

C03 Diabetic Macular Edema (DME)

Construct a diagnosis concept set for *Diabetic Macular Edema (DME)*—macular thickening and/or intra-/sub-retinal fluid explicitly attributable to diabetes mellitus—to support a treatment-anchored phenotype. The set must capture *current, clinically active* DME.

This concept set will support an observational study that aims to answer the following research question:

Among adult diabetic patients on drug-a anti-diabetic medication what is the incidence rate of developing *Diabetic Macular Edema (DME)*.

The concept set will be used in the phenotype of the outcome *Diabetic Macular Edema (DME)*.

Clinical case definition: Retinal thickening and/or intra/sub-retinal fluid in the macula due to diabetes mellitus (type 1 or 2). Diagnostic criteria is confirmed through OCT evidence of macular thickening and/or intra/sub-retinal fluid.

Presentation & Course: Blurred vision, metamorphopsia; may be asymptomatic early. Often chronic, managed with anti-VEGF, steroids, and/or focal/grid laser; treat-and-extend or PRN patterns are common.

Differential Diagnoses (Conditions to be distinguished and not considered inclusive)

- Neovascular age-related macular degeneration (nAMD)
- Retinal vein occlusions (CRVO/BRVO) with macular edema
- Polypoidal choroidal vasculopathy; myopic CNV
- Post-operative cystoid macular edema (Irvine–Gass)
- Uveitic cystoid macular edema
- Unspecified macular edema without diabetic attribution

Common Treatments/Management: Intravitreal anti-VEGF; intravitreal/periocular corticosteroids (dexamethasone, fluocinolone implants); focal/grid macular laser; serial OCT monitoring.

Clinical Scope and Granularity

- **Disease entity:** Diabetes-attributable macular edema characterized by retinal thickening and/or intra/sub-retinal fluid at the macula; typical presentation includes blurred vision and metamorphopsia. Clinical confirmation commonly relies on OCT; management includes intravitreal anti-VEGF, corticosteroid implants, and/or focal/grid laser.
- **Temporality:** Incidence and **current** disease; historical or resolved disease alone is out of scope.

- **Severity & acuity:** All severities (center-involved or non-center-involved; unilateral or bilateral) are in scope when DME is explicitly diagnosed.
- **Manifestations:** Diabetic retinopathy that is explicitly linked to macular edema. Both laterality or “center-involved” are within scope.
- **Etiology:** Restrict to DME due to type 1 or type 2 diabetes; macular edema from other causes (post-operative, uveitic, retinal vein occlusion, neovascular AMD, myopic/PCV CNV) are not within scope.
- **Population:** Adults with diabetes; pediatric use is not targeted by this concept set.

Related, differential conditions or comorbidities that are not sufficient for inclusion

- Neovascular age-related macular degeneration.
- Retinal vein occlusions (CRVO/BRVO) with macular edema.
- Polypoidal choroidal vasculopathy; myopic choroidal neovascularization.
- Post-operative cystoid macular edema (Irvine–Gass); uveitic cystoid macular edema.
- Unspecified macular edema without diabetic linkage.
- Diabetic retinopathy without macular edema.

Synonyms

- Diabetic macular edema (DME)
- Diabetic retinopathy with macular edema
- Diabetic maculopathy with macular edema/ “with macular edema” modifiers
- Center-involved DME (CI-DME)
- Clinically significant macular edema (CSME) — when explicitly diabetic