

ELAPRASE REIMBURSEMENT GUIDE

What is ELAPRASE[®] (Idursulfase)?

ELAPRASE is a prescription medicine for patients with Hunter syndrome.

ELAPRASE has been shown to improve walking ability in patients 5 yrs and older.

In patients 16 months to 5 yrs old, ELAPRASE did not show improvement in disease-related symptoms or long term clinical result; however, treatment with ELAPRASE has reduced spleen size similarly to patients 5 yrs and older.

It is not known if ELAPRASE is safe and effective in children under 16 months old.

IMPORTANT SAFETY INFORMATION

RISK OF SERIOUS ALLERGIC REACTIONS:

Some patients have experienced serious allergic reactions (including life-threatening anaphylactic reactions) during and up to 24 hours after treatment, regardless of how long they were taking ELAPRASE. Anaphylactic reactions are immediate and include breathing problems, low oxygen levels, low blood pressure, hives and/or swelling of the throat or tongue. If a patient (you or your child) has experienced an anaphylactic reaction, the patient may require an extended period of observation by the patient's healthcare team. If you or your child has breathing problems, a fever, or a respiratory illness, you or your child may be at risk of life-threatening worsening of those conditions due to allergic reactions from ELAPRASE. Your healthcare team should be advised of those conditions before treatment with ELAPRASE because the information may affect the timing of ELAPRASE treatment.

**For Healthcare Professionals
and Patients and Caregivers**

elaprase[®]
(idursulfase)

For more information,
please visit www.ELAPRASE.com

Please see Important Safety Information on [pages 12-13](#) and [CLICK HERE](#) to see accompanying Full Prescribing Information, including Boxed WARNING for Risk of Anaphylaxis.

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INFORMATION ABOUT ELAPRASE

ELAPRASE 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.¹



IMPORTANT SAFETY INFORMATION (CONTINUED)

You or your child should be closely watched during and after ELAPRASE treatment and you should confirm with your healthcare team in advance of treatment that it is prepared to manage serious allergic reactions, including anaphylactic reactions. **Tell your healthcare team immediately if any signs of an allergic reaction happen.** Those signs may include breathing problems, low blood pressure, rash, hives, itching, flushing, fever and/or headache.

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INTRODUCTION

When considering treatment, it's important to learn as much as possible about the reimbursement process. In doing so, you'll be prepared to provide the necessary information to the insurer or state Medicare, Medicaid, or Medicaid managed care office. While this process may seem unfamiliar at first, OnePath can help you navigate potential coverage issues.

This booklet reviews some key issues pertaining to ELAPRASE coverage and reimbursement.



IMPORTANT SAFETY INFORMATION (CONTINUED)

When serious allergic reactions happened during clinical trials, later ELAPRASE treatments were managed with allergy-controlling drugs before or during treatment, a slower rate of ELAPRASE treatment, and/or early discontinuation of treatment.

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KEY FACTS ABOUT ELAPRASE COVERAGE

There are several potential sources of coverage:

- A patient's insurance benefits for ELAPRASE will depend on their coverage. Some sources of coverage include private insurance companies, preferred provider organizations (PPOs), health maintenance organizations (HMOs), Medicare, and Medicaid. There may also be other sources of coverage available.
- Each insurer may have different coverage policies.
- Because each plan can be different, be sure to check its specific guidelines and requirements for ELAPRASE coverage. That way you can determine the information and action necessary to avoid potential issues and delay in beginning treatment and obtaining reimbursement.
- Most insurers require some kind of prior authorization and/or statement of medical necessity for ELAPRASE therapy. Coverage also differs depending on the site of care—hospital, inpatient, outpatient, physician office, or at home. Insurers may require completion of forms such as a Statement of Medical Necessity or a Letter of Intent to Treat prior to establishing coverage for ELAPRASE treatment.
- Each insurer determines how it will cover ELAPRASE; for example, it may choose the physician who will administer and monitor therapy, as well as the facility for treatment. The insurer may also require periodic reauthorization or recertification for continued treatment.
- The Affordable Care Act prohibits healthcare plans from putting a lifetime limit on essential health benefits. The ban on lifetime dollar limits applies to every health plan, whether you buy coverage for yourself or your family, or you receive coverage through your employer.²



