

# Elfabrio® Start Form

Fax completed form to: 1-877-435-2524



The Elfabrio Start Form is designed to collect the necessary information to initiate Elfabrio treatment.

## Instructions for completion:

### Sections 1 and 2:

#### Patient Information and Insurance Information

- To be completed by the **patient and/or their legal representative**
- If neither is available, these sections may be completed by a healthcare provider on the patient's behalf

### Sections 3-6:

#### Provider and Prescription-Related Information

- Must be completed by the **treating healthcare provider**
- Provider signatures are required to authorize diagnosis and treatment initiation

### Sections 7 and 8:

#### HIPAA Authorization and Chiesi Total Care<sup>SM</sup> Enrollment

- To be completed by the **patient and/or their legal representative**
- Provides details on HIPAA authorization and Chiesi Total Care<sup>SM</sup>, a patient support service dedicated to assisting patients during their treatment journey
- Patient authorization signature acknowledging HIPAA authorization and Chiesi Total Care<sup>SM</sup> terms and conditions is required
- **Enrollment in Chiesi Total Care<sup>SM</sup> is optional and not required to receive Elfabrio treatment**

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**Patients or Legal Representatives: Please complete Sections 1 and 2 below and then continue onto pages 4 and 5 for Chiesi Total Care<sup>SM</sup> Enrollment and signature (Sections 7 and 8). If Patient or Legal Representative is not present, Physician or Office Staff must complete Sections 1 and 2.**

## 1. Patient Information

|                                                                                                                                                 |                                                                                                            |               |     |
|-------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------|---------------|-----|
| Patient Name (Last, First, MI)                                                                                                                  | Sex at Birth                                                                                               | Date of Birth |     |
| Address                                                                                                                                         | City                                                                                                       | State         | ZIP |
| Are you a resident of the US or one of its territories? <input type="checkbox"/> Yes <input type="checkbox"/> No                                | Language <input type="checkbox"/> English <input type="checkbox"/> Spanish <input type="checkbox"/> Other: |               |     |
| Preferred Phone Number <input type="checkbox"/> Home <input type="checkbox"/> Mobile                                                            | Alternate Phone Number <input type="checkbox"/> Home <input type="checkbox"/> Mobile                       |               |     |
| Patient Email                                                                                                                                   |                                                                                                            |               |     |
| <input type="checkbox"/> I give permission to Chiesi Total Care <sup>SM</sup> to disclose my patient case information to the following parties: |                                                                                                            |               |     |
| Alternate Authorized Contact Name                                                                                                               | Relationship to Patient                                                                                    |               |     |
| Phone                                                                                                                                           | Email                                                                                                      |               |     |

## 2. Insurance Information

|                                                                                                                              |    |                         |       |
|------------------------------------------------------------------------------------------------------------------------------|----|-------------------------|-------|
| Primary Plan                                                                                                                 | ID | Group #                 | Phone |
| Policy Holder                                                                                                                |    | Relationship to Patient |       |
| Secondary Plan                                                                                                               | ID | Group #                 | Phone |
| Policy Holder                                                                                                                |    | Relationship to Patient |       |
| <input type="checkbox"/> I have attached a copy of my insurance card(s) (front & back) <input type="checkbox"/> No insurance |    |                         |       |

**Physicians & Office Staff: Please complete Sections 3 and 4 below and then continue onto page 3.**

## 3. Provider/Office Information

|                                                    |                     |        |  |
|----------------------------------------------------|---------------------|--------|--|
| Prescriber Name (Print)                            | Practice/Group Name |        |  |
| Address                                            | Suite               |        |  |
| City                                               | State               | ZIP    |  |
| Office Contact Person                              |                     |        |  |
| Office Phone                                       | Office Fax          |        |  |
| License #                                          | NPI #               | Tax ID |  |
| Preferred Infusion Facility (Name, Phone)          |                     |        |  |
| List of Facilities Where Prescriber Has Privileges |                     |        |  |

## 4. Medical Information

|                                                                                                                                                                                                  |                                       |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------|
| Diagnosis <input type="checkbox"/> Fabry (-Anderson) Disease ICD-10-CM E75.21 <input type="checkbox"/> Other:                                                                                    |                                       |
| Allergies <input type="checkbox"/> None <input type="checkbox"/> Yes; specify:                                                                                                                   |                                       |
| Method of Diagnosis (Check All That Apply) <input type="checkbox"/> Enzyme Assay <input type="checkbox"/> Genetic Testing <input type="checkbox"/> Tissue Biopsy <input type="checkbox"/> Other: |                                       |
| Prior Treatment and Dose                                                                                                                                                                         | Last Date of Prior Treatment and Dose |

**Please see Important Safety Information for Elfabrio, including Boxed Warning, on pages 4 and 5, and full Prescribing Information.**

**Questions? Chiesi Total Care<sup>SM</sup> is here to help!**  
Phone: 1-800-784-5840 Email: [us.chiesitotalcare@chiesi.com](mailto:us.chiesitotalcare@chiesi.com)

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Physicians & Office Staff: Please complete Section 5 below and then sign and date Provider Certification (Section 6).

## 5. Elfabrio® (pegunigalsidase alfa-iwxj) Prescription

Dosage—Available as Elfabrio 20 mg/10 mL and 5 mg/2.5 mL single-dose vials.  
Pharmacy to dispense quantity sufficient for a 28-day supply.

|                     |                   |                             |
|---------------------|-------------------|-----------------------------|
| Patient Weight (kg) | Total Dose (mg)*  | Route of Administration: IV |
| Frequency           | Number of Refills | Infusion Rate (mL/hour)     |

Quantity  
20 mg/10 mL single-dose vials:  
5 mg/2.5 mL single-dose vials:

**\*The recommended dosage is 1 mg/kg (actual body weight) administered every 2 weeks as an intravenous infusion.**

Please list any additional treatment information, including follow-up evaluations:

Dispense As Written

Licensed Prescriber  
Signature (No Stamps)

Date

Name (Print)

## 6. Provider Certification

By submitting this form, I certify that I am the prescribing provider mentioned above; that the person named on this form is my patient; that the information provided herein is, to the best of my knowledge, current, complete, and accurate; that the therapy described above is medically necessary for this patient and the patient's records contain supporting documentation that substantiates the utilization and medical necessity of the therapy; that I have prescribed the therapy to the patient; that the decision to prescribe the therapy was based solely on my independent medical judgment; and that I am authorized under state law to prescribe the therapy. I will be supervising the patient's treatment, and I have reviewed the current prescribing information for the therapy. Further, I certify that I have discussed Chiesi Total Care<sup>SM</sup> (the "Program") with my patient and that my patient would like to be screened for eligibility for the Program and provided, if applicable, any services under the Program [as described on page 5] for which my patient is eligible.

I understand that my patient's information provided to Chiesi, its successors, vendors, agents, and representatives (collectively, "Chiesi") is for the use of the Program to verify my patient's insurance coverage; to facilitate the filling of my patient's prescription; to assess my patient's eligibility for the Program and other support programs; and to otherwise administer the Program for the patient. I certify that I am disclosing the patient's Protected Health Information ("PHI") on this form to the Program for treatment, payment, or healthcare operations purposes, in accordance with the requirements under the Health Insurance Portability and Accountability Act of 1996 and its implementing regulations, as amended ("HIPAA"). Additionally, I provide my permission to use my personal information for the purposes described above and certify that I have obtained the patient's written authorization in accordance with applicable state and federal law, including HIPAA, to provide the PHI on this form to the Program for such purposes. If my patient is 18 years old or younger, I attest that I have obtained such authorization from the patient's legal guardian. I acknowledge and agree that the Program may reach out to my patient to obtain additional consents or authorizations as deemed appropriate in connection with the Program.

I authorize the Program to conduct a benefits investigation for my patient (and to act on my behalf for the limited purpose of transmitting this prescription to the appropriate pharmacy based on the results of that benefits investigation). If coverage is not available and the patient qualifies for and will receive free product under the Program, I understand that no request for reimbursement for free product or administration of such product may be submitted to any payer, including Medicare, Medicaid, and any government-funded programs. Receiving free product is not contingent on any purchase obligations, and no free product may be sold, traded, or distributed for sale. I understand that any falsification, omission, or concealment of material fact related to my patient's eligibility for such free product may result in criminal liability.

I consent to Chiesi contacting me by fax, mail, or email to provide additional information about the product(s) marked above or the Program. I understand that the Program may revise, change, or terminate any Program services at any time without notice to me.

