspecified eye    |
| E11.3391 | Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, right eye       |
| E11.3392 | Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, left eye        |
| E11.3393 | Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, bilateral       |
| E11.3399 | Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, unspecified eye |
| E11.3411 | Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, right eye            |
| E11.3412 | Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy with                                     |

|          |   |
|----------|---|
|          | macular edema, left eye   |
| E11.3413 | Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, bilateral                                |
| E11.3419 | Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, unspecified eye                          |
| E11.3491 | Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, right eye                             |
| E11.3492 | Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, left eye                              |
| E11.3493 | Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, bilateral                             |
| E11.3499 | Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, unspecified eye                       |
| E11.3511 | Type 2 diabetes mellitus with proliferative diabetic retinopathy with macular edema, right eye  |
| E11.3512 | Type 2 diabetes mellitus with proliferative diabetic retinopathy with macular edema, left eye   |
| E11.3513 | Type 2 diabetes mellitus with proliferative diabetic retinopathy with macular edema, bilateral  |
| E11.3519 | Type 2 diabetes mellitus with proliferative diabetic retinopathy with macular edema, unspecified eye                                    |
| E11.3521 | Type 2 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, right eye       |
| E11.3522 | Type 2 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, left eye        |
| E11.3523 | Type 2 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, bilateral       |
| E11.3529 | Type 2 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, unspecified eye |
| E11.3531 | Type 2 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, right eye   |
| E11.3532 | Type 2 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, left eye    |

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| E11.3533 | Type 2 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, bilateral                             |
| E11.3539 | Type 2 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, unspecified eye                       |
| E11.3541 | Type 2 diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, right eye       |
| E11.3542 | Type 2 diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, left eye        |
| E11.3543 | Type 2 diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, bilateral       |
| E11.3549 | Type 2 diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, unspecified eye |
| E11.3551 | Type 2 diabetes mellitus with stable proliferative diabetic retinopathy, right eye  |
| E11.3552 | Type 2 diabetes mellitus with stable proliferative diabetic retinopathy, left eye   |
| E11.3553 | Type 2 diabetes mellitus with stable proliferative diabetic retinopathy, bilateral  |
| E11.3559 | Type 2 diabetes mellitus with stable proliferative diabetic retinopathy, unspecified eye  |
| E11.3591 | Type 2 diabetes mellitus with proliferative diabetic retinopathy without macular edema, right eye   |
| E11.3592 | Type 2 diabetes mellitus with proliferative diabetic retinopathy without macular edema, left eye  |
| E11.3593 | Type 2 diabetes mellitus with proliferative diabetic retinopathy without macular edema, bilateral   |
| E11.3599 | Type 2 diabetes mellitus with proliferative diabetic retinopathy without macular edema, unspecified eye   |
| E13.311  | Other specified diabetes mellitus with unspecified diabetic retinopathy with macular edema  |
| E13.319  | Other specified diabetes mellitus with unspecified diabetic retinopathy without macular edema   |
| E13.3211 | Other specified diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, right eye   |

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| E13.3212 | Other specified diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, left eye               |
| E13.3213 | Other specified diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, bilateral              |
| E13.3219 | Other specified diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, unspecified eye        |
| E13.3291 | Other specified diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, right eye           |
| E13.3292 | Other specified diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, left eye            |
| E13.3293 | Other specified diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, bilateral           |
| E13.3299 | Other specified diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, unspecified eye     |
| E13.3311 | Other specified diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, right eye          |
| E13.3312 | Other specified diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, left eye           |
| E13.3313 | Other specified diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, bilateral          |
| E13.3319 | Other specified diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, unspecified eye    |
| E13.3391 | Other specified diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, right eye       |
| E13.3392 | Other specified diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, left eye        |
| E13.3393 | Other specified diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, bilateral       |
| E13.3399 | Other specified diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, unspecified eye |
| E13.3411 | Other specified diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, right eye            |
| E13.3412 | Other specified diabetes mellitus with severe nonproliferative diabetic  |

