Gateway Health It's Wholecare.

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

I. Requirements for Prior Authorization of Progestational Agents

A. Prescriptions That Require Prior Authorization

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

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

2. A prescription for hydroxyprogesterone caproate.

B. Review of Documentation for Medical Necessity

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

1. For a non-preferred Progestational Agent, **one** of the following:

   a. Has a history of therapeutic failure, contraindication, or intolerance of the preferred Progestational Agents approved or medically accepted for the beneficary's indication
   b. For an intravaginal Progestational Agent, is prescribed the intravaginal Progestational Agent for treatment of a diagnosis that is indicated in the U.S. Food and Drug Administration-approved package labeling OR a medically accepted indication, excluding use to promote fertility;

   AND

2. For hydroxyprogesterone caproate, **all** of the following:

   a. Is a pregnant female with a single fetus,

   b. Is between 16 weeks 0 days and 36 weeks 6 days gestation,

   c. Has a documented history of a prior spontaneous preterm singleton birth (defined as prior to 37 weeks gestation),

   d. Is being, or was, initiated into treatment between 16 weeks 0 days and 20 weeks 6 days,

   e. Does not have a history of a contraindication to hydroxyprogesterone caproate;

   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.

C. Clinical Review Process

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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 a Progestational Agent. 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.

D. Dose and Duration of Therapy

Approvals of requests for prior authorization of prescriptions for hydroxyprogesterone caproate will be consistent with the FDA-approved package labeling.

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MAKENA and HYDROXYPROGESTERONE CAPROATE PRIOR AUTHORIZATION FORM

☐New request ☐Renewal request	total # 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

Drug requested:		Strength:	Dosage form (auto-injector, vial, etc.)
Dose/directions:		Quantity:	Refills:
Diagnosis *(submit documentation)*:	☐ pregnancy with history of pre-term labor	☐ other: _____	
Dx codes (*required*):	Start date of therapy: _____ / _____ / 20_____		
	Current gestational age: weeks: _____ days: _____		

Is the beneficiary currently pregnant with a single fetus?	☐Yes ☐No *Submit documentation.*
Does the beneficiary have a documented history of a prior spontaneous preterm singleton birth (defined as prior to 37 weeks' gestation)?	☐Yes ☐No *Submit documentation.*
Does the beneficiary have any of the following contraindications to the use of Makena? *Check all that apply.* ☐current or history of thrombosis or thromboembolic disorders ☐history of or current known or suspected breast cancer or other hormone-sensitive cancer ☐undiagnosed abnormal vaginal bleeding unrelated to pregnancy ☐cholestatic jaundice of pregnancy ☐benign or malignant liver tumors or active liver disease ☐uncontrolled hypertension	☐Yes ☐No *Submit documentation.*
For a non-preferred hydroxyprogesterone caproate product: Does the beneficiary have a history of trial and failure of or contraindication or intolerance to the preferred hydroxyprogesterone caproate products in this class approved or medically accepted for treatment of the beneficiary's condition? *Refer to https://papdl.com/preferred-drug-list for a list of preferred and non-preferred drugs in this class.*	☐Yes – *Submit documentation.* ☐No

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:

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: