# Clinical Description: Diabetic Macular Edema (DME), Active Disease

**Synonyms:** Clinically Significant Macular Edema (CSME) (Historical term); Diabetic Maculopathy (Often used interchangeably when edema is the primary feature).

## 1. Clinical Case Definition

Diabetic Macular Edema (DME) is a sight-threatening microvascular complication of diabetes mellitus (Type 1 and Type 2). It results from chronic hyperglycemia leading to the breakdown of the inner blood-retinal barrier. This process is characterized by increased vascular permeability—mediated by factors such as Vascular Endothelial Growth Factor (VEGF) and inflammatory mediators—leading to the accumulation of extracellular fluid and lipoprotein exudates within the macula, the retinal area responsible for central, high-acuity vision.

Clinically, patients may be asymptomatic in early stages but commonly present with gradual, painless blurring or distortion of central vision (metamorphopsia), particularly when the edema involves the fovea (center-involved DME). Assessment involves visual acuity testing and dilated fundus examination (slit-lamp biomicroscopy). Examination findings typically include retinal thickening, microaneurysms, intraretinal hemorrhages, and hard exudates.

The diagnosis relies heavily on imaging. Optical Coherence Tomography (OCT) is the gold standard for confirming and quantifying DME. Key OCT findings indicative of active disease include increased Central Subfield Thickness (CST) (e.g., often exceeding thresholds like 300 µm), the presence of intraretinal fluid (IRF, often appearing as cysts), and/or subretinal fluid (SRF). Fluorescein Angiography (FA) may be used adjunctively to assess vascular leakage patterns (focal vs. diffuse) and identify macular ischemia. This phenotype specifically targets the active disease state characterized by the presence of edema warranting clinical management.

## 2. Phenotype Scope & Granularity

- **Temporal Context:** Prevalent; intended to identify all existing cases of active DME during the observation period.
- **Severity:** Active disease warranting clinical intervention. This scope is inclusive of treatment-naïve patients (typically center-involved) and previously treated patients with persistent or recurrent edema.
- **Acuity / Chronicity:** Focuses on the active state of fluid accumulation. This scope is not inclusive of quiescent or resolved DME where retinal anatomy is stable.
- **Etiology:** Secondary to Diabetes Mellitus (Type 1 or Type 2).
- **Population Context:** Adult patients with an established diagnosis of Diabetes Mellitus.

## 3. Related Conditions & Scope Boundaries

The following conditions represent related pathologies or differential diagnoses for macular edema but are not precisely within the scope of this specific phenotype:

- **Diabetic Retinopathy (DR) without Macular Edema:** While DR (non-proliferative or proliferative) is the underlying condition, this phenotype specifically requires the presence of edema involving the macula.
- **Non-Diabetic Macular Edema:** Macular edema primarily attributable to other etiologies is outside the scope of this diabetes-specific phenotype. These include:
    - Retinal Vein Occlusion (RVO)
    - Uveitis (inflammatory macular edema)
    - Irvine-Gass Syndrome (post-surgical macular edema)
    - Age-related Macular Degeneration (AMD)

## 4. Key Complications & Common Comorbidities

The following conditions are common comorbidities or complications associated with DME, but should be recognized as distinct clinical entities, separate from the core definition of the macular edema itself.

- **Complications:**
    - Moderate to severe vision loss
- **Common Comorbidities / Associated Conditions:**
    - Diabetic Retinopathy (Non-proliferative and Proliferative)
    - Hypertension
    - Chronic Kidney Disease
    - Cataracts
    - Glaucoma

## 5. Intended Data Sources

This clinical description is intended for building concept sets against real-world administrative claims, electronic health record (EHR) databases, and patient registries. The target data should be standardized to the OMOP Common Data Model. Examples of licensable data sources where this concept set would be applied include:

- **Optum®** (Clinformatics® Data Mart, SES, Pan-Therapeutic)
- **Merative™** (MarketScan® Commercial Claims and Encounters)
- **Veradigm** (Health Verity, Practice Fusion EHR)
- **IQVIA** (AmbEMR, PharMetrics Plus)
- **HealthVerity**