John Bel Edwards
GOVERNOR

Rebekah E. Gee MD, MPH
SECRETARY

State of Louisiana

Louisiana Department of Health
Bureau of Health Services Financing

MEMORANDUM

DATE: June 18, 2019

TO: All Louisiana Medicaid Prescribing Providers and Pharmacists

FROM: Jen Steele, Medicaid Director

SUBJECT: Updated Single Preferred Drug List (PDL) for Elagolix (Orilissa®), Ivabradine (Corlanor®), Ergotamines, and Calcitonin Gene-Related Peptide (CGRP) Antagonists

Effective July 1, 2019, the Louisiana Medicaid Fee for Service (FFS) Pharmacy Program and Managed Care Organizations (MCOs) will update the Single PDL. The Single PDL applies to FFS and Medicaid MCOs (Aetna, AmeriHealth Caritas, Healthy Blue, Louisiana Healthcare Connections, and United Healthcare). The updated Single PDL will include elagolix (Orilissa®), ivabradine (Corlanor®), ergotamines, and Calcitonin Gene-Related Peptide (CGRP) antagonists.

Preferred Drug List and Non-Preferred Drug List

Pharmacy claims for **preferred** agents [(Elagolix (Orilissa®), Galcanezumab-gnlm Pen and Syringe (Emgality®)] will require clinical authorization. To obtain prior and/or clinical authorization, prescribers must complete in full and submit the *Louisiana Uniform Prescription Drug Prior Authorization Form.*

Refer to http://ldh.la.gov/assets/HealthyLa/Pharmacy/PDL.pdf for the PDL, which is inclusive of the listings for preferred/non-preferred agents, criteria, and the *Louisiana Uniform Prescription Drug Prior Authorization Form.*

If you have questions about the content of this memo, you may contact the FFS pharmacy help desk by phone at (800) 437-9101.

If you have questions about pharmacy claims billing, you may contact the appropriate plan at their pharmacy help desk listed in the chart below.

Healthcare Provider	**Pharmacy Help Desk**	**Pharmacy Help Desk Phone Number**
Aetna	CVS Health	(855) 364-2977
AmeriHealth Caritas	PerformRx	(800) 684-5502
Fee for Service	DXC Technology	(800) 648-0790
Healthy Blue	CVS	(833) 236-6194
Louisiana Healthcare Connections	CVS Caremark	(800) 311-0543
United Healthcare	Optum Rx	(866) 328-3108

Please forward this notice to other providers to assist with notification. Your continued cooperation and support of the Louisiana Medicaid Program efforts to coordinate care and improve health are greatly appreciated.

JS/MBW/GJS

c: Healthy Louisiana Plans
Melwyn B. Wendt
DXC Technology

Louisiana Fee-for-Service Medicaid
Elagolix (Orilissa®)

Elagolix (Orilissa®) requires clinical authorization. The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request authorization for elagolix (Orilissa®).

Requests for initial approval must meet the following criteria:

- Recipient is 18 years of age or older on the date of the request; **AND**
- Elagolix (Orilissa®) is being prescribed by a gynecologist; **AND**
- Recipient has been diagnosed with moderate-to-severe pain associated with endometriosis; **AND**
- Recipient **DOES NOT** have severe hepatic impairment; **AND**
- **ONE** of the following:
    - Recipient has a history of at least a 3-month trial and inadequate response to at least one non-steroidal anti-inflammatory agent (NSAID); **OR**
    - Recipient has a contraindication or intolerance to NSAIDS; **AND**
- **ONE** of the following:
    - Recipient has a history of at least a 3-month trial and inadequate response to a progestin or a hormonal contraceptive; **OR**
    - Recipient has a contraindication or intolerance to progestins and hormonal contraceptives; **AND**
- **ONE** of the following:
    - Recipient is naïve to elagolix (Orilissa®); **OR**
    - Recipient is receiving 150mg once daily, has no coexisting conditions, and has utilized elagolix (Orilissa®) for a combined total duration of less than 24 months in their lifetime; **OR**
    - Recipient is receiving 150mg once daily, has moderate hepatic impairment (Child-Pugh class B), and has utilized elagolix (Orilissa®) for a combined total duration of less than 6 months in their lifetime; **OR**
    - Recipient is receiving 200mg twice daily, has dyspareunia, and has utilized elagolix (Orilissa®) for a combined total duration of less than 6 months in their lifetime; **AND**
- By submitting the authorization request, the prescriber attests to the following:
    - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
    - All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
    - The recipient has no concomitant drug therapies or disease states that limit the use of elagolix and will not be receiving elagolix in combination with any medication that is contraindicated or not recommended per FDA labeling.

