

# 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**

Please see additional 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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For more information,  
please visit [www.ELAPRASE.com](http://www.ELAPRASE.com)

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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.<sup>1</sup>



## 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.

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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# 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, Takeda Patient Support may be able to help. Takeda Patient Support is a no-cost program, provided by Takeda, that provides support services to eligible enrolled patients to help them get access to ELAPRASE.

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



## 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.

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

# 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.<sup>2</sup>

## 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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## 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.<sup>3</sup> In most cases, ELAPRASE must be considered medically necessary to be covered under Medicare, Medicaid, or Medicaid managed care.<sup>4</sup> 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 support specialists who are available to address your questions and concerns, and help determine next steps. To get started, please visit [www.takedapatientssupport.com](http://www.takedapatientssupport.com) or call the Takeda Patient Support specialists below.



Our support specialists are never more than a tap or a call away —  
**1-866-888-0660**, Monday through Friday, 8:30 am to 8:00 pm ET.



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Takeda Patient Support

After you and your physician choose a treatment path, Takeda Patient Support is here for you with a range of personalized services for your treatment journey — even when you need to travel away from home.

We know that living with Hunter syndrome looks different for everyone. As we get to know you, understand who you are, and learn what’s important to you, we can help provide the support you need when it comes to your treatment.

To learn more about Takeda Patient Support, click [here](#)



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

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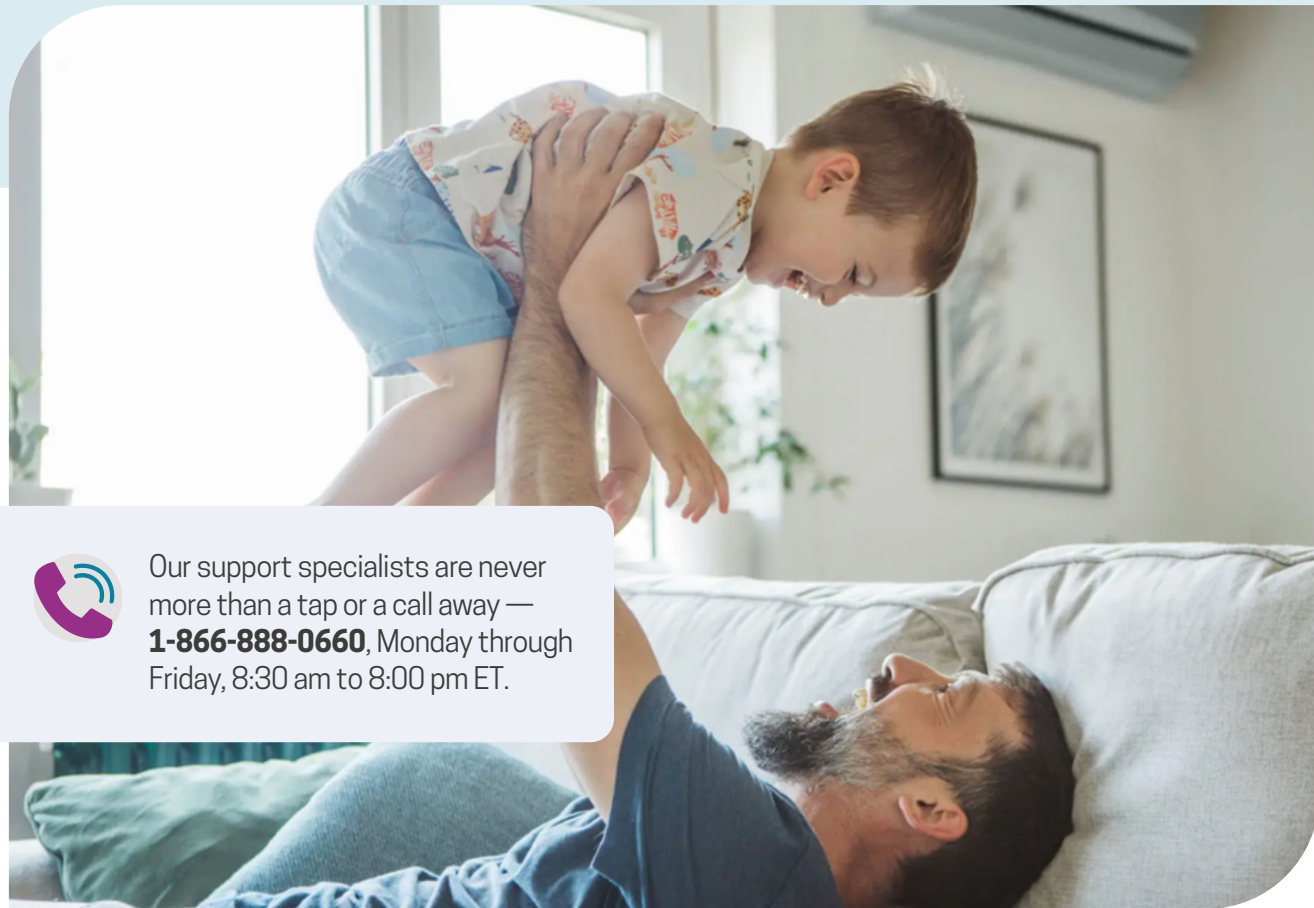
Tailored Support

Our support specialists are here to address your questions and concerns, and help get you the answers, resources, and tools you need. Some of the ways we can help include:

- **Copay** assistance for those who are eligible,\* as well as assistance with navigating complex reimbursement and insurance issues
- **Coordination** between your specialty pharmacy and your site of care, even if you are traveling out of town or relocating
- **Helping** you find information, education, and community resources about your condition and Hunter syndrome
- **Assistance** during life transitions like relocation, moving to college, or changing jobs

\*To be eligible, you must be enrolled in Takeda Patient Support and have commercial insurance. Other terms and conditions apply. Call us for more details.

To get started, click [here](#) to visit our convenient online enrollment portal or Print & Fax our downloadable Start Form [here](#)



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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) disorders<sup>5</sup>

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

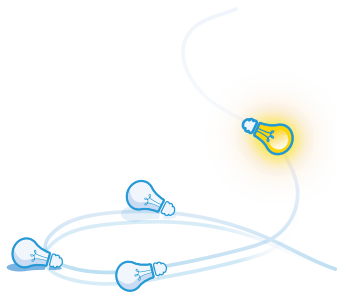
- E76.1 — Mucopolysaccharidosis, type II<sup>6</sup>
- E76.3 — Mucopolysaccharidosis, unspecified<sup>6</sup>

**NDC** (National Drug Code)

- 54092-700<sup>7</sup>
- 54092-700-01 (10-digit code is required by some payers)<sup>7</sup>

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

- J1743 — Injection, Idursulfase 1 mg<sup>8</sup>
- Q0081 — Non-chemotherapeutic infusion (hospital only)<sup>9</sup>
- 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 diem<sup>10</sup>



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.

**CPT-4** (CPT: Current Procedural Terminology)\*

- 96365 — IV infusion for therapy/prophylaxis, administered by physician or under direct supervision of physician; up to 1 hour<sup>11</sup>
- 96366 — Each additional hour, up to 8 hours<sup>11</sup>

### Revenue codes

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

- 0636 — Drugs and biologicals requiring an HCPCS code<sup>12</sup>

Other revenue codes that may be used by hospitals include:

- 0258 — IV solutions<sup>13</sup>
- 0260 — General IV therapy service<sup>14</sup>
- 0261 — Infusion pump<sup>15</sup>

\*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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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.

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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](http://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.<sup>16</sup>

### 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.<sup>2</sup>

### 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.<sup>17</sup>



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### 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.<sup>17</sup>

### Managed care

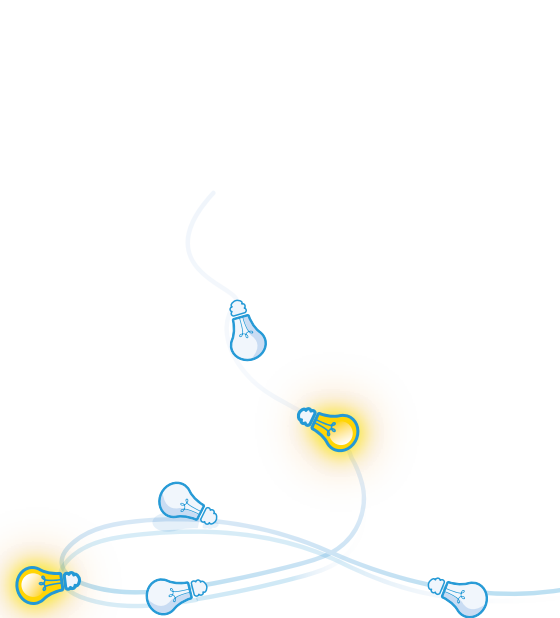
Managed care is a healthcare delivery system organized to manage cost, utilization, and quality. Medicaid managed care provides the delivery of Medicaid health benefits through contracted arrangements between the state Medicaid agencies and managed care organizations.<sup>3</sup>

### 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.<sup>18</sup>

### Medicare

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



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APPENDIX A  
For Healthcare Providers

Sample coding for ELAPRASE

The following coding information for ELAPRASE (idursulfase) is an example only. Specific codes will vary based on payer guidelines, patient-specific treatment, and diagnosis.

CMS-1500 – Physician Office Setting

|  |                            |  |   |   |
|--|----------------------------|--|---|---|
| 17. NAME OF REFERRING PROVIDER OR OTHER SOURCE   |                            | 17a. NPI   | 18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES |   |
|  |                            |  | FROM MM DD YY   | TO MM DD YY   |
| 19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)  |                            |  |   |   |
| 21. DIAGNOSIS OR NATURE OF   |                            | 19. RESERVED FOR LOCAL USE   |   | 24E. DIAGNOSIS POINTER  |
| A. ICD-9   |                            | List the product name, dose administered, route of administration, and NDC #. ELAPRASE NDC: 54092-700-01   |   | Specify the diagnosis code position from Box 21 that relates to the code listed in Box 24D (e.g., 1, 2, 3).   |
| E. ICD-10  |                            |  |   |   |
| I. ICD-11  |                            |  |   |   |
| 24. A. DATE(S) OF SERVICE  | B. PLACE OF SERVICE        | C. D. PROCEDURES, SERVICES, OR SUPPLIES  | E. DIAGNOSIS POINTER                                  | F. \$ CHARGES   |
| From MM DD YY To MM DD YY  | Office 11 Home 12 Other 99 | (Explain Unusual Circumstances) CPT/HCPCS MODIFIER   |   |   |
| 21. DIAGNOSIS CODE   |                            | 24D. PROCEDURE CODE  |   | 24G. UNITS  |
| Document the primary diagnosis on line 1 and the secondary diagnosis on line 2 using ICD-9 diagnosis codes.  |                            | Document the drug administration with an appropriate CPT code and the product administered with the HCPCS code (J-Code). Some Medicaid plans and managed care plans may require the NDC # to be listed here. |   | For each HCPCS or CPT code, insert the number of units administered.  |
| • ELAPRASE ICD-9 code: 277.5 for all mucopolysaccharidosis (MPS) disorders (Hunter syndrome)                 |                            | Intravenous infusion for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour, administered by physician or under direct supervision of physician: 96365                    |   | • ELAPRASE: For Medicare and Medicaid, multiply the number of vials by 6. For example, 1 vial = 6 units. For private payers, enter the number of vials. For example, 1 vial = 1 unit. For drug administration up to 1 hour, enter 1 unit. |
| • ELAPRASE secondary ICD-9 code: 99.29 injection or infusion of other therapeutic or prophylactic substances |                            | • ELAPRASE HCPCS J-Code: J1743   |   |   |

CMS-1450 (UB-04) – Hospital Outpatient Setting

|  |   |  |   |
|--|---|--|---|
| 42. REVENUE CODE   | 43. DESCRIPTION   | 44. PRODUCT AND PROCEDURE CODE   | 46. UNITS   |
| See payer's requirements. Medicare and most other payers require a revenue code for each procedure executed, so one line is required for the product and another line for the procedure. | Provide the description associated with the HCPCS J-Code or the revenue code entered in Box 42. | Enter the HCPCS J-Code on the product line and enter the CPT code on the procedure line.   | Enter the number of units. On the product line, enter the number of units administered.   |
|  | • For the product: - ELAPRASE (idursulfase for injection) - IV solution (for 0258)              | • For the product: - ELAPRASE HCPCS J-Code: J1743  | • ELAPRASE: For Medicare and Medicaid, multiply the number of vials by 6. For example, 1 vial = 6 units. For private payers, enter the number of vials. For example, 1 vial = 1 unit. For drug administration up to 1 hour, enter 1 unit. |
|  | • For the procedure: - IV therapy, general (for 0260) - Infusion therapy (for 0261)             | • For the procedure: - For intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour, administered by physician or under direct supervision of physician, enter: 96365 - For IV infusion therapy each additional hour, up to 8 hours, enter: 96366 - For non-chemotherapeutic infusion, enter: Q0081 | • On the procedure line, enter 1 unit for 1 hour  |
| 69. DIAGNOSIS CODE   | 68. ADDITIONAL DIAGNOSIS  |  |   |
| Enter the appropriate ICD-9 diagnosis codes as documented in the patient's clinical record.  | Enter the appropriate ICD-9 codes for additional diagnoses.                                     |  |   |
| • ELAPRASE ICD-9 Code: 277.5 for all mucopolysaccharidosis (MPS) disorders (Hunter syndrome)   |   |  |   |
| 90. REMARKS  |   |  |   |
| This field is used to report additional information to support the claim's review and payment. Record the product name, NDC #, dose administered, and route of administration.           |   |  |   |
| • ELAPRASE NDC: 54092-700-01   |   |  |   |

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APPENDIX B

State Medicaid offices\*

CMS Headquarters

Centers for Medicare and Medicaid Services (CMS), 7500 Security Boulevard  
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Regional Contacts

Region One – Boston

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Region Three – Philadelphia

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Region Five – Chicago

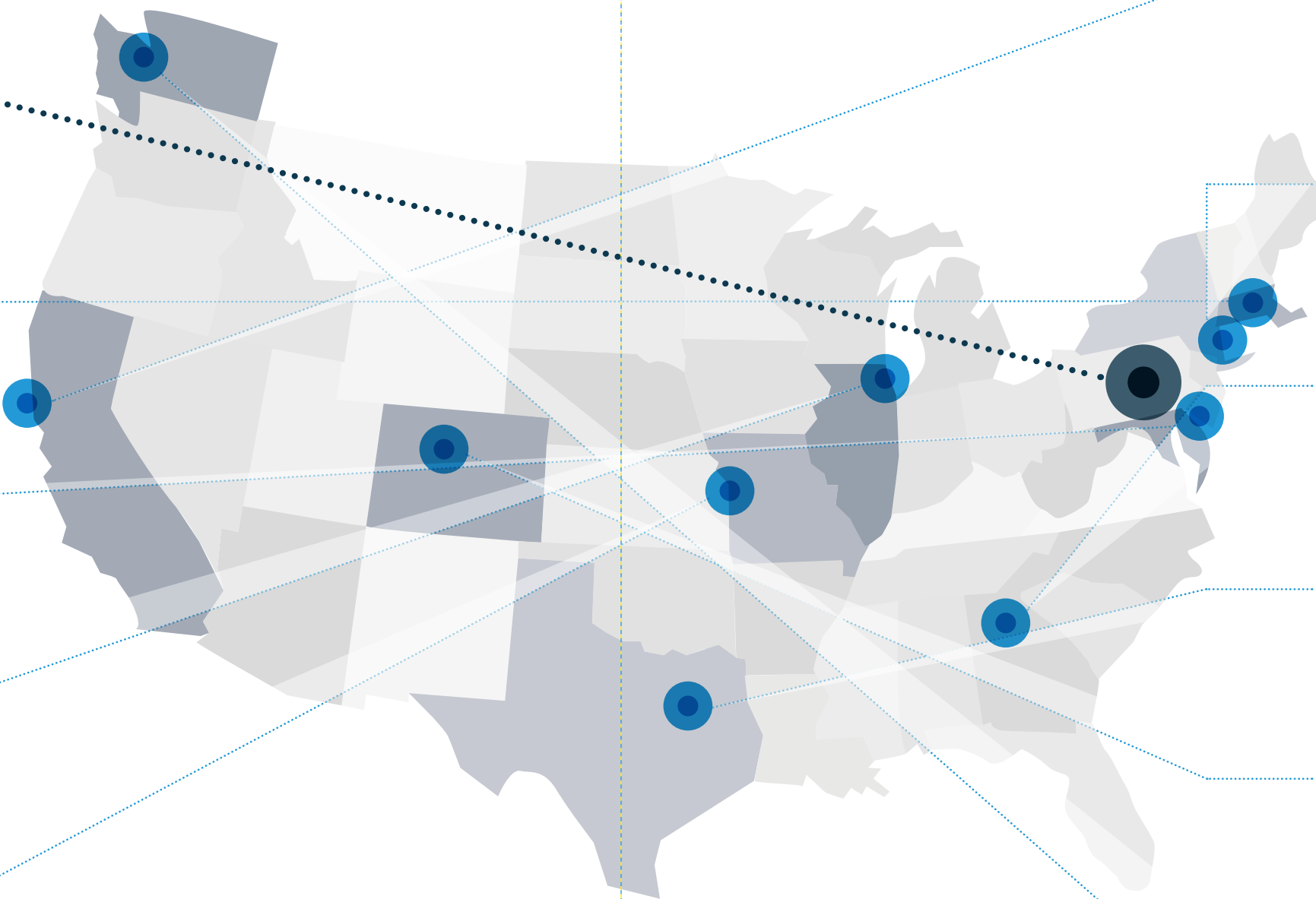
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\*Validated as of 03/15/22

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.



Region Nine – San Francisco

Arizona, California, Hawaii, Nevada, and Pacific Territories  
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Region Four – Atlanta

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Region Six – Dallas

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Region Eight – Denver

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Region Ten – Seattle

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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.

**For more information, please visit**  
**[www.ELAPRASE.com](http://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.