Statement of Medical Necessity for KANUMA™ (sebelipase alfa)

Patient information

First name: _____ Last name: _____

Address: _____

City: _____ State: _____ ZIP: _____

Date of birth: ____ /____ /____

Phone No: _____

☐ Home ☐ Work ☐ Cell

☐ OK to call ☐ OK to text

Gender:

☐ Male ☐ Female

☐ Prefer not to answer

Insurance information

☐ No insurance

Primary insurance: _____

Phone No: _____

Policy ID: _____ Group No: _____

Policyholder name: _____

Pharmacy plan name: _____

Rx BIN No: _____ Rx PCN No: _____

Diagnosis: LAL-D

____ /____ /____
DATE OF DIAGNOSIS

Method of diagnosis: _____

☐ LAL enzyme assay: _____ Result: _____ units _____

Testing lab reference range: ____ /____ /____ units _____

☐ Genetic analysis: _____ Mutation: _____
ALLELE 1

Mutation: _____
ALLELE 2

☐ Other: _____

Treatment recommendations

☐ KANUMA

Weight: _____ lb/kg Dosage: _____ mg/kg

Anticipated start date: ____ /____ /____

Please see Important Safety Information on reverse side.

Medical assessment

Date: ____ /____ /____ Height: ____ cm/in Weight: ____ kg/lb

Aspartate aminotransferase: _____

Alanine aminotransferase: _____

Total cholesterol: _____

Triglycerides: _____

Cholesterol: _____ _____
HIGH-DENSITY LIPOPROTEIN LOW-DENSITY LIPOPROTEIN

Bilirubin direct: _____

Bilirubin indirect: _____

Liver biopsy: ____ /____ /____

☐ Steatosis ☐ Portal fibrosis ☐ Bridging fibrosis ☐ Cirrhosis

Date: ____ /____ /____ ☐ Stroke ☐ Hepatomegaly ☐ Splenomegaly

Date: ____ /____ /____ ☐ Myocardial infarction

Treatment history

Date: ____ /____ /____ ☐ Hematopoietic stem cell transplant ☐ Liver transplant

☐ Statins: _____
DATE AND DOSAGE

☐ Ezetimibe: _____
DATE AND DOSAGE

☐ Other lipid-lowering medications: _____
DATE AND DOSAGE

☐ Glitazone: _____
DATE AND DOSAGE

☐ Other: _____
DATE AND DOSAGE

Physician authorization

I certify the above indicated therapy is medically necessary and the information provided is correct to the best of my knowledge.

Physician's name: _____ Date: ____ /____ /____
PRINTED

Address: _____ City: _____

State: ____ ZIP: _____ Phone: _____ Fax: _____

NPI No: _____ Tax ID: _____

Office contact name: _____

CLICK TO ENABLE DOCUSIGN OR PRINT TO SIGN ____ /____ /____
Physician's signature DATE

Once this form is completed, please send it to Alexion to be processed. Fax: 1-800-420-5150 Email: Kanuma.CM@alxn.com

Important Safety Information

INDICATIONS AND USAGE

KANUMA™ (sebelipase alfa) is indicated for the treatment of patients with a diagnosis of Lysosomal Acid Lipase Deficiency (LAL-D).

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

None.

WARNINGS AND PRECAUTIONS

Hypersensitivity Reactions Including Anaphylaxis:

Hypersensitivity reactions, including anaphylaxis, have been reported in KANUMA-treated patients. In clinical trials, 3 of 106 (3%) patients treated with KANUMA experienced signs and symptoms consistent with anaphylaxis. These patients experienced reactions during infusion with signs and symptoms including chest discomfort, conjunctival injection, dyspnea, generalized and itchy rash, hyperemia, swelling of eyelids, rhinorrhea, severe respiratory distress, tachycardia, tachypnea, and urticaria. Anaphylaxis has occurred as early as the sixth infusion and as late as 1 year after treatment initiation.

In clinical trials, 21 of 106 (20%) KANUMA-treated patients, including 9 of 14 (64%) infants and 12 of 92 (13%) pediatric patients, 4 years and older, and adults experienced signs and symptoms either consistent with or that may be related to a hypersensitivity reaction. Signs and symptoms of hypersensitivity reactions, occurring in two or more patients, included abdominal pain, agitation, fever, chills, diarrhea, eczema, edema, hypertension, irritability, laryngeal edema, nausea, pallor, pruritus, rash, and vomiting. The majority of reactions occurred during or within 4 hours of the completion of the infusion. Patients were not routinely pre-medicated prior to infusion of KANUMA in these clinical trials.

Due to the potential for anaphylaxis, appropriate medical support should be readily available when KANUMA is administered.

Hypersensitivity to Eggs or Egg Products: Consider the risks and benefits of treatment in patients with known systemic hypersensitivity reactions to eggs or egg products.

ADVERSE REACTIONS

The most common adverse reactions are:

In patients with Rapidly Progressive Disease Presenting within the First 6 Months of Life (≥30%): diarrhea, vomiting, fever, rhinitis, anemia, cough, nasopharyngitis, and urticaria.

In pediatric and adult patients (≥8%): headache, fever, oropharyngeal pain, nasopharyngitis, asthenia, constipation, and nausea.

For full Prescribing Information, visit KANUMA.com.

Kanuma™
sebelipase alfa
intravenous infusion

ALEXION®