IMPORTANT SAFETY INFORMATION (CONTINUED)

Children with serious genetic mutations may be at risk for allergic reactions, serious side effects and antibody development. In a clinical study of children 7 years and younger, patients with certain types of genetic mutations experienced a higher number of allergic reactions, serious side effects, and development of an immune response to treatment. This immune response may interfere with the effectiveness of ELAPRASE. Talk to your healthcare team about whether you or your child may be at risk.

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KEY FACTS ABOUT ELAPRASE COVERAGE (CONTINUED)

Medicare, Medicaid, and Medicaid managed care plans vary from state to state

For those who are covered under a Medicare, Medicaid, or Medicaid managed care program, it's important to find out the coverage options and regulations pertaining to the patient's state of residence.³ In most cases, ELAPRASE must be considered medically necessary to be covered under Medicare, Medicaid, or Medicaid managed care.⁴ Some states require prior approval by the state care program to begin ELAPRASE; for example, a state may require a Letter of Intent to Treat or provider referrals before beginning ELAPRASE therapy.

Be aware that each state's Medicare, Medicaid, or Medicaid managed care office may have different policies regarding ELAPRASE therapy, including the location where it can be provided. To be certain of coverage guidelines, please call the state's local Medicare, Medicaid, or Medicaid Managed Care office. You can find the number of each state's office at the back of this booklet (Appendix B, page 18).

It's important to take the first step

While this process may seem complicated at first, try not to be discouraged. There are many ways to obtain reimbursement—and there are many people who are available to help you and provide the information you need. To get started, please visit www.onepath.com or call the OnePath support service on **1-866-888-0660**.

If you are enrolled in OnePath, contact your Patient Support Manager, available Monday through Friday from 8:30 a.m. to 8:00 p.m. ET, to locate resources and information about Medicare, Medicaid, and Medicaid managed care programs and receiving ELAPRASE in a state in which you are not a resident.

IMPORTANT SAFETY INFORMATION (CONTINUED)

If you or your child has breathing problems, other respiratory illness, heart problems, or susceptibility to fluid overload, you or your child may be at higher risk of fluid overload during ELAPRASE treatment. Your healthcare team should be advised of those problems before treatment and you should confirm with your healthcare team in advance of treatment that it is appropriately trained to watch for signs of fluid overload and provide the necessary medical support. Patients at risk for fluid overload may require longer observation time.

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OnePath[®] SUPPORT SERVICES

Dedicated product support specialists you can count on

When you're prescribed ELAPRASE (idursulfase), OnePath dedicated support is here for you.

At OnePath, we see a person, not a patient. We know that living with Hunter syndrome looks different for everyone. So whether you've just been diagnosed or have been on treatment for a long time, we tailor our support by getting to know you, understanding who you are, and learning what's most important to you—so we can focus on what you specifically need when it comes to your prescribed Takeda treatment. Our goal is to make your journey a little easier.



Dedicated OnePath specialists are never more than a tap or a phone call away. Contact OnePath at 1-866-888-0660, Monday through Friday, 8:30 a.m. to 8:00 p.m.

If English is not your preferred language, let us know. We can communicate with you over the phone using a translation service.

Joyce and Laura,
OnePath Patient Support Managers

IMPORTANT SAFETY INFORMATION (CONTINUED)

What are possible side effects of ELAPRASE? The most common side effects of ELAPRASE include:

- In patients aged 5 and older:
 - Headache
 - Itching
 - Muscle and bone pain
 - Hives
 - Diarrhea
 - Cough
- In patients aged 7 years or younger:
 - Fever
 - Rash
 - Vomiting
 - Hives

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OnePath[®] SPECIALIST TEAM



Patient Support Manager (PSM)

When you enroll in OnePath, your PSM is your go-to person. Your PSM can address your questions and concerns and help determine next steps. They can also:

- Work with your insurance provider to help you receive your prescribed Takeda treatment
- Work with your specialty pharmacy and site of care
- Enroll you in the OnePath Co-Pay Assistance Program, if you qualify*
- Connect you with other dedicated OnePath specialists as needed



Patient Access Manager (PAM)

Your PAM is an insurance expert. Your PAM can:

- Walk you through the insurance process step by step
- Help you understand what's covered, what's not, and what to do next
- Provide information about options that may help cover your prescribed Takeda treatment costs



Healthcare Educator (HCE)

Your HCE can provide you with health education support. Your HCE can:

- Help you understand your condition and your prescribed Takeda treatment
- Connect you with community support and advocacy resources
- Direct you to information to help you manage your condition
- Provide you with assistance in Spanish, if needed

*To be eligible, you must be enrolled in OnePath and have commercial insurance. Other terms and conditions apply. Call OnePath for more details.

CLICK HERE to download the OnePath Start Form, or visit www.ELAPRASE.com/getting-started-support/onepath

Takeda is committed to supporting patients and their families. To learn more, simply call OnePath toll free on 1-866-888-0660, or visit www.onepath.com

IMPORTANT SAFETY INFORMATION (CONTINUED)

The most common side effects needing medical attention were allergic reactions, and included rash, hives, itching, flushing, fever, and headache. **Tell your healthcare team immediately if any signs of an allergic reaction happen.** These are not all the possible side effects of ELAPRASE.

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ELAPRASE REIMBURSEMENT: A CODING GUIDE FOR HEALTHCARE PROVIDERS

Completing forms with the appropriate codes is a necessary part of the reimbursement process and is the responsibility of the healthcare providers who are administering ELAPRASE therapy. Some of the codes that may be required for billing are listed here. Please be aware that codes and billing procedures sometimes change. Before completing a reimbursement form, be sure to obtain the most up-to-date information.

Key codes and services for billing

ICD-9-CM (International Classification of Diseases, 9th Revision, Clinical Modification)

- 277.5 — Diagnosis code for all mucopolysaccharidosis (MPS) disorders⁵

ICD-10-CM (International Classification of Diseases, 10th Revision, Clinical Modification). Please note, ICD-10-CM replaced ICD-9-CM in October 2015.

- E76.1 — Mucopolysaccharidosis, type II⁶
- E76.3 — Mucopolysaccharidosis, unspecified⁶

NDC (National Drug Code)

- 54092-700⁷
- 54092-700-01 (10-digit code is required by some payers)⁷

HCPCS (Healthcare Common Procedure Coding System). The HCPCS drug code that may be used to bill for ELAPRASE is:

- J1743 — Injection, Idursulfase 1 mg⁸
- Q0081 — Non-chemotherapeutic infusion (hospital only)⁹
- S9357 — Home infusion therapy, enzyme replacement intravenous (IV) therapy (e.g., imiglucerase); administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately) per diem¹⁰

IMPORTANT SAFETY INFORMATION

RISK OF SERIOUS ALLERGIC REACTIONS:

Some patients have experienced serious allergic reactions (including life-threatening anaphylactic reactions) during and up to 24 hours after treatment, regardless of how long they were taking ELAPRASE. Anaphylactic reactions are immediate and include breathing problems, low oxygen levels, low blood pressure, hives and/or swelling of the throat or tongue. If a patient (you or your child) has experienced an anaphylactic reaction, the patient may require an extended period of observation by the patient's healthcare team. If you or your child has breathing problems, a fever, or a respiratory illness, you or your child may be at risk of life-threatening worsening of those conditions due to allergic reactions from ELAPRASE. Your healthcare team should be advised of those conditions before treatment with ELAPRASE because the information may affect the timing of ELAPRASE treatment.

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ELAPRASE REIMBURSEMENT: A CODING GUIDE FOR HEALTHCARE PROVIDERS (CONTINUED)

CPT-4 (CPT: Current Procedural Terminology)*

- 96365 — IV infusion for therapy/prophylaxis, administered by physician or under direct supervision of physician; up to 1 hour¹¹
- 96366 — Each additional hour, up to 8 hours¹¹

Revenue codes

Hospitals must use the following revenue code on Form UB-04:

- 0636 — Drugs and biologicals requiring an HCPCS code¹²

Other revenue codes that may be used by hospitals include:

- 0258 — IV solutions¹³
- 0260 — General IV therapy service¹⁴
- 0261 — Infusion pump¹⁵

*CPT is a registered trademark of the American Medical Association.

The information contained in this guide has been developed to help you understand insurance benefits and the process of submitting claims. Takeda cannot guarantee that the information in this guide will result in coverage or payment. As payer policies may change, please consult with those policies to get the most up-to-date information.

IMPORTANT SAFETY INFORMATION (CONTINUED)

You or your child should be closely watched during and after ELAPRASE treatment and you should confirm with your healthcare team in advance of treatment that it is prepared to manage serious allergic reactions, including anaphylactic reactions. **Tell your healthcare team immediately if any signs of an allergic reaction happen.** Those signs may include breathing problems, low blood pressure, rash, hives, itching, flushing, fever and/or headache.

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What is ELAPRASE[®] (Idursulfase)?

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ELAPRASE has been shown to improve walking ability in patients 5 yrs and older.

In patients 16 months to 5 yrs old, ELAPRASE did not show improvement in disease-related symptoms or long term clinical result; however, treatment with ELAPRASE has reduced spleen size similarly to patients 5 yrs and older.

It is not known if ELAPRASE is safe and effective in children under 16 months old.

Important Safety Information

RISK OF SERIOUS ALLERGIC REACTIONS:

Some patients have experienced serious allergic reactions (including life-threatening anaphylactic reactions) during and up to 24 hours after treatment, regardless of how long they were taking ELAPRASE. Anaphylactic reactions are immediate and include breathing problems, low oxygen levels, low blood pressure, hives and/or swelling of the throat or tongue. If a patient (you or your child) has experienced an anaphylactic reaction, the patient may require an extended period of observation by the patient's healthcare team. If you or your child has breathing problems, a fever, or a respiratory illness, you or your child may be at risk of life-threatening worsening of those conditions due to allergic reactions from ELAPRASE. Your healthcare team should be advised of those conditions before treatment with ELAPRASE because the information may affect the timing of ELAPRASE treatment.

You or your child should be closely watched during and after ELAPRASE treatment and you should confirm with your healthcare team in advance of treatment that it is prepared to manage serious allergic reactions, including anaphylactic reactions. **Tell your healthcare team immediately if any signs of an allergic reaction happen.** Those signs may include breathing problems, low blood pressure, rash, hives, itching, flushing, fever and/or headache.

When serious allergic reactions happened during clinical trials, later ELAPRASE treatments were managed with allergy-controlling drugs before or during treatment, a slower rate of ELAPRASE treatment, and/or early discontinuation of treatment.

Important Safety Information (continued)

Children with serious genetic mutations may be at risk for allergic reactions, serious side effects and antibody development. In a clinical study of children 7 years and younger, patients with certain types of genetic mutations experienced a higher number of allergic reactions, serious side effects, and development of an immune response to treatment. This immune response may interfere with the effectiveness of ELAPRASE. Talk to your healthcare team about whether you or your child may be at risk.