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|          | retinopathy with macular edema, left eye   |
| E13.3413 | Other specified diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, bilateral                                |
| E13.3419 | Other specified diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, unspecified eye                          |
| E13.3491 | Other specified diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, right eye                             |
| E13.3492 | Other specified diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, left eye                              |
| E13.3493 | Other specified diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, bilateral                             |
| E13.3499 | Other specified diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, unspecified eye                       |
| E13.3511 | Other specified diabetes mellitus with proliferative diabetic retinopathy with macular edema, right eye  |
| E13.3512 | Other specified diabetes mellitus with proliferative diabetic retinopathy with macular edema, left eye   |
| E13.3513 | Other specified diabetes mellitus with proliferative diabetic retinopathy with macular edema, bilateral  |
| E13.3519 | Other specified diabetes mellitus with proliferative diabetic retinopathy with macular edema, unspecified eye                                    |
| E13.3521 | Other specified diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, right eye       |
| E13.3522 | Other specified diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, left eye        |
| E13.3523 | Other specified diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, bilateral       |
| E13.3529 | Other specified diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, unspecified eye |
| E13.3531 | Other specified diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, right eye   |
| E13.3532 | Other specified diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, left eye    |

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| E13.3533 | Other specified diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, bilateral                             |
| E13.3539 | Other specified diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, unspecified eye                       |
| E13.3541 | Other specified diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, right eye       |
| E13.3542 | Other specified diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, left eye        |
| E13.3543 | Other specified diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, bilateral       |
| E13.3549 | Other specified diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, unspecified eye |
| E13.3551 | Other specified diabetes mellitus with stable proliferative diabetic retinopathy, right eye  |
| E13.3552 | Other specified diabetes mellitus with stable proliferative diabetic retinopathy, left eye   |
| E13.3553 | Other specified diabetes mellitus with stable proliferative diabetic retinopathy, bilateral  |
| E13.3559 | Other specified diabetes mellitus with stable proliferative diabetic retinopathy, unspecified eye  |
| E13.3591 | Other specified diabetes mellitus with proliferative diabetic retinopathy without macular edema, right eye   |
| E13.3592 | Other specified diabetes mellitus with proliferative diabetic retinopathy without macular edema, left eye  |
| E13.3593 | Other specified diabetes mellitus with proliferative diabetic retinopathy without macular edema, bilateral   |
| E13.3599 | Other specified diabetes mellitus with proliferative diabetic retinopathy without macular edema, unspecified eye   |
| H34.8110 | Central retinal vein occlusion, right eye, with macular edema  |
| H34.8120 | Central retinal vein occlusion, left eye, with macular edema   |

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| H34.8130 | Central retinal vein occlusion, bilateral, with macular edema                  |
| H34.8190 | Central retinal vein occlusion, unspecified eye, with macular edema            |
| H34.8310 | Tributary (branch) retinal vein occlusion, right eye, with macular edema       |
| H34.8320 | Tributary (branch) retinal vein occlusion, left eye, with macular edema        |
| H34.8330 | Tributary (branch) retinal vein occlusion, bilateral, with macular edema       |
| H34.8390 | Tributary (branch) retinal vein occlusion, unspecified eye, with macular edema |
| H35.101  | Retinopathy of prematurity, unspecified, right eye                             |
| H35.102  | Retinopathy of prematurity, unspecified, left eye                              |
| H35.103  | Retinopathy of prematurity, unspecified, bilateral                             |
| H35.109  | Retinopathy of prematurity, unspecified, unspecified eye                       |
| H35.111  | Retinopathy of prematurity, stage 0, right eye                                 |
| H35.112  | Retinopathy of prematurity, stage 0, left eye                                  |
| H35.113  | Retinopathy of prematurity, stage 0, bilateral                                 |
| H35.119  | Retinopathy of prematurity, stage 0, unspecified eye                           |
| H35.121  | Retinopathy of prematurity, stage 1, right eye                                 |
| H35.122  | Retinopathy of prematurity, stage 1, left eye                                  |
| H35.123  | Retinopathy of prematurity, stage 1, bilateral                                 |
| H35.129  | Retinopathy of prematurity, stage 1, unspecified eye                           |
| H35.131  | Retinopathy of prematurity, stage 2, right eye                                 |
| H35.132  | Retinopathy of prematurity, stage 2, left eye                                  |
| H35.133  | Retinopathy of prematurity, stage 2, bilateral                                 |
| H35.139  | Retinopathy of prematurity, stage 2, unspecified eye                           |
| H35.141  | Retinopathy of prematurity, stage 3, right eye                                 |
| H35.142  | Retinopathy of prematurity, stage 3, left eye                                  |
| H35.143  | Retinopathy of prematurity, stage 3, bilateral                                 |
| H35.149  | Retinopathy of prematurity, stage 3, unspecified eye                           |

