Gateway Health It's Wholecare.

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

I. Requirements for Prior Authorization of Immunosuppressives, Oral

A. Prescriptions That Require Prior Authorization

Prescriptions for Immunosuppressives, Oral that meet any of the following conditions must be prior authorized:

1. A non-preferred Immunosuppressive, Oral. See the Preferred Drug List (PDL) for the list of preferred Immunosuppressives, Oral 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 Immunosuppressive, Oral, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Is prescribed the Immunosuppressive, Oral for the treatment of 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 prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**

3. Does not have a contraindication to the requested medication; **AND**

4. For Lupkynis (voclosporin), **all** of the following:
   a. For the treatment of lupus nephritis, has a diagnosis of active lupus nephritis that is confirmed by a kidney biopsy unless a kidney biopsy is not medically advisable,
   b. Is prescribed Lupkynis (voclosporin) by or in consultation with an appropriate specialist (e.g., nephrologist, rheumatologist),
   c. Is prescribed Lupkynis (voclosporin) in combination with background immunosuppressive therapy as tolerated,
   d. Is not prescribed Lupkynis (voclosporin) in combination with cyclophosphamide or Benlysta (belimumab);

   AND

5. For all other non-preferred Immunosuppressives, Oral, **one** of the following:
   a. Has a documented history of therapeutic failure of or a contraindication or an intolerance to the preferred Immunosuppressives, Oral approved or medically accepted for the beneficiary's diagnosis
   b. Has a current history (within the past 90 days) of being prescribed the same non-preferred Immunosuppressive, Oral;

   AND

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment 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.

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C. 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 Immunosuppressive, Oral. 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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LUPKYNIS (voclosporin) PRIOR AUTHORIZATION FORM

☐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:

CLINICAL INFORMATION

Medication: ☐Lupkynis capsule ☐Lupkynis _____	Strength:	Quantity per fill:	Refills:
Directions:			

Diagnosis:	Dx code (*required*):
Is Lupkynis prescribed by or in consultation with a specialist, such as a nephrologist or rheumatologist?	☐Yes ☐No *Submit documentation of consultation with specialist, if applicable.*
Does the beneficiary have kidney or liver impairment that necessitates an adjustment of the dose of Lupkynis?	☐Yes ☐No *Submit documentation.*
Does the beneficiary have a diagnosis of lupus nephritis that is confirmed by kidney biopsy?	☐Yes ☐No *Submit documentation.*
Will the beneficiary be taking Lupkynis in addition to background immunosuppressive therapy? Check all that apply. ☐mycophenolate mofetil/mycophenolic acid ☐prednisone or other corticosteroid ☐other (list): _____ _____	☐Yes ☐No *Submit documentation of complete current medication list.*

PLEASE FAX COMPLETED FORM TO GATEWAY – PHARMACY DIVISION

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:
Medication will be billed via: ☐ Pharmacy ☐ Medical (Jcode:)		Place of Service: ☐ Hospital ☐ Provider's Office ☐ Home ☐ Other	

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:

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