

POLICY AND PROCEDURE

POLICY NAME: Specialty Pharmacy Program	POLICY ID: LA.PHAR.OP.12
BUSINESS UNIT: Louisiana Healthcare Connections	FUNCTIONAL AREA: Pharmacy
EFFECTIVE DATE: 11/12	PRODUCT(S): Medicaid
REVIEWED/REVISED DATE: 10/13, 4/14, 11/14, 10/15, 9/16, 1/17, 8/17, 8/18, 10/18, 1/19, 1/20, 10/20, 12/21, 3/22, 5/22, 4/23, 2/24, 12/24, <u>10/25</u>	
REGULATOR MOST RECENT APPROVAL DATE(S): N/A	

POLICY STATEMENT:

It is the policy of Louisiana Healthcare Connections (LHCC) to have a comprehensive and high-quality pharmacy program that addresses the need of specialty drugs for our Medicaid members. LHCC recognizes the importance of providing adequate access to specialty drugs to our members while ensuring proper management of handling and utilization.

PURPOSE:

The Specialty Pharmacy Program is designed to allow adequate access to specialty drugs to Medicaid members while ensuring proper management of handling and utilization. LHCC follows the PDL and criteria guidance provided by LDH for providing specialty drugs and works to ensure the drugs can be provided within our network to our members who may need them.

SCOPE:

Louisiana Healthcare Connections (LHCC) Pharmacy Department, Louisiana Healthcare Connections Medical Management Department, and the contracted Pharmacy Benefits Manager (PBM) ~~Louisiana State Single PBM, which is currently Prime Therapeutics Government Solutions (Prime)~~

DEFINITIONS: (Acronyms section)

LDH – Louisiana Health Department

MCO – Managed Care Organization

PBM – Pharmacy Benefit Manager

LHCC – Louisiana Healthcare Connections

PDL – Preferred Drug List

~~Prime – Prime Therapeutics Government Solutions~~

POLICY:

LHCC complies with the specialty drug and specialty pharmacy requirements specified in the LDH MCO Manual and pursuant to contractual requirements.

1. LHCC does not limit distribution of specialty drugs or self-refer to a Centene-owned specialty pharmacy or the contracted PBM's specialty pharmacy.
2. Any pharmacy that is able to procure specialty drugs from distributors, has any one of the nationally recognized accreditations and is willing to accept the terms shall be allowed to participate in the Louisiana Single PBM's pharmacy network approved by LDH
- ~~3. All specialty pharmacy contracts between the contracted PBM and specialty pharmacy are sent to LDH Pharmacy for approval prior to processing any specialty pharmacy claims. [ER1]~~
- 4.3. LDH reserves the right to deny specialty pharmacy contracts that include what LDH deems to be overly burdensome terms or requirements, including but not limited to requirements for excessive insurance coverage, unreasonable stocking requirements, or restrictive or duplicative accreditation requirements. LHCC ~~shall~~ accepts any one of the nationally recognized accreditation programs to meet its specialty pharmacy network requirement.

LHCC follows LDH's definition of a specialty drug. A specialty drug is defined as a prescription drug which meets one of the following criteria:

1. The drug cannot be routinely dispensed at a majority of retail community pharmacies due to physical or administrative requirements that limit preparation and/or delivery in the retail community pharmacy environment. Such drugs may include but are not limited to chemotherapy, radiation drugs, intravenous therapy drugs, biologic prescription drugs approved for use by the federal Food and Drug Administration, and/or drugs that require physical facilities not typically found in a retail community pharmacy, such as a ventilation hood for preparation;
2. The drug is used to treat complex, chronic, or rare medical conditions:
 - That can be progressive;
 - That can be debilitating or fatal if left untreated or undertreated; or
 - For which there is no known cure.

3. The drug requires special handling, storage, and/or has distribution and/or inventory limitations;
4. The drug has a complex dosing regimen or requires specialized administration;
5. Any drug that is considered to have limited distribution by the federal Food and Drug Administration;
6. The drug requires:
 - Complex and extended patient education or counseling;
 - Intensive monitoring; or
 - Clinical oversight;
7. The drug has significant side effects and/or risk profile.