Licensed Prescriber  
Signature

Date

Name (Print)

*ATTENTION: The prescriber is responsible for compliance with state-specific prescription requirements.  
E-prescribe or use the official state prescription form where required by state law. No stamped signatures or signing on behalf of the prescriber.*

Please see Important Safety Information for Elfabrio, including Boxed Warning, on pages 4 and 5, and full [Prescribing Information](#).

Questions? Chiesi Total Care<sup>SM</sup> is here to help!  
Phone: 1-800-784-5840 Email: [us.chiesitotalcare@chiesi.com](mailto:us.chiesitotalcare@chiesi.com)

**Note:** If the patient is under 18 years old or unable to act on their own behalf, a legal representative must provide consent to enroll and may complete the process on their behalf.

Chiesi Total Care™ (the "Program") provides product support to eligible patients who have been prescribed a Chiesi USA, Inc. ("Chiesi") product. Program support may include: (1) reimbursement and financial support (such as investigating insurance coverage, confirming out-of-pocket costs, and reviewing eligibility for financial assistance and copay programs); (2) working with patients and pharmacies to fill prescriptions; (3) home infusion support (if applicable); and (4) providing disease-, medication-, and adherence-related educational resources and communications, including access to a Chiesi Patient Education Liaison.

## 7. HIPAA Authorization

By signing this authorization form ("Authorization"), I confirm I would like to enroll in the Program and authorize Chiesi USA, Inc., and its affiliates, service providers, agents, and successors (together, "Chiesi") to provide me with Program support. I authorize my healthcare providers and their staff, my health plan, patient assistance programs, and my pharmacies to process and share my protected health information, including, but not limited to: any information relating to my diagnosis, treatment, lab results, care management, and health insurance, as well as any contact information, and any other information provided on this form (together, "Protected Health Information") with Chiesi so that I may be enrolled in the Program, and so Chiesi can provide me Program support, administer the Program, meet legal obligations, conduct other business activities, and complete government-reporting activities. I further understand that once my Protected Health Information is disclosed to Chiesi, my Protected Health Information may no longer be protected by federal privacy laws, including HIPAA, and could be re-disclosed. However, this disclosed information may be protected by U.S. State privacy laws and/or U.S. State consumer health data laws, depending on my State of residence. I understand that I may find out more about Chiesi's privacy practices, including Chiesi's Privacy Policy, California Notice at Collection, and Consumer Health Data Privacy Policy at [www.chiesiusa.com/privacy](http://www.chiesiusa.com/privacy).

I understand that this Program is optional. I can refuse to sign this Authorization and understand that refusing to sign will not affect my treatment, insurance coverage, or eligibility for benefits or access to Chiesi products. However, I understand that I need to sign this form to participate in the Program.

I understand that I may cancel this Authorization at any time or receive a copy of this Authorization by mailing a letter requesting cancellation to Chiesi Total Care™ at One Boston Place, Suite 4030, Boston, MA 02108. Upon cancellation, to the extent required by applicable law, Chiesi will no longer process my personal information. I understand my cancellation will not apply to any of my personal information already used or disclosed based on this Authorization prior to receipt of the cancellation. Unless canceled earlier, this Authorization expires ten (10) years from the date signed below, or as otherwise required by state or local law.

By signing this form, I acknowledge that my pharmacy will be compensated by Chiesi for providing the necessary personal information needed for Program services. I acknowledge that if I am eligible for infusion co-pay assistance, the payment will be submitted to my healthcare facility where the infusion occurred. I acknowledge that if I am enrolled in a government-funded healthcare program, I am not eligible for and will not accept any financial assistance from Chiesi Total Care™. I understand and agree that if my insurance information changes at any time while I am participating in the Chiesi Total Care™ Program, I will notify Chiesi Total Care™ as soon as possible, and any such change may affect my eligibility for such assistance programs.

## Indication

Elfabrio® (pegunigalsidase alfa-iwxj) is indicated for the treatment of adults with confirmed Fabry disease.

## Important Safety Information

### **WARNING: HYPERSENSITIVITY REACTIONS INCLUDING ANAPHYLAXIS**

**Patients treated with Elfabrio have experienced hypersensitivity reactions, including anaphylaxis. Appropriate medical support measures, including cardiopulmonary resuscitation equipment, should be readily available during Elfabrio administration. If a severe hypersensitivity reaction (eg, anaphylaxis) occurs, discontinue Elfabrio immediately and initiate appropriate medical treatment. In patients with severe hypersensitivity reaction, a desensitization procedure to Elfabrio may be considered.**

Prior to Elfabrio administration, consider pretreating with antihistamines, antipyretics, and/or corticosteroids. Inform patients and caregivers of the signs and symptoms of hypersensitivity reactions and infusion-associated reactions (IARs), and instruct them to seek medical care immediately if such symptoms occur.

- If a severe hypersensitivity reaction (including anaphylaxis) or severe IAR occurs, immediately discontinue Elfabrio administration and initiate appropriate medical treatment.
- If a mild to moderate hypersensitivity reaction or IAR occurs, consider slowing the infusion rate or temporarily withholding the dose.

In clinical trials, 20 (14%) Elfabrio-treated patients experienced hypersensitivity reactions. Four Elfabrio-treated patients (3%) experienced anaphylaxis reactions that occurred within 5 to 40 minutes of the start of the initial infusion. The signs and symptoms of hypersensitivity reactions and anaphylaxis included headache, nausea, vomiting, throat tightness, facial and oral edema, truncal rash, tachycardia, hypotension, rigors, urticaria, intense pruritus, moderate upper airway obstructions, macroglossia, and mild lip edema.

In clinical trials, 41 (29%) Elfabrio-treated patients experienced one or more infusion-associated reactions, including hypersensitivity, nausea, chills, pruritus, rash, chest pain, dizziness, vomiting, asthenia, pain, sneezing, dyspnea, nasal congestion, throat irritation, abdominal pain, erythema, diarrhea, burning sensation, neuralgia, headache, paresthesia, tremor, agitation, increased body temperature, flushing, bradycardia, myalgia, hypertension, and hypotension.

**Please see additional Important Safety Information on page 5 and full Prescribing Information.**

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## 8. Chiesi Total Care<sup>SM</sup> Terms and Conditions

To enroll in Chiesi Total Care<sup>SM</sup> (the "Program") and to assess eligibility for patient support services of the Program, the patient must complete the patient portions of this Elfabrio Start Form in their entirety and have a valid prescription for an eligible product of the Program. Additional documentation may be required. The patient must be a resident of the United States or one of its territories.

A patient who receives healthcare benefits under any plan or program funded in whole or in part by federal or state governments, including Medicare, Medicaid, TRICARE, Veterans Affairs (VA), State Prescription Assistance Plans (SPAPs) (other than health insurance for federal government employees), or any state healthcare program such as the Children's Health Insurance Program, programs funded under Maternal and Child Health Program, or programs funded under Social Services Block Grant (collectively, "Government-funded Plans"), is not eligible for the financial patient support services of the Program. A patient covered under a commercial health plan purchased through a health insurance marketplace or exchange is not a government-funded plan beneficiary even if the costs of such coverage are subsidized by the federal government. If a change in prescription drug coverage should occur, the patient must notify the Program; such change may affect eligibility for the support services provided in the Program. Patients who have been prescribed a product for an indication that is not consistent with the US Food and Drug Administration-approved labeling will not be eligible for financial patient support services offered through the Program.

Patients residing in or receiving treatment in certain states may not be eligible for certain patient support services of the Program. Patients may not seek reimbursement for value received from the Program. The Program does not obligate the use of any specific medication or healthcare provider. Patients who receive treatment or reside in Massachusetts or Rhode Island are not eligible for co-pay assistance for infusion services or routine testing services. Chiesi Total Care<sup>SM</sup> may provide patients with the names of independent co-pay assistance programs, if applicable. However, Chiesi does not fund or control these organizations. Any assistance provided by an independent program is subject to its own eligibility criteria and is not guaranteed by Chiesi.

Program benefits may not be sold, purchased, traded, or offered for sale, purchase, or trade. The Chiesi Total Care<sup>SM</sup> patient support services are not valid where prohibited by law, taxed, or otherwise restricted. Offer subject to change or discontinuance without notice. Restrictions, including monthly maximums, may apply. This is not health insurance.

This is a voluntary program. Patients who choose not to enroll in the Program will be able to receive medication. Patients may participate in Chiesi Total Care<sup>SM</sup> without participating in a patient support services program of Chiesi Total Care<sup>SM</sup>. After enrolling in Chiesi Total Care<sup>SM</sup>, participants may opt out by contacting the Program, as outlined above in this form. Patients must renew their eligibility by December 31 of each year to continue to receive support under the Program.

By participating in the Program, participants acknowledge that they understand and agree to comply with the Program Terms and Conditions.

☐ Yes, I would like to opt into the Chiesi Total Care<sup>SM</sup> program.\*

☐ No, I would like to start taking Elfabrio as prescribed without enrolling in Chiesi Total Care<sup>SM</sup>.

\*I understand that this Program is optional. I can refuse to sign this authorization and understand that refusing to sign will not affect my treatment, insurance coverage, or eligibility for benefits or Chiesi products.

**You can cancel at any time by writing to Chiesi Total Care<sup>SM</sup> at One Boston Place, Suite 4030, Boston, MA 02108.**

### If opting into Chiesi Total Care<sup>SM</sup>, please review the following options:

#### Telephone Consumer Protection Act ("TCPA") Communication Consent<sup>1</sup>

Please indicate whether you authorize Chiesi to contact you via text message for the purposes of sending marketing and informational messages. Your consent to receiving text messages is not a condition of receiving medication or services from Chiesi. You may also revoke your authorization by replying STOP to any text from Chiesi Total Care<sup>SM</sup> or by contacting Chiesi Total Care<sup>SM</sup> in writing at the address above. Text HELP for help or contact us at the number or email at the bottom of the page. Message frequency may vary. Full Text Message Program terms and conditions can be found at: <https://www.chiesitotalcare.com/SMS-terms.pdf>

<sup>1</sup>Additional charges may apply. I understand that my telephone provider may charge me fees for calls or texts I receive, and I agree that Chiesi Total Care<sup>SM</sup> will not pay those fees.

☐ Yes, you may text me.

☐ No, do not text me.

#### Marketing Communications Consent

Please indicate whether you would like to be contacted, such as by mail, phone, text,<sup>1</sup> and email, with marketing communications about products, promotions, services, and research studies, and to ask your opinion about such information and topics, including market research and disease-related surveys. You can opt out of communications at any time by notifying us via phone or email (see below). Opting out of these communications will not affect your enrollment in the Program and you will still receive patient assistance through the Program, as prescribed by your physician.

<sup>1</sup>You will only receive text messages if you have consented in the TCPA Communication Consent, above.

☐ Yes, I agree to receive communications.

☐ No, do not contact me.

**By signing below, I also acknowledge that I have read and agree to the HIPAA Authorization (on page 4) and enrollment details and terms and conditions of Chiesi Total Care<sup>SM</sup> (above).**

Patient Signature

Date

Legal Representative  
Signature

Date

Patient Name (Print)

Legal Representative  
Name (Print)

Relationship  
to Patient

#### Privacy Notice

By enrolling in Chiesi Total Care<sup>SM</sup>, I hereby authorize Chiesi and its affiliates to use my personal information to communicate to me (such as by mail, phone,<sup>1</sup> text,<sup>2</sup> and email) about the Program and disease state. I also understand and agree that my personal information may be de-identified, combined with other de-identified information received by the Program, and used for lawful purposes. For more information on Chiesi's privacy practices, please view our Privacy Policy, California Notice at Collection, and Consumer Health Data Privacy Policy at [www.chiesiusa.com/privacy](http://www.chiesiusa.com/privacy). Please note that Chiesi USA, Inc. does not sell or share your personal information as defined in applicable data protection laws.

## Important Safety Information (continued)

A case of membranoproliferative glomerulonephritis with immune depositions in the kidney was reported during clinical trials. Monitor serum creatinine and urinary protein-to-creatinine ratio. If glomerulonephritis is suspected, discontinue treatment until a diagnostic evaluation can be conducted.

When switching to Elfabrio from a prior enzyme replacement therapy, the risk of hypersensitivity reactions and infusion-associated reactions may be increased in certain patients with pre-existing anti-drug antibodies (ADAs). Consider monitoring IgG and IgE ADAs and clinical or pharmacodynamic response (eg, plasma lyso-Gb3 levels).

The most common adverse reactions (≥15%) were infusion-associated reactions, nasopharyngitis, headache, diarrhea, fatigue, nausea, back pain, pain in extremity, and sinusitis.

**Please see additional Important Safety Information on page 4 and full Prescribing Information for Elfabrio.**

For more information, visit [elfabrio.com](http://elfabrio.com).

Questions? Chiesi Total Care<sup>SM</sup> is here to help!

Phone: 1-800-784-5840 Email: [us.chiesitotalcare@chiesi.com](mailto:us.chiesitotalcare@chiesi.com)

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