Requests for reauthorization with elagolix (Orilissa®) must meet the following criteria:

- Recipient has experienced clinically significant improvement in endometriosis-associated pain, which is stated on the request; **AND**
- Recipient is using 150mg once daily; **AND**
- Recipient has no coexisting conditions.

Duration of both initial and reauthorization approval:
Up to 12 months
Not to exceed the following lifetime maximum treatment durations:

24 months for 150mg dose for recipient with no coexisting conditions
6 months for 150mg dose for recipient with moderate hepatic impairment
6 months for the 200mg dose

References

American College of Obstetricians and Gynecologists. Management of Endometriosis. Practice Bulletin 114. July 2010

Orilissa® (elagolix) [package insert]. North Chicago, IL: AbbVie Inc; 2018. Retrieved from https://www.rxabbvie.com/pdf/orilissa_pi.pdf

UpToDate: Endometriosis: Treatment of pelvic pain. Current through April 2019. www.uptodate.com

Louisiana Fee-for-Service Medicaid
Ivabradine (Corlanor®)

Ivabradine (Corlanor®) requires clinical authorization. The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request authorization for ivabradine (Corlanor®).

Requests for initial approval must meet the following criteria:

- For use in adults with worsening heart failure in a diagnosis of stable, symptomatic chronic heart failure, **ALL** of the following must apply and be stated on the request:
  - Recipient is 18 years of age or older on the date of the request; **AND**
  - Recipient has a left ventricular ejection fraction of less than or equal to 35%; **AND**
  - Recipient is in sinus rhythm; **AND**
  - Recipient has a resting heart rate of greater than or equal to 70 beats per minute; **AND**
  - **ONE** of the following:
    - Ivabradine is being given concomitantly with a maximally tolerated dose of a beta-blocker; **OR**
    - The recipient has a contraindication to beta-blocker use; **OR**
- For use in pediatric recipients with stable symptomatic heart failure, **ALL** of the following must apply and be stated on the request:
  - Recipient is aged 6 months or older on the date of the request; **AND**
  - Recipient is in sinus rhythm; **AND**
  - Recipient has heart failure due to dilated cardiomyopathy (DCM); **AND**
  - Recipient has a left ventricular ejection fraction of less than or equal to 45%; **AND**
  - Recipient has an elevated resting heart rate (HR); **AND**
- Ivabradine (Corlanor®) is prescribed by or in consultation with a cardiologist; **AND**
- By submitting the authorization request, the prescriber attests to the following:
  - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
  - All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
  - The recipient has no concomitant drug therapies or disease states that limit the use of ivabradine and will not be receiving ivabradine in combination with any medication that is contraindicated or not recommended per FDA labeling.

Requests for reauthorization must meet the following criteria:

- The provider states that the recipient is established on ivabradine (Corlanor®); **AND**
- There is documentation of a positive clinical response to ivabradine (Corlanor®) therapy.

Duration of initial and reauthorization approval: 12 months

Reference

Corlanor® (ivabradine) [package insert]. Thousand Oaks, CA: Amgen Inc; 2019. Retrieved from https://www.pi.amgen.com/~/media/amgen/repositorysites/pi-amgen-com/corlanor/corlanor_pi.pdf

Louisiana Fee-for-Service Medicaid
Antimigraine Agents, Ergotamines and Other

The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request authorization for non-preferred ergotamine antimigraine agents.

NOTE: Some medications in this therapeutic class may have Black Box Warnings and/or may be subject to Risk Evaluation and Mitigation Strategy (REMS) under FDA safety regulations; refer to individual prescribing information for details.

