

SAMPLE Letter of Appeals

This is intended as a TEMPLATE Letter of Appeal

[Contact name of Pharmacy Director or other payer representative]

[Contact title]

[Name of health insurance company]

[Address]

[City, State, Zip]

Dear [Contact name],

I am writing on behalf of my patient, [Patient name], to request an appeal of the claim denial for the administration of ELAHERE™ (mirvetuximab soravtansine-gynx) for the treatment of adult patients with FR α -positive, platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer.

[Payer name] has indicated the reason for denial, which was explained in the Explanation of Benefits, was [Reason for denial from Explanation of Benefits].

As you may be aware, ELAHERE is intended to be used as a treatment for adult patients who have received one to three prior systemic treatment regimens. My patient, [Patient name], has received a diagnosis of [patient diagnosis], by an FDA-approved diagnostic, and has exhausted all other treatment options thus far (see medical history below and attached).

ELAHERE was approved by the US Food and Drug Administration on [Month Day, Year], for adult patients with FR α -positive, platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer who have received 1 to 3 systemic treatment regimens. The major efficacy results from the single-arm clinical study (Study 0417, NCT04296890) were investigator-assessed objective response rate and durability of response evaluated according to Response Evaluation Criteria in Solid Tumors (RECIST), version 1.1.¹

For the reasons stated above, I am requesting a waiver of this requirement within your medical prior authorization policy for this patient. For additional patient medical history and diagnosis information, please see below.

INDICATIONS AND USAGE

ELAHERE is indicated for the treatment of adult patients with folate receptor-alpha (FR α) positive, platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer, who have received one to three prior systemic treatment regimens. Select patients for therapy based on an FDA-approved test.

This indication is approved under accelerated approval based on tumor response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

IMPORTANT SAFETY INFORMATION

BOXED WARNING: OCULAR TOXICITY

- ELAHERE can cause severe ocular toxicities, including visual impairment, keratopathy, dry eye, photophobia, eye pain, and uveitis.
- Conduct an ophthalmic exam including visual acuity and slit lamp exam prior to initiation of ELAHERE, every other cycle for the first 8 cycles, and as clinically indicated.
- Administer prophylactic artificial tears and ophthalmic topical steroids.
- Withhold ELAHERE for ocular toxicities until improvement and resume at the same or reduced dose.
- Discontinue ELAHERE for Grade 4 ocular toxicities.

Patient medical history and diagnosis

[Patient name] is a [age]-year-old diagnosed with [patient diagnosis] (on [Month Day, Year]). [Patient name] has been in my care since [Month Day, Year], and in my clinical judgment requires treatment with ELAHERE. [Discuss clinical history and treatment plan, including information such as patient's condition, treatment history, recommended treatment course, rationale for using product, and potential impact if they don't receive this therapy].

Based on the facts provided above, ELAHERE is indicated and medically necessary for the treatment of this patient. Therefore, I respectfully request that [Payer name] cover ELAHERE when prescribed for [Patient name].

Please refer to the enclosed supporting documents for further details, and please don't hesitate to contact me at [Telephone number] if you have any further questions regarding this request.

Thank you for your prompt attention to this matter.

Sincerely,
[Doctor's name], [MD]

cc: [Patient name]

Optional enclosures: FDA Approval Letter, ELAHERE Prescribing Information, and clinical notes and records.

IMPORTANT SAFETY INFORMATION (CONT'D)

WARNINGS and PRECAUTIONS

Ocular Disorders

ELAHERE can cause severe ocular adverse reactions, including visual impairment, keratopathy (corneal disorders), dry eye, photophobia, eye pain, and uveitis.

Ocular adverse reactions occurred in 61% of patients with ovarian cancer treated with ELAHERE. Nine percent (9%) of patients experienced Grade 3 ocular adverse reactions, including visual impairment, keratopathy/keratitis (corneal disorders), dry eye, photophobia, and eye pain; and one patient (0.2%) experienced Grade 4 keratopathy. The most common ($\geq 5\%$) ocular adverse reactions were visual impairment (49%), keratopathy (36%), dry eye (26%), cataract (15%), photophobia (13%), and eye pain (12%).

The median time to onset for first ocular adverse reaction was 1.2 months (range: 0.03 to 12.9). Of the patients who experienced ocular events, 49% had complete resolution and 39% had partial improvement (defined as a decrease in severity by one or more grades from the worst grade) at last follow up. Ocular adverse reactions led to permanent discontinuation of ELAHERE in 0.6% of patients.

Premedication and use of lubricating and ophthalmic topical steroid eye drops during treatment with ELAHERE are recommended. Advise patients to avoid use of contact lenses during treatment with ELAHERE unless directed by a healthcare provider.