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| H35.151  | Retinopathy of prematurity, stage 4, right eye  |
| H35.152  | Retinopathy of prematurity, stage 4, left eye   |
| H35.153  | Retinopathy of prematurity, stage 4, bilateral  |
| H35.159  | Retinopathy of prematurity, stage 4, unspecified eye  |
| H35.161  | Retinopathy of prematurity, stage 5, right eye  |
| H35.162  | Retinopathy of prematurity, stage 5, left eye   |
| H35.163  | Retinopathy of prematurity, stage 5, bilateral  |
| H35.169  | Retinopathy of prematurity, stage 5, unspecified eye  |
| H35.3113 | Nonexudative age-related macular degeneration, right eye, advanced atrophic without subfoveal involvement       |
| H35.3114 | Nonexudative age-related macular degeneration, right eye, advanced atrophic with subfoveal involvement          |
| H35.3123 | Nonexudative age-related macular degeneration, left eye, advanced atrophic without subfoveal involvement        |
| H35.3124 | Nonexudative age-related macular degeneration, left eye, advanced atrophic with subfoveal involvement           |
| H35.3133 | Nonexudative age-related macular degeneration, bilateral, advanced atrophic without subfoveal involvement       |
| H35.3134 | Nonexudative age-related macular degeneration, bilateral, advanced atrophic with subfoveal involvement          |
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| H35.3193 | Nonexudative age-related macular degeneration, unspecified eye, advanced atrophic without subfoveal involvement |
| H35.3194 | Nonexudative age-related macular degeneration, unspecified eye, advanced atrophic with subfoveal involvement    |
| H35.3210 | Exudative age-related macular degeneration, right eye, stage unspecified  |
| H35.3211 | Exudative age-related macular degeneration, right eye, with active choroidal neovascularization                 |
| H35.3212 | Exudative age-related macular degeneration, right eye, with inactive choroidal neovascularization               |
| H35.3213 | Exudative age-related macular degeneration, right eye, with inactive scar                                       |

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| H35.3220 | Exudative age-related macular degeneration, left eye, stage unspecified                                 |
| H35.3221 | Exudative age-related macular degeneration, left eye, with active choroidal neovascularization          |
| H35.3222 | Exudative age-related macular degeneration, left eye, with inactive choroidal neovascularization        |
| H35.3223 | Exudative age-related macular degeneration, left eye, with inactive scar                                |
| H35.3230 | Exudative age-related macular degeneration, bilateral, stage unspecified                                |
| H35.3231 | Exudative age-related macular degeneration, bilateral, with active choroidal neovascularization         |
| H35.3232 | Exudative age-related macular degeneration, bilateral, with inactive choroidal neovascularization       |
| H35.3233 | Exudative age-related macular degeneration, bilateral, with inactive scar                               |
| H35.3290 | Exudative age-related macular degeneration, unspecified eye, stage unspecified                          |
| H35.3291 | Exudative age-related macular degeneration, unspecified eye, with active choroidal neovascularization   |
| H35.3292 | Exudative age-related macular degeneration, unspecified eye, with inactive choroidal neovascularization |
| H35.3293 | Exudative age-related macular degeneration, unspecified eye, with inactive scar                         |

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#### Clinical Guideline Revision / History Information

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