

Pegunigalsidase alfa-iwxj (Elfabrio)

Infusion Therapy Plan Orders

Name: _____
Kaiser Permanente Member I.D. #: _____
Date of Birth: _____

Instructions to Provider

Review orders and note any changes. All orders with will be placed unless otherwise noted. Please fax completed order form to the infusion center where the patient will be receiving treatment (see fax numbers using the link at the end of this protocol). Lab orders are not included on this form – place orders via usual method. Lab monitoring is the responsibility of the ordering physician.

Please complete all the following:

Order Date: _____	Diagnosis ICD-10 code (REQUIRED): _____
Weight: _____ kg	ICD-10 description: _____

General Plan Communication

- Use actual body weight for dose calculation, dose will be rounded to nearest 5 mg
- **Special instructions/notes:**

Provider Information

- A case of membranoproliferative glomerulonephritis with immune depositions in the kidney was reported during clinical trial.
 - Monitor serum creatinine and urinary protein to creatinine ratio.
 - If glomerulonephritis is suspected, discontinue Elfabrio until a diagnostic evaluation can be conducted.
- Consider obtaining IgG and IgE anti-pegunigalsidase alfa-iwxj antibodies prior to starting therapy in patients who have history of prior enzyme replacement therapy.
- Pre-medications are suggested for at least the first 4 to 6 infusions and can be decreased upon prescriber orders, based on patient tolerance of first 4 to 6 infusions. This therapy plan has pre-meds selected for all infusions, unless prescriber specifies otherwise.

Infusion Therapy

Pegunigalsidase alfa-iwxj (Elfabrio) 2 mg/ mL in 0.9 % Sodium Chloride

Dose: 1 mg/kg (will be rounded to the nearest 5 mg)
Route: Intravenous
Frequency: Every 2 weeks

Infusion Volume:
 (Based upon patient weight)

Patient actual body weight (kg)	Minimum Total Volume (mL)
< 70	150
70 – 100	250
> 100	500

Administration:

- Infuse using a low protein-binding 0.2 micron in-line or add-on filter.
- Flush line with 40 mL 0.9% NaCl at the same infusion rate used for the last part of Elfabrio infusion.
- Administer in a separate line from other agents.

Infusion rate for first 4 to 6 infusions is based on prior ERT experience

Infusion Rate:

Patient ABW (Total Infusion Volume)	ERT experienced Infusion Rate	ERT naïve Infusion Rate
< 70 kg (150 mL)	0.83 mL/min (50 mL/hr)	0.63 mL/min (37.5 mL/hr)
70 – 100 kg (250 mL)	1.39 mL/min (83 mL/hr)	1 mL/min (60 mL/hr)
> 100 kg (500 mL)	2.78 mL/min (167 mL/hr)	1.38 mL/min (83 mL/hr)

May decrease the duration of every third infusion if patient tolerates the initial 4 to 6 infusions. Decrement in 30 minute increments. Infuse over at least 1.5 hours.

Note any changes to above regimen:

