Sample LETTER OF APPEALS Template for ILUVIEN® (fluocinolone acetonide intravitreal implant) 0.19 mg for *diabetic macular edema (DME)* or *chronic non-infectious uveitis affecting the posterior segment of the eye (chronic NIU-PS)*

Purpose: This template may be used as a guide to submit an appeal request after the insurance company has denied coverage for ILUVIEN. The letter should provide detailed, patient-specific information explaining why ILUVIEN is medically necessary for your patient. This letter is intended as an example for consideration and may not include all the information necessary to support an appeal of the denial of coverage for your patient. The information required for an appeal may vary based on the health plan guidelines and patient benefit design. Please note that you, as the requesting provider, are solely responsible for ensuring the accuracy and completeness of all information submitted, as well as any and all medical judgments related to that information.

Instructions: Carefully review the reason for the denial of coverage or submitted claim. Within the template letter, select the scenario outlined in *pink text* that most closely matches the reason for your denial. Delete the text describing other denial scenarios that do not apply. Review the **blue text** for additional considerations and update it with pertinent details, such as the patient's clinical and insurance information, as well as your office's information. 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). Please include any documentation from the insurance company detailing their coverage determination.

ILUVIEN INDICATIONS AND IMPORTANT SAFETY INFORMATION

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.

IMPORTANT SAFETY INFORMATION (cont.)

WARNINGS AND PRECAUTIONS (cont.)

- **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.
- **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.

YUTIQ INDICATIONS AND IMPORTANT SAFETY INFORMATION

INDICATION

YUTIQ® (fluocinolone acetonide intravitreal implant) 0.18 mg is indicated for the treatment of chronic non-infectious uveitis affecting the posterior segment of the eye.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

- **Ocular or Periocular Infections:** YUTIQ 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.
- **Hypersensitivity:** YUTIQ 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 YUTIQ, have been associated with endophthalmitis, eye inflammation, increased or decreased intraocular pressure, and choroidal or retinal detachments. Hypotony has been observed within 24 hours of injection and has resolved within 2 weeks. Patients should be monitored following the intravitreal injection.
- **Steroid-related Effects:** Use of corticosteroids including YUTIQ may produce posterior subcapsular cataracts, increased intraocular pressure and glaucoma. Use of corticosteroids may enhance the establishment of secondary ocular infections due to bacteria, fungi, or viruses. Corticosteroids are not recommended to be used in patients with a history of ocular herpes simplex because of the potential for reactivation of the viral infection.
- **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.

Please see Important Safety Information for YUTIQ on pages 3-4. Please see accompanying full Prescribing Information or visit Yutiq.com.

IMPORTANT SAFETY INFORMATION (cont.)

ADVERSE REACTIONS

- In controlled studies, the most common adverse reactions reported were cataract development and increases in intraocular pressure.

Please see Important Safety Information for YUTIQ on pages 3-4. Please see accompanying full Prescribing Information or visit Yutiq.com.

ILUVIEN®
(fluocinolone acetonide intravitreal implant) 0.19mg

[Use Provider's Letterhead]

[Date]

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

Re: Appeal of Coverage Denial of ILUVIEN (fluocinolone acetonide intravitreal implant) 0.19 mg for [Patient Name]
Insurance Policy ID Number: **[Insurance Policy ID Number]**
Group Number: **[Group Number]**
Case ID Number: **[Case ID Number]**

Dear **[Insurance Company Name]**,

This letter serves as an appeal to reconsider your denial of **[coverage or submitted claim]** for ILUVIEN (fluocinolone acetonide intravitreal implant) 0.19 mg for my patient, **[Patient Name]**, as treatment for **[insert specific indication: diabetic macular edema (DME) or chronic non-infectious uveitis affecting the posterior segment of the eye (chronic NIU-PS)]**. You have indicated on **[insert date of denial decision]** that ILUVIEN is not covered because **[insert reason for denial]**. Please see the additional information below to support the use of ILUVIEN for **[Patient Name]**.

[For a denial of coverage, please select one or more relevant denial reasons below and delete the others]

[If the denial reason is related to lack of or insufficient prior treatment history] **[Patient Name]** is still symptomatic following previous treatments. They **[insert description of patient experience with prior treatments, specifically corticosteroids for DME]** to the following alternative medications **[insert drug name(s)]**, because they experienced **[insert treatment outcome]**. Limited intravitreal treatment options exist that are designed to deliver a continuous low dose of fluocinolone acetonide (FAc) for up to 3 years for patients with **[insert specific indication: diabetic macular edema (DME) or uveitis]** who need another treatment option following standard of care treatments.

[If the denial reason is related to lack of clinical evidence of ILUVIEN for chronic NIU-PS or lack of bioequivalency of ILUVIEN with YUTIQ] ILUVIEN is FDA-approved for chronic NIU-PS. The efficacy of fluocinolone acetonide (FAc) intravitreal implant was demonstrated in two randomized, double-masked, parallel-group clinical trials in patients with NIU-PS (NCT #01694186 and #02746991). FAc significantly reduced the proportion of patients experiencing a recurrence of uveitis within 6 months of follow-up compared with sham. **[If the denial letter specifically mentions YUTIQ]** According to the FDA, ILUVIEN is bioequivalent to YUTIQ (fluocinolone acetonide intravitreal implant). To minimize patient disruption following the discontinuation of YUTIQ, it is important to update the current ILUVIEN medical policy to include coverage for chronic NIU-PS promptly. As a result, ILUVIEN is an important treatment option for **[Patient Name]**.

[If the denial reason is related to drug not in the formulary/nonformulary item.] I would like to request an exception to cover ILUVIEN because I believe it is medically necessary for **[Patient Name]**. **[If a specific form for a formulary exception is required by the insurance company, as noted on their website, please locate and complete the form, and attach it to this letter. If a form is not required, please delete the following statement.]** Please refer to the attached formulary exception request form. **[Insert detailed information regarding patient's condition, specific diagnosis, appropriate ICD-10-CM code matching your patient's diagnosis, and any other relevant clinical information to support the medical necessity]**. Limited intravitreal treatment options exist that are designed to deliver a continuous low dose of fluocinolone acetonide for up to 3 years. ILUVIEN provides an available option for patients who need intravitreal corticosteroid treatment.

[For any other denial reason] **[Insert detailed information to support the medical necessity]**

[For a denial of a submitted claim for reimbursement, please select one or more relevant denial reasons below and delete the others]

[If the denial claim is related to billing/clerical errors such as inaccurate coding, etc] **[Insert explanation/rationale as a supplement to submitting the correction of the error and consider outreach to AccessPlus Program at 1-844-445-8843]**

[If the denial claim is related to insufficient documentation for medical necessity] **[Insert explanation/rationale as a supplement to the additional required documentation]**

[For any other denial reason] **[Insert detailed information to support the medical necessity]**

ILUVIEN is medically necessary for **[Patient Name]**. I respectfully request that a specialist at your organization familiar with this disease and therapeutic area review this appeal letter with the additional information provided prior to making a final decision on coverage. If you require any additional information to support your reconsideration, please contact me at **[insert phone number and/or email]**.

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.]**