If you or your child has breathing problems, other respiratory illness, heart problems, or susceptibility to fluid overload, you or your child may be at higher risk of fluid overload during ELAPRASE treatment. Your healthcare team should be advised of those problems before treatment and you should confirm with your healthcare team in advance of treatment that it is appropriately trained to watch for signs of fluid overload and provide the necessary medical support. Patients at risk for fluid overload may require longer observation time.

What are possible side effects of ELAPRASE?

The most common side effects of ELAPRASE include:

- In patients aged 5 and older:
 - Headache
 - Itching
 - Muscle and bone pain
 - Hives
 - Diarrhea
 - Cough
- In patients aged 7 years or younger:
 - Fever
 - Rash
 - Vomiting
 - Hives

The most common side effects needing medical attention were allergic reactions, and included rash, hives, itching, flushing, fever, and headache. **Tell your healthcare team immediately if any signs of an allergic reaction happen.** These are not all the possible side effects of ELAPRASE.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

[CLICK HERE](#) for Full Prescribing Information, including Boxed WARNING.

GLOSSARY

Key reimbursement terms used in this guide

Specialty pharmacy

A type of pharmacy that provides a variety of specialized services for people with complex, chronic, or rare conditions. Medications offered by specialty pharmacies are often high cost, available with limited distribution, or require special storage, handling, or administration.¹⁶

Site of care

A location where a patient receives healthcare, such as a hospital, physician office, or the patient's home.

Lifetime limits

Insurance companies cannot set a dollar limit to what they spend on essential health benefits for your care during the entire time you're enrolled in that plan. This applies to all health plans whether you receive coverage through your employer or buy it yourself. Insurance companies can still put a dollar limit on healthcare services that are not considered essential health benefits.²

HMO

Health maintenance organization. An HMO is a type of health insurance plan that usually limits coverage to care from doctors who work for or contract with the HMO network. Out-of-network care is usually not covered except in emergencies. An HMO may require you to live or work in its service area to be eligible for coverage. HMOs often provide integrated care and focus on prevention and wellness.¹⁷



IMPORTANT SAFETY INFORMATION (CONTINUED)

When serious allergic reactions happened during clinical trials, later ELAPRASE treatments were managed with allergy-controlling drugs before or during treatment, a slower rate of ELAPRASE treatment, and/or early discontinuation of treatment.

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GLOSSARY (CONTINUED)

PPO

Preferred provider organization. A PPO is a type of healthcare plan where you pay less if you use providers in the plan's network. You can use doctors, hospitals, and providers outside of the network without a referral for an additional cost.¹⁷

Managed care

Managed care is a healthcare delivery system organized to manage cost, utilization, and quality. Medicaid managed care provides the delivery of Medicaid health benefits through contracted arrangements between the state Medicaid agencies and managed care organizations.³

Medicaid

Medicaid is a federally and state-funded health insurance program for some low-income people, families and children, pregnant women, the elderly, and people with disabilities. Coverage and costs vary from state to state. Some Medicaid programs pay for care directly while others use private insurance companies to provide Medicaid coverage.¹⁸

Medicare

Medicare is a federally funded health insurance program for people who are aged 65 or older and certain younger people with disabilities.¹⁹



IMPORTANT SAFETY INFORMATION (CONTINUED)

Children with serious genetic mutations may be at risk for allergic reactions, serious side effects and antibody development. In a clinical study of children 7 years and younger, patients with certain types of genetic mutations experienced a higher number of allergic reactions, serious side effects, and development of an immune response to treatment. This immune response may interfere with the effectiveness of ELAPRASE. Talk to your healthcare team about whether you or your child may be at risk.

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APPENDIX B

State Medicaid offices*

CMS Headquarters

Centers for Medicare and Medicaid Services (CMS), 7500 Security Boulevard
Baltimore, MD 21244-1850

Toll-Free: 877-267-2323

Local: 410-786-3000

TTY Toll-Free: 866-226-1819

TTY Local: 410-786-0727

Regional Contacts

Region One – Boston

Connecticut, Maine, Massachusetts,
New Hampshire, Rhode Island, and Vermont

Richard McGreal

JFK Federal Building, Suite 2325

Boston, MA 02203-0003

617-565-1299; ROBOSDMCH@cms.hhs.gov

Region Three – Philadelphia

Delaware, District of Columbia, Maryland,
Pennsylvania, Virginia, and West Virginia

Francis McCullough

150 S. Independence Mall West

Philadelphia, PA 19106

215-861-4155; ROPHIDMCH@cms.hhs.gov

Region Five – Chicago

Illinois, Indiana, Michigan, Minnesota,
Ohio, and Wisconsin

Ruth Hughes

233 North Michigan Avenue, Suite 600

Chicago, IL 60601

312-353-1133; R5DMCH@cms.hhs.gov

Region Seven – Kansas City

Iowa, Kansas, Missouri, and Nebraska

James Scott

601 E. 12th Street, Suite 355

Kansas City, MO 64106

816-426-5925; ROKCMMCH@cms.hhs.gov

Region Nine – San Francisco

Arizona, California, Hawaii, Nevada,
and Pacific Territories

Henrietta Sam-Louie

90 – 7th Street, Suite 5-300

San Francisco, CA 94103-6706

415-744-3568; ROSFOMCD@cms.hhs.gov

Region Two – New York

New Jersey, New York, Puerto Rico,
and Virgin Islands

Michael Melendez

26 Federal Plaza, Room 3811

New York, NY 10278-0063

212-616-2400; RONYDMCH@cms.hhs.gov

Region Four – Atlanta

Alabama, Florida, Georgia, Kentucky, Mississippi,
North Carolina, South Carolina, and Tennessee

Shantrina Roberts (Acting)

61 Forsyth Street, SW, Suite 4T20

Atlanta, GA 30303-8909

404-562-7359; ROATLMCD@cms.hhs.gov

Region Six – Dallas

Arkansas, Louisiana, New Mexico,
Oklahoma, and Texas

Bill Brooks

1301 Young St. Suite 714

Dallas, TX 75202

214-767-6495; RODALDMCH@cms.hhs.gov

Region Eight – Denver

Colorado, Montana, North Dakota,
South Dakota, Utah, and Wyoming

Richard Allen

1961 Stout Street, Room 08-148

Denver, CO 80294

303-844-0634; RODENDMCH@cms.hhs.gov

Region Ten – Seattle

Alaska, Idaho, Oregon, and Washington

David Meacham

701 Fifth Avenue, Suite 1600

Seattle, WA 98104

206-615-2326; SEARODMCH@cms.hhs.gov

For more information, please visit
www.ELAPRASE.com

What is ELAPRASE[®] (Idursulfase)?

ELAPRASE is a prescription medicine for patients with Hunter syndrome.

ELAPRASE has been shown to improve walking ability in patients 5 yrs and older.

In patients 16 months to 5 yrs old, ELAPRASE did not show improvement in disease-related symptoms or long term clinical result; however, treatment with ELAPRASE has reduced spleen size similarly to patients 5 yrs and older.

It is not known if ELAPRASE is safe and effective in children under 16 months old.

IMPORTANT SAFETY INFORMATION

RISK OF SERIOUS ALLERGIC REACTIONS:

Some patients have experienced serious allergic reactions (including life-threatening anaphylactic reactions) during and up to 24 hours after treatment, regardless of how long they were taking ELAPRASE. Anaphylactic reactions are immediate and include breathing problems, low oxygen levels, low blood pressure, hives and/or swelling of the throat or tongue. If a patient (you or your child) has experienced an anaphylactic reaction, the patient may require an extended period of observation by the patient's healthcare team. If you or your child has breathing problems, a fever, or a respiratory illness, you or your child may be at risk of life-threatening worsening of those conditions due to allergic reactions from ELAPRASE. Your healthcare team should be advised of those conditions before treatment with ELAPRASE because the information may affect the timing of ELAPRASE treatment.