Refer patients to an eye care professional for an ophthalmic exam including visual acuity and slit lamp exam prior to treatment initiation, every other cycle for the first 8 cycles, and as clinically indicated. Promptly refer patients to an eye care professional for any new or worsening ocular signs and symptoms.

Monitor for ocular toxicity and withhold, reduce, or permanently discontinue ELAHERE based on severity and persistence of ocular adverse reactions.

Pneumonitis

Severe, life-threatening, or fatal interstitial lung disease (ILD), including pneumonitis, can occur in patients treated with ELAHERE. Pneumonitis occurred in 10% of patients treated with ELAHERE, including 0.8% with Grade 3 events, and 1 patient (0.2%) with a Grade 4 event. One patient (0.2%) died due to respiratory failure in the setting of pneumonitis and lung metastases.

Monitor patients for pulmonary signs and symptoms of pneumonitis. Infectious, neoplastic, and other causes for symptoms should be excluded through appropriate investigations.

Withhold ELAHERE for patients who develop persistent or recurrent Grade 2 pneumonitis until symptoms resolve to \leq Grade 1 and consider dose reduction. Permanently discontinue ELAHERE in all patients with Grade 3 or 4 pneumonitis. Patients who are asymptomatic may continue dosing of ELAHERE with close monitoring.

Peripheral Neuropathy (PN)

PN occurred in 36% of patients with ovarian cancer treated with ELAHERE across clinical trials; 2% of patients experienced Grade 3 PN. PN adverse reactions included peripheral neuropathy (19%), peripheral sensory neuropathy (9%), paraesthesia (6%), neurotoxicity (3%), hypoaesthesia (2%), peripheral motor neuropathy (1%), neuralgia (0.4%), polyneuropathy (0.2%) and oral hypoaesthesia (0.2%).

Monitor patients for signs and symptoms of neuropathy. For patients experiencing new or worsening PN, withhold dosage, dose reduce, or permanently discontinue ELAHERE based on the severity of PN.

Embryo-Fetal Toxicity

Based on its mechanism of action, ELAHERE can cause embryo-fetal harm when administered to a pregnant woman because it contains a genotoxic compound (DM4) and affects actively dividing cells.

Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with ELAHERE and for 7 months after the last dose.

ADVERSE REACTIONS

Serious adverse reactions occurred in 31% of patients. The most common (\geq 2%) serious adverse reactions were intestinal obstruction (8%), ascites (4%), infection (3%), and pleural effusion (3%). Fatal adverse reactions occurred in 2% of patients, including small intestinal obstruction (1%) and pneumonitis (1%).

Permanent discontinuation of ELAHERE due to adverse reactions occurred in 11% of patients. The most common (\geq 2%) adverse reactions leading to permanent discontinuation were intestinal obstruction (2%) and thrombocytopenia (2%). One patient (0.9%) permanently discontinued ELAHERE due to visual impairment (unilateral decrease to BCVA \leq 20/200 that resolved to baseline after discontinuation).

Dosage delays of ELAHERE due to an adverse reaction occurred in 39% of patients. Adverse reactions which required dosage delays in \geq 3% of patients included visual impairment (15%), keratopathy (11%), neutropenia (6%), dry eye (5%), cataracts (3%) and increased gamma-glutamyltransferase (3%).

Dose reductions of ELAHERE due to an adverse reaction occurred in 20% of patients. Adverse reactions which required dose reductions in \geq 3% of patients included visual impairment (9%) and keratopathy (7%).

The most common ($\geq 20\%$) adverse reactions, including laboratory abnormalities, were vision impairment, fatigue, increased aspartate aminotransferase, nausea, increased alanine aminotransferase, keratopathy, abdominal pain, decreased lymphocytes, peripheral neuropathy, diarrhea, decreased albumin, constipation, increased alkaline phosphatase, dry eye, decreased magnesium, decreased leukocytes, decreased neutrophils, and decreased hemoglobin.

DRUG INTERACTIONS

Strong CYP3A4 Inhibitors

DM4 is a CYP3A4 substrate. Concomitant use of ELAHERE with strong CYP3A4 inhibitors may increase unconjugated DM4 exposure, which may increase the risk of ELAHERE adverse reactions. Closely monitor patients for adverse reactions with ELAHERE when used concomitantly with strong CYP3A4 inhibitors.

USE IN SPECIAL POPULATIONS

Lactation

Advise women not to breastfeed during treatment with ELAHERE and for at least 1 month after the last dose.

Pediatric Use

Safety and effectiveness of ELAHERE have not been established in pediatric patients.

Hepatic Impairment

Avoid use of ELAHERE in patients with moderate or severe hepatic impairment (total bilirubin >1.5 ULN).

Reference: 1. Elahere. Prescribing information. ImmunoGen, Inc; 2022.

Please see Important Safety Information throughout and full Prescribing Information, including Boxed Warning. 4