Approval criteria, for both initial and reauthorization requests, for non-preferred agents

ALL of the following are required:

- Recipient is 18 years of age or older on date of the request; **AND**
- Prescriber attests that the requested medication will not be prescribed for chronic daily administration and will not exceed the recommended dosage per prescribing information; **AND**
- Previous use of **TWO** preferred triptan antimigraine agents- **ONE** of the following is required:
  - The recipient has had a *treatment failure* with at least **TWO** preferred triptans; **OR**
  - The recipient has had an *intolerable side effect* to at least **TWO** preferred triptans; **OR**
  - The recipient has *documented contraindication(s)* to **ALL** preferred triptans that are appropriate to use for the condition being treated; **OR**
  - There is *no preferred triptan that is appropriate* to use for the condition being treated; **AND**
- By submitting the authorization request, the prescriber attests to the following:
  - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
  - All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
  - The recipient has no concomitant drug therapies or disease states that limit the use of the requested medication.

Additional edits may apply at Point-of-Sale (POS). Override options may be available. For more information, refer to the Louisiana Department of Health Pharmacy Benefits Management Services Manual at www.lamedicaid.com/provweb1/Providermanuals/manuals/PHARMACY/PHARMACY.pdf

Duration of approval, both initial and reauthorization: 12 months

References

Cafergot® (ergotamine tartrate and caffeine tablets) [package insert]. Princeton, NJ: Sandoz Inc.; 2012. Retrieved from https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=b4a06de6-f837-43a8-ae7a-aadb38dd2a7d

Dihydroergotamine mesylate injection [package insert]. Eatontown, NJ: West-Ward; 2017. Retrieved from https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=all&query=DIHYDROERGOTAMINE+MESYLATE

Ergomar® (ergotamine tartrate sublingual tablets) [package insert]. Lake Forest, IL: TerSera Therapeutics LLC; 2018. Retrieved from https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=dac9637f-3326-4f25-b7b9-f9f54b738232

Migranal® (dihydroergotamine mesylate nasal spray) [package insert]. Bridgewater, NJ: Valeant Pharmaceuticals North America LLC; 2017. Retrieved from https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=a24befa8-b952-48ac-942a-379585250782

Migregot® (ergotamine tartrate and caffeine suppositories) [package insert]. South Plainfield, NJ: G&W Laboratories, Inc.; 2011. Retrieved from https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=all&query=MIGERGOT

Peer C Tfelt-Hansen (2013) Triptans and ergot alkaloids in the acute treatment of migraine: similarities and differences, Expert Review of Neurotherapeutics, 13:9, 961-963, DOI:10.1586/14737175.2013.832851. Retrieved from https://doi.org/10.1586/14737175.2013.832851

Louisiana Fee-for-Service Medicaid
CGRP (Calcitonin Gene-Related Peptide) Antagonists

The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request authorization for CGRP (Calcitonin Gene-Related Peptide) antagonists.

CGRP (Calcitonin Gene-Related Peptide) Antagonists
Erenumab-aooe (Aimovig®)
Fremanezumab-vfrm (Ajovy®)
Galcanezumab-gnlm (Emgality™)

Requests will be considered for initial approval if all of the following criteria are met:

- Recipient is 18 years of age or older on date of the request; **AND**
- CGRP antagonist is being prescribed by or in consultation with a neurologist or pain specialist; **AND**
- Recipient has been evaluated for medication overuse headache; **AND**
- Patient has a documented history of:
    - episodic migraine <15 headache days per month; **OR**
    - chronic migraine ≥15 headache days per month; **AND**
- A history of migraines for greater than or equal to 3 months; **AND**
- Patient has been tried and failed on a 3-month trial of at least two standard prophylactic pharmacologic therapies or has an intolerance to, or has a contraindication to standard prophylactic therapies, e.g. triptans, beta blockers, antidepressants, divalproex sodium or topiramate; **AND**
- By submitting the authorization request, the prescriber attests to the following:
    - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
    - All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
    - The recipient has no concomitant drug therapies or disease states that limit the use of CGRP antagonists and will not be receiving CGRP antagonists in combination with any medication that is contraindicated or not recommended per FDA labeling.

