ani Pharmaceuticals, Inc.

Sample LETTER OF MEDICAL NECESSITY Template for ILUVIEN (fluocinolone acetonide intravitreal implant) 0.19 mg

Purpose: This sample letter of medical necessity on page 4 of this document may be used on behalf of your patient as a guide to provide the insurance company your clinical rationale for your patient to be treated with ILUVIEN. The letter should provide detailed, patient-specific information explaining why ILUVIEN was prescribed to the patient and should include information that can be used to assess whether the medication may be approved. This letter does not guarantee that the insurance company will cover ILUVIEN and is intended for guidance purposes only.

Instructions: Update the **blue text** with pertinent information, such as the patient's clinical information and insurance company information, as well as your office's information. Include an appropriate ICD-10-CM code matching your patient's diagnosis. Additional supporting documentation may be required by the insurance company and can include the following: patient's medical records, peer-reviewed literature, supporting clinical studies, prescribing information for ILUVIEN, and/or clinical notes (including prior therapies).

INDICATIONS

ILUVIEN is a corticosteroid indicated for:

- the treatment of diabetic macular edema (DME) in patients who have been previously treated with a course of corticosteroids and did not have a clinically significant rise in intraocular pressure
- the treatment of chronic non-infectious uveitis affecting the posterior segment of the eye

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

- ILUVIEN is contraindicated in patients with active or suspected ocular or periocular infections including most viral disease of the cornea and conjunctiva including active epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, varicella, mycobacterial infections and fungal diseases.
- ILUVIEN is contraindicated in patients with glaucoma who have cup to disc ratios of greater than 0.8.
- ILUVIEN is contraindicated in patients with known hypersensitivity to any components of this product.

WARNINGS AND PRECAUTIONS

- **Intravitreal Injection-related Effects:** Intravitreal injections, including those with ILUVIEN, have been associated with endophthalmitis, eye inflammation, increased or decreased intraocular pressure, and choroidal or retinal detachments. For patients with non-infectious uveitis affecting the posterior segment, hypotony has been observed within 24 hours of injection and has resolved within 2 weeks. Patients should be monitored following the intravitreal injection. Patients may experience temporary blurred vision after injection of the implant.
- **Intraocular Pressure (IOP) Increase:** Prolonged use of corticosteroids may result in the development of glaucoma with damage to the optic nerve, defects in visual acuity and fields of vision. Steroids should be used with caution in the presence of glaucoma. Intraocular pressure should be routinely monitored during the course of the treatment.
- **Cataracts:** The use of corticosteroids may result in posterior subcapsular cataract formation.
- **Delayed Corneal Wound Healing:** The use of corticosteroids after cataract surgery may delay healing and increase the incidence of bleb formation.

IMPORTANT SAFETY INFORMATION (cont.)

WARNINGS AND PRECAUTIONS (cont.)

- **Corneal and Scleral Melting:** Various ocular diseases and long-term use of topical corticosteroids have been known to cause corneal and scleral thinning. Use of ophthalmic corticosteroids in the presence of thin corneal or scleral tissue may lead to perforation of the globe.
- **Bacterial Infections:** Prolonged use of corticosteroids may suppress the host response and thus increase the hazard of secondary ocular infections. Acute purulent or parasitic infections of the eye may be masked or activity enhanced by the presence of corticosteroid medication. If signs and symptoms fail to improve after 2 days, the patient should be reevaluated.
- **Viral Infections:** Use of ocular corticosteroids may prolong the course and may exacerbate the severity of many viral infections of the eye (including herpes simplex). Employment of a corticosteroid medication in the treatment of patients with a history of herpes simplex requires great caution; frequent slit lamp microscopy is recommended.
- **Fungal Infections:** Fungal infections of the cornea are particularly prone to develop coincidentally with long-term local corticosteroid application. Fungus invasion should be suspected in any persistent corneal ulceration where a corticosteroid has been used or is in use. Fungal cultures should be taken when appropriate.
- **Risk of Implant Migration:** Patients in whom the posterior capsule of the lens is absent or has a tear are at risk of implant migration into the anterior chamber.

ADVERSE REACTIONS

Diabetic Macular Edema

Ocular adverse reactions reported by greater than or equal to 1% of patients in the two combined 3-year clinical trials following injection of ILUVIEN for diabetic macular edema include: cataract (82%), myodesopsia (21%), eye pain (15%), conjunctival hemorrhage (13%), posterior capsule opacification (9%), eye irritation (8%), vitreous detachment (7%), conjunctivitis (4%), corneal oedema (4%), foreign body sensation in eyes (3%), eye pruritus (3%), ocular hyperaemia (3%), optic atrophy (2%), ocular discomfort (2%), photophobia (2%), retinal exudates (2%), anterior chamber cell (2%), and eye discharge (2%). Non-ocular adverse reactions reported by greater than or equal to 5% of patients include: anemia (11%), headache (9%), renal failure (9%), and pneumonia (7%).

Increased Intraocular Pressure: IOP elevation greater than or equal to 10 mm Hg from baseline at any visit was seen in 34% of ILUVIEN patients versus 10% of sham patients. IOP elevation greater than or equal to 30 mm Hg was seen in 20% of ILUVIEN patients versus 4% of sham patients. 38% of the patients who received ILUVIEN were subsequently treated with IOP-lowering medications during the study versus 14% of sham patients. 5% of the patients who received ILUVIEN needed surgical intervention for elevated IOP versus 1% of sham patients.

Cataracts and Cataract Surgery: The incidence of cataract development in patients who had a phakic study eye was higher in the ILUVIEN group (82%) compared with sham (50%). The median time of cataract being reported as an adverse event was approximately 12 months in the ILUVIEN group and 19 months in the sham group. Among these patients, 80% of ILUVIEN subjects versus 27% of sham-controlled subjects underwent cataract surgery, generally within the first 18 months (median month 15 for both ILUVIEN group and for sham) of the studies.

IMPORTANT SAFETY INFORMATION (cont.)

ADVERSE REACTIONS (cont.)

Chronic Non-Infectious Uveitis Affecting the Posterior Segment of the Eye

Ocular adverse reactions reported by greater than or equal to 1% of patients in the three combined clinical trials through 12 months following injection of fluocinolone acetonide intravitreal implant: cataract (56%), visual acuity reduced (15%), macular edema (11%), uveitis (10%), conjunctival hemorrhage (8%), eye pain (8%), hypotony of eye (7%), anterior chamber inflammation (5%), dry eye (4%), vitreous opacities (4%), conjunctivitis (4%), posterior capsule opacification (4%), ocular hyperemia (4%), vitreous haze (3%), foreign body sensation in eyes (3%), vitritis (3%), vitreous floaters (3%), eye pruritus (3%), conjunctival hyperemia (2%), ocular discomfort (2%), macular fibrosis (2%), glaucoma (2%), photopsia (2%), vitreous hemorrhage (2%), iridocyclitis (1%), eye inflammation (1%), choroiditis (1%), eye irritation (1%), visual field defect (1%), and lacrimation increased (1%). Non-ocular adverse reactions reported by greater than or equal to 2% of patients include: nasopharyngitis (5%), hypertension (3%), and arthralgia (2%).

Increased Intraocular Pressure: IOP elevation greater than or equal to 10 mm Hg from baseline at any visit was seen in 22% of fluocinolone acetonide patients versus 12% of sham patients. IOP elevation greater than or equal to 30 mm Hg was seen in 12% of fluocinolone acetonide patients versus 3% of sham patients. 43% of the patients who received fluocinolone acetonide were subsequently treated with IOP-lowering medications during the study versus 41% of sham patients. 2% of the patients who received fluocinolone acetonide needed surgical intervention for elevated IOP versus 2% of sham patients.

Please see Important Safety Information for ILUVIEN on pages 1-3. Please see accompanying full Prescribing Information or visit Iluvien.com.

ILUVIEN®
(fluocinolone acetonide intravitreal implant) 0.19mg

[Use Provider's Letterhead]

[Date]

[Insurance Company Contact Name]
[Insurance Company Contact Name Title]
[Insurance Company Organization Name]
[Address]
[City, State ZIP]

Re: Medical Necessity for ILUVIEN (fluocinolone acetonide intravitreal implant) 0.19 mg for [Patient Name]
Insurance Policy ID Number: **[Insurance Policy ID Number]**
Group Number: **[Group Number]**

Dear **[Insurance Company Contact Name]**,

This letter serves as an explanation of medical necessity for coverage of ILUVIEN, as treatment for **[insert indication]**, for my patient **[Patient Name]**.

Diagnosis: **[Insert information regarding the diagnosis, appropriate ICD-10-CM code matching your patient's diagnosis, etc.]**

Clinical course of disease: **[Insert detailed information regarding disease progression, symptoms, etc.]**

Previous treatments: **[Patient Name]** is still symptomatic following previous treatments. They **[insert description of patient experience with prior treatments, specifically corticosteroids]** the following alternative medications **[insert drug name(s)]**, because they experienced **[insert treatment outcome]**.

Despite various therapeutic interventions to manage the symptoms of **[insert indication]**, my patient's visual acuity continues to decline.

ILUVIEN is FDA-approved for the treatment of **[insert patient's relevant indication]**.

In summary, ILUVIEN is medically necessary for **[Patient Name]**, and I am requesting coverage for this medication. Please contact me at **[insert phone number or email]** if additional information is required.

Sincerely,

[Insert provider's name, credentials, and signature]

Enclosures: **[Attach any additional clinical documentation such as relevant clinical notes, ILUVIEN prescribing information, or other information as required in the payer's policy or per your clinical judgment to support your request.]**