Please complete sections 1-6 and fax the completed pages 1 & 2 to: 1-888-990-0008 Phone: 1-866-888-0660

elaprase® (idursulfase) OnePath®

ELAPRASE® (Idursulfase) START Form and Authorization for OnePath® Services

Please see the Indication and Important Safety Information, including Boxed Warning regarding Risk of Anaphylaxis, on page 3 and click here for Full Prescribing Information.

1. Prescribing Physician Information

Name (First, Last)

National Provider ID #

Tax ID # | State License #

Street Address | City

State | Zip Code | Telephone ( )

Office Contact | Fax ( )

2. Site of Care Information

Site of Care Name

☐ Home Infusion (provide address of Home Infusion Company below)

Street Address | City

State | Zip Code | Telephone ( )

Office Contact | Fax ( )

National Provider ID #

3. Patient Information

Name (First, Middle Initial, Last)

Age | Last 4 digits of SSN | ☐ Male ☐ Female

DOB: Month/Day/Year | Mobile Telephone ( )

Work Telephone ( ) | Home Telephone ( )

Street Address | City

State | Zip Code | Email Address

Patient Weight (kg) | Caregiver Name (First, Last)

Caregiver Telephone ( ) | Relationship to Patient

4. Insurance Information

Please attach copies of both sides of patient's insurance card(s)

☐ Check if patient does not have insurance

Primary Insurance | Insurance Telephone ( )

Policy Holder Name (First, Last) | Relationship to Patient

Policy ID # | Group #

Pharmacy Plan Name | Rx Bin #

Pharmacy Plan Telephone ( ) | Rx PCN #

Secondary Insurance | Insurance Telephone ( ) | Policy ID # | Group#

Policy Holder Name (First, Last) | Relationship to Patient

5. Physician Authorization

By signing this form, I certify that therapy with Elaprase is medically necessary for the patient identified in this application ("Patient"). I have reviewed the current Elaprase Prescribing Information and will be supervising Patient's treatment. I have received from Patient, or his/her personal representative, the necessary authorization to release, in accordance with applicable federal and state law regulations, referenced medical and/or other patient information relating to Elaprase therapy to Takeda Pharmaceutical Company Limited, including its agents or contractors, for the purpose of seeking information related to coverage and/or assisting in initiating or continuing Elaprase therapy. I authorize OnePath® to transmit this prescription to the appropriate pharmacy designated by me, Patient, or Patient's plan. I agree that product provided through the Program shall only be used for Patient, must not be resold, offered for sale or trade or returned for credit.

Sign here

Prescriber Signature (STAMPS NOT ACCEPTABLE) DISPENSE AS WRITTEN Date

Please ensure that patient reads and signs page 2 for appropriate authorization.

Please complete sections 1-6 and fax the completed pages 1 & 2 to: 1-888-990-0008 Phone: 1-866-888-0660

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Authorization for OnePath® Services

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Patient Name DOB: Month/Day/Year

6. Patient Authorization to Share Protected Health Information and OnePath® Enrollment

☑ I authorize any health plan, physician, health care professional, hospital, clinic, pharmacy provider or other health care provider (collectively, "Providers") to disclose my protected health information, including personal information relating to my medical condition, treatment, care management, and health insurance, as well as all information provided on this form and any prescription ("Information"), to Takeda Pharmaceutical Company Limited, its affiliates and their representatives, agents, and contractors (collectively, the "Company" or "Takeda") in connection with the Company's provision of products, supplies, or services. I understand the Company will provide this Information to a specialty pharmacy to fulfill the prescription. This Information may also be used for internal uses by the Company, including data analysis. Further, I understand that my health care provider may receive financial remuneration from Takeda for marketing services.

Further, the Company may use this Information for OnePath® Product Support Services (if I agree below) such as verification of insurance benefits and drug coverage, prior authorization support, financial assistance with co-pays, patient assistance programs, alternate funding sources, other related programs, communication with me or my prescribing physician by mail, email, or telephone about my medical condition, treatment, care management, product information and health insurance.