Provider Signature: _____ **Date:** _____

Printed Name: _____ **Phone:** _____ **Fax:** _____

**Pegunigalsidase alfa-iwxj (Elfabrio)
 Infusion Therapy Plan Orders**

Name: _____
Kaiser Permanente Member I.D. #: _____
Date of Birth: _____

Pre-Medications			
<input checked="" type="checkbox"/>	acetaminophen (TYLENOL) tablet <i>Dose:</i> 650 mg <i>Route:</i> Oral <i>Frequency:</i> Once, 30 minutes prior to infusion. May also be given once as needed during infusion for achiness, headache, or fever		
<input checked="" type="checkbox"/>	cetirizine (ZYRTEC) tablet <i>Dose:</i> 10 mg <i>Route:</i> Oral <i>Frequency:</i> Once, 60 minutes prior to infusion (if not taken at home)		
<input checked="" type="checkbox"/>	Other: _____ <i>Dose:</i> _____ <i>Route:</i> Oral <i>Frequency:</i> Once, 30 minutes prior to infusion		
IV Line Care			
<input checked="" type="checkbox"/>	0.9% Sodium Chloride (NS) infusion 250 mL <i>Rate:</i> 30 mL/hr <i>Route:</i> Intravenous <i>Frequency:</i> Run continuously to keep vein open. Start peripheral IV if no central line		
PRN & Hypersensitivity Reaction Medications			
<input checked="" type="checkbox"/>	acetaminophen (TYLENOL) tablet <i>Dose:</i> 650 mg <i>Route:</i> Oral <i>Frequency:</i> Take 650 mg PO every 4 hours PRN for fever (greater than 100.4 F), myalgias, arthralgias or headache.		
<input checked="" type="checkbox"/>	alteplase (CATHFLO ACTIVASE) injection <i>Dose:</i> 2 mg <i>Route:</i> Intracatheter <i>Frequency:</i> Instill 2 mg to affected port(s) of central venous catheter if sluggish or occluded. Allow to dwell for 30 minutes, if unable to aspirate blood allow to dwell for an additional 90 minutes. May repeat one time if unsuccessful.		
<input checked="" type="checkbox"/>	diphenhydrAMINE (BENADRYL) injectable <i>Dose:</i> 50 mg <i>Route:</i> Intravenous <i>Frequency:</i> Give IV push over 2 minutes PRN for hives, rash, itching, flushing, and/or swelling in a suspected hypersensitivity reaction. May repeat one time. Notify provider if patient experiences a hypersensitivity reaction.		
<input checked="" type="checkbox"/>	famotidine (PEPCID) (PF) injection <i>Dose:</i> 20 mg <i>Route:</i> Intravenous <i>Frequency:</i> Give IV push over 2 minutes one time PRN for hives, rash, itching, flushing, and/or swelling in a suspected hypersensitivity reaction. Give immediately after diphenhydrAMINE. Notify provider if patient experiences a hypersensitivity reaction.		
<input checked="" type="checkbox"/>	methylPREDNISolone Sod Succ (PF) Inj 125 mg (SOLU-Medrol PF) <i>Dose:</i> 125 mg <i>Route:</i> Intravenous <i>Frequency:</i> Give 125 mg IV push one time PRN for shortness of breath, bronchospasm, or other symptoms of a suspected hypersensitivity reaction not otherwise specified. Notify provider if patient experiences a hypersensitivity reaction.		
<input checked="" type="checkbox"/>	sodium Chloride 0.9% IV bolus <i>Dose:</i> 1000 mL <i>Route:</i> Intravenous <i>Frequency:</i> Give IV over 1 hour one time PRN for hypotension due to presumed anaphylaxis. Notify provider if patient experiences a hypersensitivity reaction.		

Provider Signature: _____ Date: _____

Printed Name: _____ Phone: _____ Fax: _____

Pegunigalsidase alfa-iwxj (Elfabrio) Infusion Therapy Plan Orders

Page 3 of 3

Name: _____

Kaiser Permanente Member I.D. #: _____

Date of Birth: _____

 EPINEPHrine (Epi-Pen) 0.3 mg/0.3 mL IM Auto-Injector**Dose:** 0.3 mg**Route:** Intramuscular**Frequency:** Give IM once PRN for anaphylaxis/allergic reaction. May repeat one time.

KPWA Asthma/Allergy and Pediatrics endorse:

For patients < 25 kg (55 lbs): 0.15 mg. For patients ≥ 25 kg (55 lbs): 0.3 mg.
Inject into anterolateral aspect of the thigh.**Nursing Orders**

- Begin 0.9% NS as primary line to keep vein open.
- Perform assessment for toxicity and tolerance.
- Anaphylaxis (e.g., hypotension, angioedema, urticaria or other rash, pruritus, and dyspnea) has been reported in patients. Discontinue infusion if any of these symptoms are observed and report to MD for additional instructions.
- Monitor for temperature greater than 100.4F, chills, pruritus, chest pain, blood pressure changes (notify MD if greater than 10% drop in systolic blood pressure or if patient is symptomatic), or dyspnea.
- **If infusion related reaction:**
 1. STOP infusion immediately
 2. Begin primary solution at wide open rate
 3. Notify MD
 4. Monitor vital signs and administer PRN medication for infusion reaction
 5. After symptoms have resolved, consult with MD on rate to resume infusion
- Discontinue IV line when therapy is complete and patient is stabilized.
- Monitor patient for at least one hour after medication has infused for evidence of adverse reaction.
- Review discharge medications, instructions, and future appointments.

References

Pegunigalsidase alfa-iwxj® (ELFABRIO) injection for intravenous use Prescribing Information. Revised May 2024.

Kaiser Permanente Infusion Locations

Please refer to the link below for the current list and contact information:

<https://wa-provider.kaiserpermanente.org/patient-services/ambulatory-infusion>

Provider Signature: _____ Date: _____

Printed Name: _____ Phone: _____ Fax: _____