Requests to continue treatment with CGRP antagonists will be considered for approval if all of the following criteria are met:

- Used for prevention of migraine; **AND**
- Recipient is 18 years of age or older; **AND**
- CGRP antagonist is being prescribed by or in consultation with a neurologist or pain specialist; **AND**
- Recipient continues to be monitored for medication overuse headache; **AND**
- There is documentation of a positive clinical response to CGRP antagonists therapy defined by ONE of the following:
    - Decrease in migraine frequency from baseline

- Decrease in use of acute migraine medications
- Reduction of at least 3 migraines or more per month

Duration of initial and reauthorization approval: 12 months

Point-of-Sale Quantity Limits for CGRP Antagonists

Medication	Quantity
fremanezumab-vfrm (*Ajovy*®) 225mg single-dose syringe	3 (225mg) single-dose syringe/90 days
erenumab-aooe (*Aimovig*®) 70mg, 140mg single-dose syringe	3 single-dose syringe/90days
galcanezumab-gnim (*Emgality*™) 120 mg single-dose pen/syringe	7 single-dose syringes/180 days

References:

Aimovig (erenumab-aooe) [prescribing information]. Thousand Oaks, CA: Amgen Inc; March 2019. https://www.pi.amgen.com/~/media/amgen/repositorysites/pi-amgen-com/aimovig/aimovig_pi_hcp_english.ashx

Ajovy (fremanezumab-vfrm) [prescribing information]. North Wales, PA: Teva Pharmaceuticals; September 2018 https://www.ajovyhcp.com/globalassets/ajovy/ajovy-pi.pdf

Emgality (galcanezumab-gnlm) [prescribing information]. Indianapolis, IN: Eli Lilly and Company; September 2018. http://uspl.lilly.com/emgality/emgality.html#pi

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PRIOR AUTHORIZATION REQUEST COVERSHEET

Please check the member's appropriate health plan listed below:

☐ **Aetna Better Health of Louisiana**
Phone: 1-855-242-0802 Fax: 1-844-699-2889
www.aetnabetterhealth.com/louisiana/providers/pharmacy

☐ **AmeriHealth Caritas Louisiana**
Phone: 1-800-684-5502 Fax: 1-855-452-9131
www.amerihealthcaritasla.com/pharmacy/index.aspx

☐ **Fee-for-Service (FFS) Louisiana Legacy Medicaid**
Phone: 1-866-730-4357 Fax: 1-866-797-2329
www.lamedicaid.com

☐ **Healthy Blue**
Phone: 1-844-521-6942 Fax: 1-844-864-7865
https://providers.healthybluela.com/la/pages/home.aspx

☐ **LA Healthcare Connections**
Phone: 1-888-929-3790 Fax: 1-866-399-0929
www.louisianahealthconnect.com/for-members/pharmacy-services/

☐ **United Healthcare**
Phone: 1-800-310-6826 Fax: 1-866-940-7328
https://www.uhcprovider.com/en/health-plans-by-state/louisiana-health-plans/la-comm-plan-home/la-cp-pharmacy.html
Electronic Prior Authorization: https://provider.linkhealth.com/#/

LOUISIANA UNIFORM PRESCRIPTION DRUG PRIOR AUTHORIZATION FORM

SECTION I — SUBMISSION

Submitted to:	Phone:	Fax:	Date:

SECTION II — PRESCRIBER INFORMATION

Last Name, First Name MI:		NPI# or Plan Provider #:	Specialty:	
Address:		City:	State:	ZIP Code:
Phone:	Fax:	Office Contact Name:	Contact Phone:	

SECTION III — PATIENT INFORMATION

Last Name, First Name MI:	DOB:	Phone:	☐ Male ☐ Female ☐ Other ☐ Unknown
Address:	City:	State:	ZIP Code:
Plan Name (if different from Section I):	Member or Medicaid ID #:	Plan Provider ID:	