Additionally, if I check the box below regarding marketing communications, I authorize the Company to use and disclose my Information to send marketing materials to me (as described below).

I understand that once disclosed to the Company, my Personal Health Information disclosed under this Authorization may no longer be protected by federal privacy law, including HIPAA. I understand that I am entitled to a copy of this Authorization. I understand that I may cancel this Authorization at any time by sending written notice of revocation to OnePath, 300 Shire Way, Lexington, MA 02421. I understand that such revocation will not apply to any information already used or disclosed through this Authorization. This Authorization will expire within five (5) years from today's date, unless a shorter period is provided for by state law. I understand that I may refuse to sign this Authorization and that refusing to sign this Authorization will not change the way my physician, health insurance, and pharmacy providers treat me. I also understand that if I do not sign this Authorization, I will not be able to receive OnePath® Product Support Program products, supplies, or services.

☐ **OnePath® Enrollment** (must check box to be enrolled in product support services through OnePath®)

I am electing to enroll in OnePath® Product Support Services ("Services") and direct all disclosures of my Information in connection with such Services (which may include, but is not limited to, verification of insurance benefits and drug coverage, prior authorization support, financial assistance with co-pays, patient assistance programs, alternate funding sources, other related programs, communication with me or my prescribing physician by mail, email, or telephone about my medical condition, treatment, care management, product information and health insurance).

☐ By checking this box, I authorize the use of my Information for Takeda marketing activities and consent to receiving marketing and promotional communications from Takeda. I hereby give consent to Takeda, its affiliates, and their agents and representatives to send communications and information to me via the contact information I have provided above. I understand that this consent will be in effect until I cancel such authorization.

Sign here

Patient/ Legal Representative Signature Indicate Relationship Date

INDICATIONS AND USAGE

ELAPRASE® (Idursulfase) is indicated for patients with Hunter syndrome (Mucopolysaccharidosis II, MPS II). ELAPRASE has been shown to improve walking capacity in patients 5 years and older. In patients 16 months to 5 years of age, no data are available to demonstrate improvement in disease-related symptoms or long term clinical outcome; however, treatment with ELAPRASE has reduced spleen volume similarly to that of adults and children 5 years of age and older. The safety and efficacy of ELAPRASE have not been established in pediatric patients less than 16 months of age.

IMPORTANT SAFETY INFORMATION

WARNING: RISK OF ANAPHYLAXIS

Life-threatening anaphylactic reactions have occurred in some patients during and up to 24 hours after ELAPRASE infusions. Anaphylaxis, presenting as respiratory distress, hypoxia, hypotension, urticaria and/or angioedema of throat or tongue have been reported to occur during and after ELAPRASE infusions, regardless of duration of the course of treatment. Closely observe patients during and after ELAPRASE administration and be prepared to manage anaphylaxis. Inform patients of the signs and symptoms of anaphylaxis and have them seek immediate medical care should symptoms occur. Patients with compromised respiratory function or acute respiratory disease may be at risk of serious acute exacerbation of their respiratory compromise due to hypersensitivity reactions, and require additional monitoring.

- **Hypersensitivity Reactions Including Anaphylaxis:** Ensure that personnel administering product are adequately trained in cardiopulmonary resuscitative measures, and have ready access to emergency medical services (EMS).
  If anaphylactic or other acute reactions occur, immediately discontinue the infusion of ELAPRASE and initiate appropriate medical treatment. Observe patients closely for an appropriate period of time after administration of ELAPRASE, taking into account the time to onset of anaphylaxis seen in premarketing clinical trials and postmarketing reports. Inform patients of the signs and symptoms of anaphylaxis, and instruct them to seek immediate medical care should signs and symptoms occur. When severe reactions have occurred during clinical trials, subsequent infusions were managed with antihistamine and/or corticosteroids prior to or during infusions, a slower rate of ELAPRASE infusion, and/or early discontinuation of the ELAPRASE infusion.
- **Risk of Hypersensitivity, Serious Adverse Reactions, and Antibody Development in Hunter Syndrome Patients with Severe Genetic Mutations:** Hunter syndrome patients aged 7 years and younger with complete gene deletion, large gene rearrangement, nonsense, frameshift or splice site mutations experienced a higher incidence of hypersensitivity reactions, serious adverse reactions and anti-idursulfase antibody development.
- **Risk of Acute Respiratory Complications:** Patients with compromised respiratory function or acute febrile or respiratory illness may be at higher risk of life-threatening complications from hypersensitivity reactions. Careful consideration should be given to the patient's clinical status prior to administration of ELAPRASE and consider delaying the ELAPRASE infusion.
- **Risk of Acute Cardiorespiratory Failure:** Caution should be exercised when administering ELAPRASE to patients susceptible to fluid overload, or patients with acute underlying respiratory illness or compromised cardiac and/or respiratory function for whom fluid restriction is indicated. These patients may be at risk of serious exacerbation of their cardiac or respiratory status during infusions. Appropriate medical support and monitoring measures should be readily available during ELAPRASE infusion, and some patients may require prolonged observation times that should be based on the individual needs of the patient.
- **Adverse Reactions:** In clinical trials, the most frequent serious adverse reactions following ELAPRASE treatment were hypoxic episodes. Other notable serious adverse reactions that occurred in the ELAPRASE treated patients but not in the placebo treated patients included one case each of: cardiac arrhythmia, pulmonary embolism, cyanosis, respiratory failure, infection, and arthralgia.
  The most common adverse reactions occurring in at least three patients (≥9%) aged five years and older were headache, pruritus, musculoskeletal pain, urticaria, diarrhea, and cough. The most common adverse reactions occurring in at least three patients (≥10%) aged seven years and younger were pyrexia, rash, vomiting, and urticaria. In all clinical trials, the most common adverse reactions requiring medical intervention were hypersensitivity reactions, and included rash, urticaria, pruritus, flushing, pyrexia, and headache.
- **Immunogenicity:** In clinical trials in patients 5 years and older, 32 of 63 (51%) patients tested positive for anti-idursulfase IgG antibodies (Ab) at least one time. Of the 32 Ab-positive patients, 23 of 32 (72%) tested positive for Ab at three or more different time points (persistent Ab). The incidence of hypersensitivity reactions was higher in patients who tested positive for Ab than those who tested negative.
  Thirteen of 32 (41%) Ab-positive patients also tested positive for antibodies that neutralize idursulfase uptake into cells (neutralizing antibodies, NAb) or enzymatic activity at least one time, and 8 (25%) of Ab-positive patients had persistent NAb. There was no clear relationship between the presence of either Ab or NAb and therapeutic response.
  In the clinical trial in patients 7 years and younger, 19 of 28 (68%) patients treated with ELAPRASE 0.5 mg/kg once weekly tested Ab-positive, with 16 of 19 (84%) having persistent Ab. In addition, 15 of 19 (79%) Ab-positive patients tested positive for NAb, with 14 of 15 (93%) having persistent NAb.
- **Postmarketing Experience:** Late-emergent symptoms and signs of anaphylactic reactions have occurred up to 24 hours after initial treatment and recovery from an initial anaphylactic reaction. In addition, patients experienced repeated anaphylaxis over a two to four month period, up to several years after initiating ELAPRASE treatment.
  Serious adverse reactions that resulted in death included cardiorespiratory arrest, respiratory failure, respiratory distress, cardiac failure, and pneumonia.

Please click here for Full Prescribing Information, including Boxed Warning regarding Risk of Anaphylaxis.

To report SUSPECTED ADVERSE REACTIONS, contact Shire Medical Information at 1-866-888-0660 or FDA at 1-866-FDA-1088 or www.fda.gov/medwatch