Gateway Health
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Gateway Health Plan
Pharmacy Division
Phone 800-392-1147 Fax 888-245-2049

ANTIHYPERURICEMICS

I. Requirements for Prior Authorization of Antihyperuricemics

A. Prescriptions That Require Prior Authorization

Prescriptions for Antihyperuricemics that meet any of the following conditions must be prior authorized:

1. A non-preferred Antihyperuricemic. See the Preferred Drug List (PDL) for the list of preferred Antihyperuricemics at: https://papdl.com/preferred-drug-list.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Antihyperuricemic, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Is being treated for a diagnosis that is indicated in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication; **AND**

2. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**

3. Is prescribed a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**

4. Does not have a contraindication to the prescribed medication; **AND**

5. For a non-preferred Antihyperuricemic, **one** of the following:

   a. For a non-preferred xanthine oxidase inhibitor, has a documented history of therapeutic failure of or a contraindication or an intolerance to maximum tolerated doses of the preferred xanthine oxidase inhibitors,
   b. For a non-preferred single-ingredient colchicine agent, has a documented history of therapeutic failure of or a contraindication or an intolerance to the preferred single-ingredient colchicine agents that would not be expected to occur with the requested medication,
   c. For all other non-preferred Antihyperuricemics, has a documented history of therapeutic failure of or a contraindication or intolerance to maximum tolerated doses of the preferred Antihyperuricemics that are FDA-approved or medically accepted for the beneficiary's diagnosis;

   AND

6. For Krystexxa (pegloticase), **all** of the following:

   1. Is prescribed Krystexxa (pegloticase) by or in consultation with an appropriate specialist (i.e., rheumatologist, endocrinologist),

   2. **Both** of the following:

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a. Has a recent uric acid level that is above goal based on American College of Rheumatology guidelines

b. **One** of the following:
   i. Continues to have frequent gout flares (≥2 flares/year)
   ii. Has non-resolving subcutaneous tophi,

3. Will not be using Krystexxa (pegloticase) concomitantly with oral urate-lowering agents,

4. Has documentation of counseling regarding **both** of the following:
   a. Appropriate dietary and lifestyle modifications
   b. Discontinuation of other medications known to precipitate gout attacks (e.g., thiazide diuretics);

NOTE: If the beneficiary does not meet the clinical review guidelines above but, in the professional judgement of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

FOR RENEWALS OF PRIOR AUTHORIZATION FOR KRYSTEXXA (PEGLOTICASE): The determination of medical necessity of a request for renewal of a prior authorization for Krystexxa (pegloticase) that was previously approved will take into account whether the beneficiary:

1. Has documentation of improvement in disease severity since initiating treatment with Krystexxa (pegloticase); **AND**

2. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**

3. Is prescribed Krystexxa (pegloticase) by or in consultation with an appropriate specialist (i.e., rheumatologist, endocrinologist); **AND**

4. Does not have a history of a contraindication to Krystexxa (pegloticase); **AND**

5. Will not be using Krystexxa (pegloticase) concomitantly with oral urate-lowering agents;

NOTE: If the beneficiary does not meet the clinical review guidelines above but, in the professional judgement of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

b. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for an Antihyperuricemic. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

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COLCHICINE (single-ingredient) PRIOR AUTHORIZATION FORM

☐New request ☐Renewal request	total # of pgs: _____	Prescriber name:	
Name of office contact:		Specialty:	
Contact's phone number:		NPI:	State license #:
LTC facility contact/phone:		Street address:	
Beneficiary name:		Suite #:	City/state/zip:
Beneficiary ID#:	DOB:	Phone:	Fax:
Medication will be billed via: ☐ Pharmacy ☐ Medical (Jcode:)		Place of Service: ☐ Hospital ☐ Provider's Office ☐ Home ☐ Other	

CLINICAL INFORMATION

Medication requested:
☐colchicine 0.6 mg capsule *(preferred, clinical PA req'd)*
☐colchicine 0.6 mg tablet *(preferred, clinical PA req'd)*
☐Colcrys tablet *(non-preferred)*
☐Mitigare capsule *(non-preferred)*
☐ _____

Strength:	Directions:	Quantity:	Refills:

Diagnosis *(submit documentation)*:	Dx code (required):

SINGLE-INGREDIENT COLCHICINE (COLCRYS, MITIGARE, COLCHICINE TABLET/CAPSULE) REQUESTS

Does the beneficiary have a history of any of the following? *Check all that apply.* ☐liver impairment or failure ☐ascites ☐hepatitis ☐renal/kidney impairment ☐cirrhosis ☐encephalopathy	☐Yes – *Submit results of recent kidney and liver function tests.* ☐No
Is the beneficiary currently taking, or taken within the past 14 days, a medication that is an inhibitor of P-glycoprotein (P-gp) or a strong inhibitor of cytochrome P450 3A4 (CYP3A4) (ex., amiodarone, diltiazem, certain HIV medications, quinidine, Ranexa, verapamil)?	☐Yes ☐No *Submit beneficiary's current complete medication list.*
For NON-PREFERRED Colcrys or Mitigare: Does the beneficiary have a history of trial and failure of or contraindication/intolerance to the preferred agents, colchicine capsule & colchicine tablet?	☐Yes ☐No *Submit all supporting documentation.*

COLCHICINE (COLCRYS, MITIGARE, COLCHICINE TABLET/CAPSULE) FOR ACUTE GOUT ATTACKS

Did the beneficiary try and fail, or have a contraindication or intolerance to, the following standard therapies for the CURRENT gout attack? *Check all that apply.* ☐Intra-articular (joint injection) or oral corticosteroids (ex., Depo-Medrol, Kenalog, Aristospan, etc.) ☐NSAIDs (ex., ibuprofen, indomethacin, naproxen, piroxicam, etc.) or COX-2 inhibitor (ex., Celebrex)	☐Yes – *Submit all supporting documentation of drug regimen (drug name, strength, directions, and dates tried) and treatment outcome.* ☐No