Patient is currently a hospital inpatient getting ready for discharge? ____ Yes ____ No Date of Discharge:_____
Patient is being discharged from a psychiatric facility? ____ Yes ____ No Date of Discharge:_____
Patient is being discharged from a residential substance use facility? ____ Yes ____ No Date of Discharge:_____
Patient is a long-term care resident? ____ Yes ____ No If yes, name and phone number:_____
EPSDT Support Coordinator contact information, if applicable:

SECTION IV — PRESCRIPTION DRUG INFORMATION

Requested Drug Name:

Strength:	Dosage Form:	Route of Admin:	Quantity:	Days' Supply:	Dosage Interval/Directions for Use:	Expected Therapy Duration/Start Date:

To the best of your knowledge this medication is: _____New therapy/Initial request
_____Continuation of therapy/Reauthorization request

For Provider Administered Drugs only:

HCPCS/CPT-4 Code:_____NDC#:_____Dose Per Administration:_____

Other Codes:_____

Will patient receive the drug in the physician's office? ____Yes ____No

– If no, list name and NPI of servicing provider/facility: _____

SECTION V — PATIENT CLINICAL INFORMATION

Primary diagnosis relevant to this request:	ICD-10 Diagnosis Code:	Date Diagnosed:
Secondary diagnosis relevant to this request:	ICD-10 Diagnosis Code:	Date Diagnosed:

For pain-related diagnoses, pain is: _____Acute _____Chronic
For postoperative pain-related diagnoses: Date of Surgery_____

Pertinent laboratory values and dates (attach or list below):

Date	Name of Test	Value

SECTION VI - This Section For Opioid Medications Only

Does the quantity requested exceed the max quantity limit allowed? ___Yes ___No (If yes, provide justification below.)
Cumulative daily MME_____

Does cumulative daily MME exceed the daily max MME allowed? ___Yes ___No (If yes, provide justification below.)

	YES (True)	NO (False)	THE PRESCRIBER ATTESTS TO THE FOLLOWING:
SHORT AND LONG-ACTING OPIOIDS			A. A complete **assessment** for pain and function was performed for this patient.
			B. The patient has been **screened for substance abuse / opioid dependence**. *(Not required for recipients in long-term care facility.)*
			C. The **PMP** will be accessed **each** time a controlled prescription is written for this patient.
			D. A **treatment plan** which includes current and previous goals of therapy for both pain and function has been developed for this patient.
			E. **Criteria** for failure of the opioid trial and for stopping or continuing the opioid has been established and explained to the patient.
			F. **Benefits and potential harms** of opioid use have been discussed with this patient.
			G. An **Opioid Treatment Agreement** signed by both the patient and prescriber is on file. *(Not required for recipients in long-term care facility.)*
LONG-ACTING OPIOIDS			H. The patient requires continuous **around the clock** analgesic therapy for which alternative treatment options have been inadequate or have not been tolerated.
			I. Patient previously utilized at least two weeks of short-acting opioids for this condition. Please enter drug(s), dose, duration and date of trial in pharmacologic/non-pharmacologic treatment section below.
			J. Medication has **not** been prescribed to treat acute pain, mild pain, or pain that is not expected to persist for an extended period of time.
			K. Medication has **not** been prescribed for use as an as-needed (PRN) analgesic.
			L. Prescribing information for requested product has been **thoroughly reviewed** by prescriber.

*IF NO FOR **ANY** OF THE ABOVE (A-L), PLEASE EXPLAIN:*

SECTION VII - Pharmacologic & non-pharmacologic treatment(s) used for this diagnosis (both previous & current):

Drug name	Strength	Frequency	Dates Started and Stopped or Approximate Duration	Describe Response, Reason

Drug Allergies:	Height (if applicable):	Weight (if applicable):

Is there clinical evidence or patient history that suggests the use of the plan's pre-requisite medication(s), e.g. step medications, will be ineffective or cause an adverse reaction to the patient? ____Yes ____No (If yes, please explain in Section VIII below.)

SECTION VIII — JUSTIFICATION (SEE INSTRUCTIONS)

By signing this request, the prescriber attests that the information provided herein is true and accurate to the best of his/her knowledge. Also, by signing and submitting this request form, the prescriber attests to statements in the 'Attestation' section of the criteria specific to this request, if applicable.

Signature of Prescriber:_____ Date:_____