MRN:_____

DOB:_____

STANDARD Fabrazyme® (agalsidase beta) PLAN OF

NOTE: *We may require a detailed Letter of Medical Necessity or clinical supporting documentation (depending on diagnosis), to be able to verify eligibility and payment for this treatment through Medicare and/or other insurance plans.*

1. Patient Name:_____ Height (inches):_____ Weight (lbs):_____

2. Allergies: _____

3. Primary Diagnosis: E75.21 Fabry Disease

***4.* Pre-medications:** *Administered 30 minutes prior to infusion as selected:*

****Product information suggest premedication with any patient experiencing infusion reactions.***

Acetaminophen: □ 1000 mg PO □ 650 mg PO □ 500 mg PO □ 325 mg PO	Diphenhydramine: □ 25 mg PO, □ 50 mg PO, □ 25 mg IVP, □ 50 mg IVP or Fexofenadine □ 60mg or □ 180 mg, □ Cetirizine 10 mg, □ Loratadine 10 mg Methylprednisolone □ 40 mg IVP □ 125 mg IVP or other_____mg IVP Famotidine: □ 20 mg PO, □ 40 mg PO, □ 20 mg IVP, □ 40 mg IVP

Pre-medicate with other: _____

5. Dose/Frequency: *Dose will be round to nearest 5 mg vial

Fabrazyme® (agalsidase beta) 1mg/kg or _____mg in 0.9% Sodium Chloride IV every (2) weeks infused as per protocol* via pump with 0.22-micron filter or over_____hours as specified

Treatment should be further diluted with 0.9% Sodium Chloride to a total volume based on weight

Patient Weight (kg)	Minimum Total Volume (ml)
≤ 35	50
35.1 - 70	100
70.1- 100	250
> 100	500

Special Orders: _____

_____

6. Lab orders: ☐ MD office will draw and monitor Serum GL-3 and IgG levels or

Serum GL-3 & IgG antibody will be drawn every 3 months for first 18 months, then every ☐6 months or ☐Annually

If adverse drug reaction occurs, utilize the ADVERSE DRUG REACTION GUIDELINES

7. Physician's Signature:_____/_____ Date: _____

No Stamp Signatures (Dispense as written) (Substitution permitted)

Printed Physician's Name with Credentials:_____ NPI: _____

MRN:_____

DOB:_____

Fabrazyme® (agalsidase beta)

*Infusion Rate Protocol:

Initial Infusion rate will be no greater than 15 mg/hr. The infusion rate may be slowed in the event of infusion reaction and referring physician will be notified. After patient tolerance to the infusion is well established, the infusion rate may be increased in increments of 3 – 5 mg/hr with each subsequent infusion.

- For patients weighing < 30 kg, the maximum infusion rate should remain at 15 mg/hr
- For patients weighing ≥ 30 kg, the administration duration should not be less than 1.5 hours (based on individual patient tolerability)

Total infusion volume will be between 50-500 ml based on weight: (Infusion rate will be patient specific)

Infusions 1-8:

Infusion rate will not exceed 15 mg/hr; continuous infusion rate of_____ml/hr for total infusion time of_____hours

If patient weights ≥ 30 kg and is tolerating infusion, then increase as follows:

Infusion 9:

Rate may be increased to 20 mg/hr; continuous infusion rate of_____ml/hr for total infusion time of_____hours

Infusion 10:

Rate may be increased to 25 mg/hr; continuous infusion rate of_____ml/hr for total infusion time of_____hours

Infusion 11 and beyond: * Rate will not to exceed total infusion time of 1.5 hours

Rate may be increased 30 mg/hr; continuous infusion rate of_____ml/hr for total infusion time of_____hours

Clinical Lab Monitoring Collection Kits:

Serum IgG antibody and GL-3 levels can be drawn routinely, and kits will be kept at infusion site.

Sample collection kits and materials may be obtained from Genzyme Customer Operations at 1-800-745-4447 (press 1 for orders)

*Serum IgE antibody testing may be indicated for patient who experience suspected allergic reactions. If warranted, sample draw no sooner than 72 hours following completion of the infusion and only by physician order. Sample kits are not routinely available and require special ordering or the patient may require testing at alternate site of service.

Fabrazyme Product Website: www.fabrazyme.com **Fabry Registry: www.RegistryNXT.com**
Genzyme Medical Information: 1-800-745-4447, option 2
Genzyme Case Managers: 1-800-745-4447, option 3

MRN:_____

DOB:_____

Guidelines for Prescribing Fabrazyme® (agalsidase beta)

(Required documentation with all initial referrals)

Patient Name: _____ **Referral Date:**_____

☐ Include signed and completed **Plan of Treatment**.

☐ Include patient demographic information and insurance information. (Copy of insurance cards if available)

☐ **Supporting clinical MD notes to include any past tried and/or failed therapies, intolerance, outcomes or contraindications to conventional therapy. Include any lab results and/or tests to support diagnosis.**

- Fabrazyme® (agalsidase beta) is used to treat patients with Fabry disease. Fabrazyme lowers the amount of a substance called globotriaosylceramide (GL-3), which builds up in cells lining the blood vessels of the kidney and certain other cells. The lowering of GL-3 suggests that Fabrazyme may improve how Fabry disease affects your body; however a relationship of lower GL-3 to specific signs and symptoms of Fabry disease has not been proven.

☐ Other as requested: _____

_____

Pre-Screening

☐ **Serum IgG Antibody and GL-3 level**

** Warnings/Precautions: **Life-threatening anaphylactic and severe allergic reactions**: have been observed in some patients during Fabrazyme® infusions. If severe allergic or anaphylactic reactions occur, immediately discontinue administration of Fabrazyme® and provide necessary emergency treatment. **Infusion reactions:** occurred in approximately 50 to 55% of patients during Fabrazyme® administration in clinical trials. In patients experiencing infusion reactions, pretreatment with an antipyretic and antihistamine is recommended. **Cardiac Risks:** Patients with advanced Fabry disease may have compromised cardiac function, which may predispose them to a higher risk of severe complications from infusion reactions. These patients should be monitored closely during Fabrazyme® administration. **Re-administration**: Fabrazyme® patients who have previously experienced severe or serious allergic reactions to Fabrazyme® should be done only after careful consideration of the risks and benefits of continued treatment, and only under the direct supervision of qualified personnel and with appropriate medical support measures readily available. See full prescribing information.

Checklist for referrals to AccuRX Infusion Center:

Fax referral to 1-866-990-3192

- Patient demographics – address, phone number, SS#, etc.
- Insurance Information – copy of the card(s) if possible
- Plan of Treatment/Orders
- Most recent physician office notes to include tried and failed therapies – all insurance companies that require a pre-authorization require the note. This includes Medicare/Medicaid HMOs
- Any lab results or other diagnostic procedures to support the diagnosis

AccuRx Infusion Center will complete insurance verification and submit all required clinical documentation to the patient's insurance company for eligibility. Our office will notify you if any further information is required. We will review financial responsibility with the patient and refer them to any available Co-pay assistance as required. Thank you for the referral.