John Bel Edwards
GOVERNOR

Rebekah E. Gee MD, MPH
SECRETARY

State of Louisiana

Department of Health and Hospitals
Bureau of Health Services Financing

MEMORANDUM

DATE: March 22, 2017

TO: All Louisiana Fee for Service (FFS) Medicaid Providers

FROM: Jen Steele, Medicaid Director

SUBJECT: Point of Sale (POS) Edits and Clinical Pre-Authorization for tasimelteon (Hetlioz®) and lumacaftor/ivacaftor (Orkambi®)

Effective March 28, 2017, the Louisiana Medicaid Pharmacy Program in collaboration with the Louisiana Medicaid Drug Utilization Review (DUR) Board has established Point of Sale (POS) edits and Clinical Pre-Authorization criteria for tasimelteon (Hetlioz ®) and lumacaftor/ivacaftor (Orkambi®).

TASIMELTEON (HETLIOZ®)

Clinical Pre-Authorization for tasimelteon (Hetlioz®)
Pharmacy claims for tasimelteon (Hetlioz®) will be reimbursed at POS when the prescriber has obtained an approved clinical pre-authorization. Prescribers must complete the pharmacy Clinical Pre-Authorization Form in full and fax to 1-866-797-2329. See complete instructions following this document or refer to www.lamedicaid.com.

Pharmacy claims for tasimelteon (Hetlioz®) without an approved clinical pre-authorization will deny at POS with:

NCPDP rejection code 88 (DUR Reject Error) mapped to
EOB code 066 (Clinical Pre-Authorization Required)

Override provisions should be addressed through the Clinical Pre-Authorization process.

Maximum Dose for tasimelteon (Hetlioz®)

Pharmacy claims for tasimelteon (Hetlioz®) which exceed a dose of 20mg/day will deny at POS with:

NCPDP rejection code 88 (DUR Reject Error) mapped to
EOB code 529 (Exceeds maximum daily dose)

There are no override provisions through the POS system using NCPDP service codes.

Therapeutic Duplication for tasimelteon (Hetlioz®)
Pharmacy claims for tasimelteon (Hetlioz®) will deny at POS if there is an active claim for another sedative-hypnotic agent.

NCPDP rejection code 88 (DUR Reject Error) mapped to
EOB code 482 (Therapeutic Duplication)

After consultation with the prescriber to verify the necessity of the therapeutic duplication, the pharmacist may override the therapeutic duplication denial by submitting in:

NCPDP 439-E4 field (Reason for Service Code) TD (Therapeutic Duplication)
NCPDP 440-E5 field (Professional Service Code) MO (Prescriber Consulted)
NCPDP 441-E6 field (Result of Service Code) 1G (Filled with Prescriber Approval)

The pharmacist must document the override codes on the hardcopy prescription or in the pharmacy's electronic recordkeeping system.

LUMACAFTOR/IVACAFTOR (ORKAMBI®)

Clinical Pre-Authorization for lumacaftor/ivacaftor (Orkambi®)
Pharmacy claims for lumacaftor/ivacaftor (Orkambi®) will be reimbursed at POS when the prescriber has obtained an approved clinical pre-authorization. Prescribers must complete the Pharmacy Clinical Pre-Authorization Form in full and fax to 1-866-797-2329. See complete instructions following this document or refer to www.lamedicaid.com.

Pharmacy claims for lumacaftor/ivacaftor (Orkambi®) without an approved clinical pre-authorization will deny at POS with:

NCPDP rejection code 88 (DUR Reject Error) mapped to
EOB code 066 (Clinical Pre-Authorization Required)

Override provisions should be addressed through the Clinical Pre-Authorization process.

Diagnosis Code Requirement for lumacaftor/ivacaftor (Orkambi®)
Pharmacy claims for lumacaftor/ivacaftor (Orkambi®) require a valid ICD-10-CM diagnosis code submitted at POS in NCPDP field 424-DO (Diagnosis Code). The diagnosis code must be documented on the hardcopy prescription or in the pharmacy's electronic recordkeeping system. The following table lists the acceptable diagnosis code for lumacaftor/ivacaftor (Orkambi®).

Description	ICD-10-CM Diagnosis Code
Cystic fibrosis	E84.*

* - any number or letter or combination of UP TO FOUR numbers and letters of an assigned ICD-10-CM diagnosis code

Lumacaftor/ivacaftor (Orkambi®) claims submitted at POS without a valid diagnosis code will deny with:

NCPDP rejection code 39 (Missing or Invalid diagnosis code) mapped to EOB code 575 (Missing or Invalid diagnosis code)

Prescribing providers may call the Louisiana Medicaid RxPA Operations at the University of Louisiana at Monroe (ULM) at 1-866-730-4357 for guidance when recipients are established on medications but the ICD-10-CM diagnosis code(s) submitted are not included in the covered diagnoses.