COLCHICINE (COLCRYS, MITIGARE, COLCHICINE TABLET/CAPSULE) FOR CHRONIC GOUT PROPHYLAXIS

Does the beneficiary have a recent uric acid level above goal based on American College of Rheumatology guidelines?	☐Yes – *Submit recent lab results.* ☐No
Did the beneficiary recently start taking a uric acid-lowering medication for gout prophylaxis, such as allopurinol, probenecid, or Uloric?	☐Yes – *Submit documentation of UA-lowering med. prescribed, including dose and start date.* ☐No

For a beneficiary who has been taking a uric acid lowering medication for more than 6 months, submit documentation of the following:
☐a recent uric acid level ☐therapeutic outcomes of uric acid lowering medication(s)
☐uric acid lowering medication(s) currently using or previously tried (including name, strength, daily dosage, dates taken)

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Prescriber Signature:	Date:

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KRYSTEXXA (pegloticase) PRIOR AUTHORIZATION FORM

☐New request ☐Renewal request	total # of pgs: _____	Prescriber name:	
Name of office contact:		Specialty:	
Contact's phone number:		NPI:	State license #:
LTC facility contact/phone:		Street address:	
Beneficiary name:		Suite #:	City/state/zip:
Beneficiary ID#:	DOB:	Phone:	Fax:

CLINICAL INFORMATION

Drug requested: ☐Krystexxa 8 mg/ml vial ☐Krystexxa _____		
Directions:	Quantity:	Refills:
Diagnosis *(submit documentation)*:	Dx code (required):	

ALL requests		
Is Krystexxa being prescribed by or in consultation with a specialist?	☐Yes ☐No	*Submit documentation of consultation if applicable.*
Does the beneficiary have glucose-6-phosphate dehydrogenase (G6PD) deficiency?	☐Yes ☐No	*Submit documentation of G6PD screening for at-risk beneficiaries.*
Will the beneficiary be using Krystexxa concomitantly with any oral urate-lowering medications?	☐Yes ☐No	*Submit beneficiary's current complete medication list.*
INITIAL requests		
Does the beneficiary have a history of trial and failure of maximally tolerated doses of xanthine oxidase inhibitors (e.g., allopurinol, febuxostat) as indicated by any of the following? *Check all that apply.* ☐Continues to have frequent gout flares (≥2 flares per year) ☐Has non-resolving subcutaneous tophi	☐Yes ☐No	*Submit documentation.*
Does the beneficiary have a recent uric acid level that is above goal (based on ACR guidelines) despite maximally tolerated doses of xanthine oxidase inhibitors (e.g., allopurinol, febuxostat)?	☐Yes ☐No	*Submit lab results.*
Does the beneficiary have a contraindication or an intolerance to maximally tolerated doses of xanthine oxidase inhibitors (e.g., allopurinol, febuxostat)?	☐Yes ☐No	*Submit documentation.*
Was the beneficiary counseled regarding the following? *Check all that apply.* ☐Appropriate dietary and lifestyle modifications ☐Discontinuation of other medications known to precipitate gout attacks	☐Yes – *Submit documentation.* ☐No	
RENEWAL requests		
Did the beneficiary experience improvement in disease severity since initiating treatment with Krystexxa?	☐Yes ☐No	*Submit documentation of clinical response.*

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Prescriber Signature:	Date:

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NON-PREFERRED MEDICATION PRIOR AUTHORIZATION FORM *(form effective 01/01/20)*

☐New request ☐Renewal request	# of pages: _____	Prescriber name:	
Name of office contact:		Specialty:	
Contact's phone number:		NPI:	State license #:
LTC facility contact/phone:		Street address:	
Beneficiary name:		Suite #:	City/State/Zip:
Beneficiary ID#:	DOB:	Phone:	Fax:

Please refer to https://papdl.com/preferred-drug-list for the list of preferred and non-preferred medications in each Preferred Drug List class.

Non-preferred medication name:	Dosage form:	Strength:
Directions:	Quantity:	Refills:
Diagnosis *(submit documentation)*:	Dx code (*required*):	

Has the beneficiary taken the requested non-preferred medication in the past 90 days? *(submit documentation)*..... ☐Yes ☐No

Describe all applicable medical reasons the beneficiary cannot use the preferred medication(s) in the same Preferred Drug List class. *Submit documentation (e.g., recent chart/clinic notes, diagnostic evaluations, lab results, etc.) supporting this non-preferred request.*

☐Treatment failure or inadequate response with preferred medication(s) *(include drug name, dose, and start/stop dates)*:

_____

_____

☐Unacceptable side effects, hypersensitivities, or other intolerances to preferred medication(s) *(include description and drug name(s))*:

_____

_____

☐Contraindication to preferred medication(s) *(include description and drug name(s))*:

_____

_____

☐Unique clinical or age-specific indications supported by FDA approval or medical literature *(describe)*:

_____

_____

☐Absence of preferred medication(s) with appropriate formulation *(list medical reason formulation is required)*:

_____

_____

☐Drug-drug interaction with preferred medication(s) *(describe)*:

_____

_____

☐Other medical reason(s) the beneficiary cannot use the preferred medication(s) *(describe)*:

_____

_____

☐For renewal requests of previously approved medications, submit documentation of tolerability and beneficiary's clinical response.

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Prescriber Signature:	Date: