SAMPLE LETTER OF MEDICAL NECESSITY

(This sample letter is for reference purposes only and is not intended to be a substitute for the independent medical judgment of the prescriber. Use of information in this letter does not guarantee coverage, reimbursement, or payment of any claim.)

[Date]

[Attention, Claims Department Contact]
[Payer]
[Address]
[City, State, Zip Code]

Re: Authorization for ILUVIEN® (fluocinolone acetonide intravitreal implant) 0.19 mg for the treatment of diabetic macular edema

[Patient Name]
[Subscriber ID Number]
[Policy Number]
[Group Number]

Dear [Payer contact name],

I am writing on behalf of my patient, [Patient's name], to demonstrate the medical necessity of ILUVIEN. This letter provides clinical justification for prescribing ILUVIEN and supporting documentation, including relevant information about the patient's history, diagnosis, and prior treatments. In addition, I have attached a copy of the product's label information.

Clinical Information

[Patient's name] was diagnosed with diabetic macular edema on [date]. This disease has resulted in [explain symptoms and impact on quality of life, particularly calling out impact on visual acuity]. [If appropriate, describe patient's experience with other medications to treat diabetic macular edema.]

Treatment and Therapeutic Rationale

ILUVIEN was approved by the FDA on September 26, 2014. ILUVIEN is an intravitreal implant designed to deliver a sustained amount of fluocinolone acetonide, a synthetic corticosteroid, and is indicated for the treatment of diabetic macular edema in patients who have been previously treated with a course of corticosteroids and did not have a clinically significant rise in intraocular pressure. In clinical trials, ILUVIEN was shown to be effective in improving visual acuity. [Patient's name] is an appropriate candidate for ILUVIEN based on their [describe previous use of corticosteroids] with no clinically significant rise in intraocular pressure.

By treating [Patient's name] with ILUVIEN, I expect [describe expected clinical benefits]. [Describe any past experiences with ILUVIEN, if appropriate.]

In summary, I believe ILUVIEN is medically necessary and appropriate for [Patient's name]. Please do not hesitate to contact me directly at [contact phone number]. I would appreciate your prompt attention and approval of this therapy.

Sincerely,

[Physician name]

Enclosures [Suggested]: ILUVIEN package insert and supportive medical records