When the diagnosis code written on the prescription is not included in the list of covered diagnoses AND when the pharmacist cannot reach the prescriber OR when the RxPA Center is closed, the pharmacist, using his/her professional judgment, may deem the filling of the prescription to be an "emergency". In these emergency cases, the pharmacist must indicate "Emergency Prescription" on the hardcopy prescription or in the pharmacy's electronic recordkeeping system AND may override the diagnosis code requirement by:

Placing the 'alternative' ICD-10-CM diagnosis code in the NCPDP field 424-DO (Diagnosis Code) and by placing '03' in NCPDP 418-DI field (Level of Service)

Compliance associated with program policy will be verified through our Louisiana Medicaid Pharmacy Compliance Audit Program.

Your continued cooperation and support of the Louisiana Medicaid Program efforts to coordinate care and improve health are greatly appreciated.

If you have questions about the contents of this memo, you may contact the Pharmacy Help Desk at (800) 437-9101 or refer to www.lamedicaid.com.

JS/MBW/GJS

c: Healthy Louisiana Plans
Dr. James Hussey
Dr. Rebekah Gee
Melwyn B. Wendt
Molina

Hetlioz® (tasimelteon) Clinical Pre-Authorization Criteria for Louisiana Legacy (Fee-for-Service) Medicaid Recipients

A. Initial Authorization of Hetlioz® for 6 months will be approved based on the following criteria:

- Diagnosis of non-24-hour sleep-wake disorder (also known as free-running disorder, free-running or non-entrained type circadian rhythm sleep disorder, or hypernychthemeral syndrome); AND
- Patient is totally blind (has no light perception in either eye); AND
- Insufficient response or intolerance to other preferred medication(s) for sleep; OR
- The medication is prescribed by, or in consultation with, a physician who specializes in the treatment of sleep disorders.

B. Reauthorization of Hetlioz® for 12 months will be approved based upon the following:

- The patient has a diagnosis of total blindness in both eyes (e.g., nonfunctioning retinas); AND
- The patient is NOT able to perceive light in either eye; AND
- Documentation of positive clinical response to Hetlioz® therapy (e.g., such as the patient is experiencing increased total nighttime sleep and/or decreased daytime nap duration).

References:

Hetlioz® Prescribing Information located at http://www.hetliozpro.com/Content/Pdfs/HetliozPI.pdf

Clinical Pre-Authorization Criteria for Lumacaftor/Ivacaftor (Orkambi®)
for Fee-for-Service Louisiana Medicaid Recipients

Requests for lumacaftor/ivacaftor will be considered for approval if all of the following criteria are met:

1. Recipient is 6 years old or older on the date of the request with a documented diagnosis of cystic fibrosis; AND
2. Information provided on clinical pre-authorization request form indicates that the recipient:
    a. is homozygous for the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene; AND
    b. does not have a documented contraindication, including contraindicated medication, to lumacaftor/ivacaftor. See prescribing information for a list of drug interactions.

Louisiana Medicaid
Pharmacy Clinical Pre-Authorization Form

Fax or Mail this form to:
1-866-797-2329
La Medicaid RxPA Operations
ULM School of Pharmacy
1800 Bienville Drive
Monroe, LA 71201-3765

MEMBER INFORMATION

Revised Date: 2/12/2015

Patient Name: Last Name	First Name	MI	
Date of Birth:	Sex: ☐ Male ☐ Female	Height:	Weight:
Address:	City	State	Zip Code
Phone #:	Medicaid Recipient ID#: (required)	Plan Policy ID#: (optional)	

PRESCRIBING PRACTITIONER INFORMATION

Practice Name:	Specialty:	NPI # (2):	
Prescribing Practitioner Name:	Medicaid Provider ID #: (required)	NPI # (1):	DEA/License #:
Address:	City	State	Zip Code
Phone #:	Fax #:	Office Contact:	EPSDT Support Coordinator (Name / Address): (optional)

MEDICATION INFORMATION

Drug Name:	Dosage Form:	Quantity:
Strength:	Directions:	
Dispense as Written: ☐ Yes ☐ No	Substitutes Permitted: ☐ Yes ☐ No	Number of Refills:
Currently on This Medication: ☐ Yes ☐ No	Other Medications Tried toTreat This Condition:	Dates:
List Other Current Medications: ☐ *See attached list*		
Reasons for Discontinuation of Tried Therapies:		
Diagnosis/Indication:		ICD Diagnosis Code:
Rationale and/or Other Information Relevant (☐ *included* lab results) to the Review of This Authorization Request:		
Drug Allergies:		

PHARMACY INFORMATION (Optional)

Pharmacy Name:	Phone #:	Fax #:

Prescribing Practitioner Signature: _____ **Date:** _____

For more information, refer to www.lamedicaid.com and follow the "Pharmacy and Prescribing Providers" link.