Please note: All information below is required to process this request.
Mon-Fri: 6am to 6pm Eastern / Sat: 6am to 6pm Eastern

Galafold™ Prior Authorization Request Form (Page 1 of 2)

DO NOT COPY FOR FUTURE USE. FORMS ARE UPDATED FREQUENTLY AND MAY BE BARCODED

Member Information (required)			Provider Information (required)		
Member Name:			Provider Name:		
Insurance ID#:			NPI#:	Specialty:	
Date of Birth:			Office Phone:		
Street Address:			Office Fax:		
City:	State:	Zip:	Office Street Address:		
Phone:			City:	State:	Zip:

Medication Information (required)

Medication Name:	Strength:	Dosage Form:
❑ Check if requesting **brand**	Directions for Use:	
❑ Check if request is for **continuation of therapy**		

Clinical Information (required)

Select the diagnosis below:

❑ Fabry disease

❑ Other diagnosis: _____ ICD-10 Code(s): _____

Prescriber's Specialty:

Select if Galafold is prescribed by the following specialist:

❑ Cardiologist ❑ Nephrologist ❑ Specialist in genetics or metabolic disorders

Clinical Information:

Has the patient's current eGFR been documented? ❑ **Yes** ❑ **No**

Select if the patient's diagnosis has been confirmed by the following:

- ❑ Documentation of complete deficiency or less than 5% of mean normal alpha-galactosidase A (alpha-Gal A) enzyme activity in leukocytes, dried blood spots, or serum (plasma) analysis
- ❑ Documented galactosidase alpha (GLA) gene mutation by gene sequencing

Does the patient have an amenable GLA gene variant based on the Good Laboratory Practice (GLP)-validated Human Embryonic Kidney (HEK) assay? ❑ **Yes** ❑ **No**

Test result confirmation of the above must be submitted for documentation

Select if the patient has the following symptoms or physical findings attributable to Fabry disease:

- ❑ Burning pain in extremities (acroparesthesias)
- ❑ Cutaneous vascular lesions (angiokeratomas)
- ❑ Corneal verticillata (whorls)
- ❑ Decreased sweating (anhidrosis or hypohidrosis)
- ❑ Personal or family history of exercise, heat, or cold intolerance
- ❑ Personal or family history of kidney failure

Chart notes of the above must be submitted for documentation

Has patient's number of globotriaosylceramide (GL3) inclusions per kidney interstitial capillary at baseline been documented? ❑ **Yes** ❑ **No**

Histological scoring of kidney biopsy must be submitted for documentation

Does the patient have urinary GL3 level that is greater than or equal to 4 times the upper limit of normal? ❑ **Yes** ❑ **No**

Laboratory value of the above must be submitted for documentation

Does the patient have severe renal impairment (eGFR < 30 mL/min) or end-stage renal disease requiring hemodialysis? ❑ **Yes** ❑ **No**

Has the patient received or will be scheduled to receive a kidney transplant? ❑ **Yes** ❑ **No**

Will Galafold be used in combination with Fabrazyme or other enzyme replacement therapy (ERT) for the treatment of Fabry disease? ❑ **Yes** ❑ **No**

Galafold™ Prior Authorization Request Form (Page 2 of 2)

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Reauthorization:

If this is a reauthorization request, answer the following:

Has the patient's current eGFR been documented? ❑ **Yes** ❑ **No**

Has the patient's number of globotriaosylceramide (GL3) inclusions per kidney interstitial capillary decreased by at least 50% from baseline? ❑ **Yes** ❑ **No**
Current histological scoring of kidney biopsy must be submitted for documentation

Has the patient's urinary GL3 level decreased from baseline and is stabilized below baseline level? ❑ **Yes** ❑ **No**
Laboratory value of the above must be submitted for documentation

Does the patient have severe renal impairment (eGFR < 30 mL/min) or end-stage renal disease requiring hemodialysis? ❑ **Yes** ❑ **No**

Has the patient received or will be scheduled to receive a kidney transplant? ❑ **Yes** ❑ **No**

Will Galafold be used in combination with Fabrazyme or other enzyme replacement therapy (ERT) for the treatment of Fabry disease? ❑ **Yes** ❑ **No**

****Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.****
Previous therapies will be verified through pharmacy paid claims or submitted chart notes.

Prescriber Signature: _____ **Date:** _____

Are there any other comments, diagnoses, symptoms, medications tried or failed, and/or any other information the physician feels is important to this review?

_____

_____

Please note: This request may be denied unless all required information is received.
For urgent or expedited requests please call 1-800-711-4555.
This form may be used for non-urgent requests and faxed to 1-800-527-0531.