Galafold® (migalastat) Referral Form

Email forms to: assist@amicusrx.com | Fax completed forms to: 1-833-264-2873
Questions? Call toll-free: 1-833-AMICUS-A (1-833-264-2872)
Please include copies of all insurance cards and print legibly, using blue or black ink.

This form serves a dual purpose. It allows patients to register for AMICUS ASSIST® and also serves as a prescription for Galafold.

☐ I opt not to enroll in AMICUS ASSIST at this time. I understand that this will not prohibit my receiving therapy with Galafold.

Step 1: Complete the following information to register the patient for AMICUS ASSIST.
This form will also act as a prescription and statement of medical necessity for Galafold.

Patient Information (The correct patient information is necessary for timely processing. Complete all fields and provide accurate information to register the patient with AMICUS ASSIST.)

First Name: _____ MI: _____ Last Name: _____

Address 1: _____ Address 2: _____

City: _____ State: _____ Zip: _____ DOB: _____ Gender: ☐ Male ☐ Female

Preferred Phone #: _____ Can we leave a message on this phone? ☐ Yes ☐ No

Alternate Authorized Contact: _____ Phone #: _____

Relationship to Patient: _____

May an AMICUS ASSIST Case Manager contact the patient by email? ☐ Yes ☐ No Email: _____

Preferred Method of Contact: _____ Preferred Time of Contact: _____

Insurance Information (If available, photocopy the front and back of the patient's medical and prescription insurance cards and submit them with this form.)

☐ No Insurance

Primary Insurance: _____ **Secondary Insurance:** _____

Policy Holder: _____ Policy Holder: _____

Policy ID #: _____ Policy ID #: _____

Group #: _____ Group #: _____

Phone #: _____ Phone #: _____

Prescription Card (Name): _____ Phone #: _____

Group #: _____ ID #: _____ Rx Bin #: _____ PCN #: _____

Prescriber Information (Complete all information in this section as it is essential for the Galafold prescription to be filled.)

First Name: _____ Last Name: _____

Office/Institution: _____

Address: _____

City: _____ State: _____ Zip: _____ Phone # _____ Fax #: _____

Email: _____ NPI #: _____ State License #: _____

Contact Person: _____

Contact Phone # (direct): _____ Contact Email: _____

This section serves as a prescription for Galafold. Include the number of refills necessary to prevent disruptions in product access. Any changes will require the submission of a new form. Note: this may not serve as a prescription in all states.

Prescription Information: Galafold® (migalastat) 123 mg/cap NDC #: 71904-100-01 (wallet containing 14 capsules)

Rx
ICD-10 Code: E75.21
Dosing Instructions: 123 mg PO (by mouth) every other day for continuous use
Dispensing Quantity: _____ No. of Refills: _____

I certify that the above therapy is medically necessary for the treatment of Fabry and that the information provided is accurate to the best of my knowledge. I appoint AMICUS ASSIST, on my behalf, to provide this form or any information contained on this form to the insurer of the above-named patient or to the dispensing pharmacy. I hereby certify that my office has obtained HIPAA-compliant authorization from the above-mentioned patient to disclose the protected health information necessary for Amicus to provide services described in the Patient Authorization on page 2 of the Galafold Referral Form. I also allow AMICUS ASSIST to contact the patient/caregiver as needed to process this Referral Form.

The prescriber's signature is required to initiate registration in AMICUS ASSIST and to fill the prescription for Galafold.

Prescriber's Signature: _____ Date: _____
(No stamped signatures permitted.)

Generic substitution permissible:

Prescriber's Signature: _____ Date: _____
(No stamped signatures permitted.)

Instructions: Complete the Patient Authorization on page 2 and the Statement of Medical Necessity on page 3.

Please see Important Safety Information on page 4 and accompanying Full Prescribing Information, also available at https://www.amicusrx.com/pi/galafold.pdf.

Galafold® (migalastat) 123 mg capsule

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Step 2: Obtain patient authorization. Please have patient review and sign authorization below in order to enroll in AMICUS ASSIST®.

Patient Authorization for Use and Disclosure of Health Information Pursuant to 45 C.F.R. §164.508

By signing this authorization ("Authorization"), I hereby certify and agree to the following:

I am (i) the Patient (identified in Step 1 above) and legally permitted to make decisions about how my health information is used and disclosed or (ii) the parent, legal guardian, or authorized representative of the Patient and legally permitted to make decisions about how the Patient's health information is used and disclosed.

I authorize my physician, identified on page 1 of this Referral Form, and their staff to disclose my health and other personal and protected health information, including but not limited to, the information on this Referral Form and information deemed relevant by my physician that may be considered sensitive or specially protected under state law, to Amicus and its agents and representatives (collectively "Amicus") so that Amicus may use and further disclose my information to healthcare providers, pharmacies, insurance companies, prescription drug plans, and other third-party payers (collectively, "Third Parties") in order to: (1) facilitate the filling of my prescription for and the delivery and administration of Galafold; (2) assist me in obtaining insurance coverage for Galafold; (3) contact me by mail, email, and/or telephone or text message to enroll me in, and administer, programs that provide Galafold support services; (4) contact me via those methods specified in (3) to provide me with free educational information and product materials; (5) conduct quality assurance, surveys, and other internal business activities in connection with Galafold and Galafold support services; and/or (6) address adverse events and product quality complaints.

I authorize my healthcare providers, including my physician identified on page 1 of this Referral Form, and their staff and my pharmacies to disclose my health and other personal and protected health information, including but not limited to the information about me in their possession, to Amicus in order to assist Amicus in accomplishing the purposes described above.

I understand that information disclosed pursuant to this Authorization could be re-disclosed by Recipients. Such re-disclosed information may no longer be protected by federal or state medical privacy laws, including the Health Insurance Portability and Accountability Act or "HIPAA."

I understand that I may refuse to sign this Authorization and such refusal will not affect my ability to receive Galafold, my treatment, payment for treatment, enrollment in a health plan or eligibility for benefits, but it will limit my ability to receive support services for Galafold from Amicus.

This Authorization will expire in 10 years after the date it is signed unless a shorter period is mandated by state law or I revoke or cancel my Authorization by contacting Amicus in writing at:

ATTENTION: AMICUS ASSIST
Amicus Therapeutics
3675 Market Street
Philadelphia, PA 19104

If I revoke this Authorization, Amicus will stop using and disclosing my information as soon as possible, but the revocation will not affect prior use or disclosure of my information in reliance on this Authorization.

I understand that the services provided by Amicus that I have agreed to, and that are described in this Authorization, may be reduced or terminated at any time, without prior notice.

I understand that my pharmacy, health insurer(s), or healthcare providers may receive remuneration from Amicus for disclosing pursuant to this Authorization certain personal and medical information related to the AMICUS ASSIST activities conducted on my behalf so that Amicus may administer, assess and improve the quality of services being provided to patients. I also understand that my pharmacy may receive remuneration from Amicus for administering some of the services which are described above.

I am aware that I can review the Amicus Privacy Policy, including information for California residents, by visiting www.amicusrx.com/privacy-policy.

I have received a copy of this Authorization.

Patient's Signature _____ Date _____

Patient's Name (please print) _____

Patient's Authorized Representative (please print) _____

Relationship to Patient _____

Authorized Representative's Signature _____ Date _____

The patient's signature is required to release his/her health information to AMICUS ASSIST and to open a dialogue about insurance.

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Step 3: Submit the completed form.

Statement of Medical Necessity – Galafold

Patient Name/Information:

First Name: _____ MI: _____ Last Name: _____

DOB: _____

Drug/Non-Drug Allergies: _____ ☐ No known drug allergies

Diagnosis:

Fabry Disease ICD-10 Code: E75.21

Date of Diagnosis: _____

Method of Diagnosis (check all that apply):

☐ Clinical signs ☐ α-Gal A enzyme activity levels ☐ Genotype

☐ Other _____

Amenable *GLA* Gene Variant:

☐ Yes ☐ No ***GLA* Gene Variant:** _____

Clinical Signs and Symptoms: _____

Current/Prior Treatment Plan: _____

Therapy: _____ **Dose:** _____

Date Initiated: _____ **Date Discontinued (if applicable):** _____

Therapy: _____ **Dose:** _____

Date Initiated: _____ **Date Discontinued (if applicable):** _____

Other Medications: _____

_____

_____

I certify that the above therapy is medically necessary for the treatment of Fabry and that the information provided is accurate to the best of my knowledge. I appoint AMICUS ASSIST®, on my behalf, to provide this form or any information contained on this form to the insurer of the above-named patient or to the dispensing pharmacy.

Prescriber's Name (please print): _____ Date: _____

Prescriber's Signature: _____

State License #: _____

Galafold® (migalastat) Referral Form

INDICATIONS AND USAGE

Galafold® (migalastat) is indicated for the treatment of adults with a confirmed diagnosis of Fabry disease and an amenable galactosidase alpha gene (*GLA*) variant based on *in vitro* assay data.

This indication is approved under accelerated approval based on reduction in kidney interstitial capillary cell globotriaosylceramide (KIC GL-3) substrate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

IMPORTANT SAFETY INFORMATION

ADVERSE REACTIONS

The most common adverse drug reactions reported with Galafold (≥10 %) are headache, nasopharyngitis, urinary tract infection, nausea, and pyrexia.

USE IN SPECIFIC POPULATIONS

There is insufficient clinical data on Galafold use in pregnant women to inform a drug associated risk for major birth defects and miscarriage. Advise women of the potential risk to a fetus.

It is not known if Galafold is present in human milk. Therefore, the developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Galafold and any potential adverse effects on the breastfed child from Galafold or from the underlying maternal condition.

Galafold is not recommended for use in patients with severe renal impairment or end-stage renal disease requiring dialysis.

The safety and effectiveness of Galafold have not been established in pediatric patients.

To report Suspected Adverse Reactions, contact Amicus Therapeutics at 1-877-4-AMICUS or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see accompanying Full Prescribing Information, also available at https://www.amicusrx.com/pi/galafold.pdf.