Access to Specialty Drugs: LHCC ~~and Prime~~ ~~do~~ ~~es~~ not establish definitions, or require accreditation or licensure, effectively limiting access to prescription drugs, including specialty drugs, other than the appropriate governmental or regulatory bodies.

PROCEDURE:

~~Prime~~ ~~LHCC~~ will review provider/prescriber submitted requests for prior authorization of specialty medications or for other pharmacy benefit limitations and restrictions. Provider/Prescribers may submit prior authorization requests to Prime for eligible plan members by facsimile transmission utilizing the statewide universal prior authorization form. All information relevant to the prior authorization request, that is submitted from a reliable data source, (prescriber, pharmacy, or when applicable, the member) will be accepted and is kept confidential, in accordance with state and federal confidentiality laws. All applicable state and federal laws to protect the confidentiality of individual medical records are followed in order to limit on the distribution of information on a "need to know" basis. Refer to policy LA.PHAR.08 Pharmacy Prior Authorization and Medical Necessity for additional information.

The statewide universal prior authorization form is posted and utilized as specified in Act 423 of the 2018 Louisiana Regular Session. In order to obtain necessary information for prior authorization processing, the following therapeutic drug classes are considered specialty for prior authorization purposes only: Hepatitis C Direct Acting Antiviral Agents (as directed by LDH) Spinraza, Aduhelm, and Synagis.

~~Prime~~ ~~LHCC~~ utilizes the LDH form and criteria for these specialty classes filled in an outpatient pharmacy setting.

~~LHCC, along with Prime,~~ adheres to the provisions of La. R.S. 46:153.3(C)(1) which exempt HIV/AIDS drugs from the prior authorization process.

Specialty medications, for which the provider has been contractually approved for office use, may also require prior authorization. These requests are not adjudicated as retail benefits and are considered "buy and bill". All such requests should be faxed directly to Louisiana Healthcare Connections. Upon receipt, the "buy and bill" requests will be forwarded to the pharmacy department for clinical review. Approvals or denials are communicated back to the prescriber's office within the timeframes outlined in the Timeliness of UM Decisions policy (LA.UM.05)

REFERENCES:

[Louisiana Healthcare Connections Louisiana Department of Health Contract and Amendments](#)
[Louisiana Medicaid Managed Care Organization \(MCO\) Manual](#)
[Louisiana Medicaid Single Preferred Drug List \(PDL\)](#)
[Louisiana Uniform Prescription Drug Prior Authorization \(PA\) Form and Fax Coversheet](#)
 LA.PHAR.OP.08
 LA.UM.05
 La. R.S. 46:153.3(C)(1)

ATTACHMENTS: N/A

ROLES & RESPONSIBILITIES: N/A

REGULATORY REPORTING REQUIREMENTS:

La R.S. 46:460.54 applies to material changes for this policy

REVISION LOG

REVISION TYPE	REVISION SUMMARY	DATE APPROVED & PUBLISHED
New Policy Document	N/A	11/2012
Annual Review	Under Procedure added "The Specialty Medication Prior Authorization Form is posted on the plan website (see Attachment A)." Under Attachments, added "Attachment A – LHC Specialty Medication Prior Authorization Form"	10/2013
Ad Hoc Review	Clarified policy on "buy and bill" products Revised language in procedure to more clearly define process and flow Added policy to reference, LA.PHAR.08 for Prior Authorization procedure.	04/24/14
Annual Review	LA Procurement 2015 Policy Update	11/2014
Annual Review	Under Scope, changed Centene Corporate Pharmacy Department to Corporate Pharmacy Solutions Group	10/26/15
Annual Review	Annual Review; changed threshold to \$670; updated PA requests process flow; updated references Changed DHH to LDH	09/26/16
Ad Hoc Review	Changed US Script to Envolve Pharmacy Solutions, added CPAC to the process; Added process of Verbal PA request	01/24/17
Annual Review	No revisions to Policy	08/24/17
Annual Review	Annual review. No revisions.	08/24/18
Ad Hoc Review	Updated State Contract language Changed Product Type from Louisiana Healthcare Connections to Medicaid	10/24/18
Annual Review	Changed Pharmacy Benefit Management (PBM) system to prior authorization system in sections 1, 2, and 3; Updated "the PT may send a response to the prescriber" to "the PT sends a response to, or calls the prescriber" in section 2a; Removed all references to "one business day" and "72 hours" from prior authorization timeframe in section 5 because they are reviewed within 24 hours; Removed "exception" requests from section 5 because they don't exist in Medicaid, only Medicare. NCQA Review: Removed sentence stating Acaria Health as the preferred Specialty Pharmacy in the Policy section because already stated in the Purpose section; Removed redundant sentence about pharmacists being appropriately licensed; Grammatical fixes; Removed Call Center reference from section 5 because already in section 6; Removed Urgent vs Non Urgent reference because it is stated that all requests are reviewed within 24 hours. Removed Acaria as pharmacy of choice; Removed Attachment A Specialty PA form	01/25/19
Annual Review	Corporate Annual Review: No changes deemed necessary	01/24/20
Ad Hoc Review	Updated language to be in compliance with Louisiana Medicaid Managed Care Organization Statement of Work 7.17.4	10/26/20
Annual Review	Annual Review – Updated language to correspond with LDH Contract Amendment 1 & 2	12/29/21
Annual Review	Updated: the statewide universal prior authorization form	03/28/22
Ad Hoc Review	Updated Language to be in compliance with Louisianan Medicaid Managed Care Organization Amendment #11: A specialty drug is defined as a prescription drug which meets three or more of the following criteria. Also updated name change Envolve Pharmacy Solutions to Centene Pharmacy Services.	05/27/22

Annual Review	<p>Moved to new P&P Template</p> <p>Updated to reflect 3/2023 MCO Manual and LDH/LHCC Contract</p> <p>Added Policy Statement</p> <p>Updated Purpose section with the following “LHCC follows PDL and criteria guidance provided by LDH for providing specialty drugs and works to ensure the drugs can be provided within our network to our members who may need them.”</p> <p>Updated Scope section – removed LDH and added contracted PBM</p> <p>Added definitions section</p> <p>Updated Policy section with the following</p> <ul style="list-style-type: none"> • Added blurb LHCC follow’s LDH specialty definition • Inserted contracted PBM instead of CPS where applicable • Updated to reflect 3/2023 MCO Manual and LDH/LHCC Contract • Removed Specialty pharmacy network requirements shall be approved by LDH 30 days prior to implementation. • Removed Any pharmacy network cancellations shall be approved by LDH at least 60 days prior to cancellation. <p>Added LHCC pharmacy staff in addition to CPS in Procedure section</p> <p>Updated Policy ID from LA.PHAR.12 to LA.PHAR.OP.12</p>	04/11/23
Annual Review	<p>Updated definition of specialty drug to reflect LDH-LHCC Contract effective 01/01/2023.</p> <p>Policy updated to reflect changes as a result of the state-mandated single PBM effective 10/28/23 in Louisiana.</p> <p>Links added to References section, References updated.</p>	02/06/24
Annual Review	<p>Updated all references to “Magellan Medicaid Administration” to now reflect “Prime Therapeutics Government Solutions (Prime)” in light of the Louisiana Single PBM entity name change. Updated definition of Specialty Drug Criteria per the MCO Manual section on defining specialty drugs. Added link to LDH’s Single PDL and link to Uniform Prescription Drug PA Form in References section. Wording updated for clarity.</p>	12/01/24
<u>Annual Review</u>	<p><u>Removed references to the Louisiana Single PBM, which was terminated 10/1/25. Updated language to reflect that LHCC reviews prior authorizations if required.</u></p>	<u>10/13/25</u>

POLICY AND PROCEDURE APPROVAL

The electronic approval retained in RSA Archer, the Company’s P&P management software, is considered equivalent to a signature.

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