

POLICY AND PROCEDURE

DEPARTMENT: Pharmacy Operations	DOCUMENT NAME: Specialty Pharmacy Program
PAGE: 1 of 7	REPLACES DOCUMENT:
APPROVED DATE: 11/12	RETIRED:
EFFECTIVE DATE: 11/12, 2/15	REVIEWED/REVISED: 10/13; 4/14, 11/14, 10/15, 09/16, 1/17, 8/17, 8/18, 10/18, 01/19; 01/20; 10/20, 12/21, 03/22
PRODUCT TYPE: Medicaid	REFERENCE NUMBER: LA.PHAR.12

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SCOPE:

Louisiana Healthcare Connections (LHCC) Pharmacy Department, Louisiana Healthcare Connections Medical Management Department, Louisiana Department of Health (LDH) and Envolve Pharmacy Solutions (EPS).

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PURPOSE: 7.17.4

The Specialty Pharmacy Program is designed to allow adequate access to specialty drugs to Medicaid members while ensuring proper management of handling and utilization.

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POLICY:

1. LHCC shall not limit distribution of specialty drugs or self-refer to a Centene-owned 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 of the Envolve Pharmacy Solutions' (EPS) contract, shall be allowed to participate in the EPS' network (any willing provider).
3. All specialty pharmacy contracts between EPS and specialty pharmacy shall be sent to LDH pharmacy for approval prior to processing any specialty pharmacy claims.
4. 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 accept any one of the nationally recognized accreditation programs to meet its specialty pharmacy network requirement.
5. Specialty pharmacy network requirements shall be approved by LDH 30 days prior to implementation.
6. Any pharmacy network cancellations shall be approved by LDH at least 60 days prior to cancellation.

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7.17.4.1.1. A specialty drug is defined as a prescription drug which meets two or more of the following criteria:

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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 EPS shall 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.

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PROCEDURE:

Envolve Pharmacy Solutions' Pharmacy Services staff 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 Envolve Pharmacy Solutions 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.

LDH Amd. 1 & 2

6.3.4.2 As of January 1, 2019, the statewide universal prior authorization form shall be 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 shall be considered specialty for prior authorization purposes only: Hepatitis C Direct Acting Antiviral Agents (as directed by LDH) Spinraza and Synagis.

LHCC will utilize the LDH form and criteria for these specialty classes filled in an outpatient pharmacy setting.

The MCO shall adhere to the provisions of La. R.S. 46:153.3(C)(1) which exempt HIV/AIDS drugs from the prior authorization process.

7.17.4.1.3 The following categories of drugs shall not be considered

Commented [MT1]: Amy- please see how to change this verbiage to be more LHCC friendly.... thanks

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specialty drugs:

- Any oral medications utilized to treat HIV, Hepatitis B or Hepatitis C; Any oral medications utilized to treat rheumatoid arthritis, multiple sclerosis or psoriasis (e.g., Aubagio, Gilenya, Otezla, Xeljanz/Xeljanz XR, etc.);
- Any oral medications utilized to treat epilepsy or an immunosuppressant (e.g., Mycophenolate, Sirolimus, Tacrolimus, etc.);
- Self-administered injectable anticoagulants (e.g., Enoxaparin, Fondaparinux, Dalteparin, Unfractionated heparin, etc.);
- Self-administered injectable human growth hormone (excluding drop-ship items) or self-administered medications for migraine prophylaxis (e.g., Aimovig, Ajovy, Emgality); and
- Self-administered TNF-alpha blockers (e.g., Enbrel, Humira, Simponi, Cimzia), multiple sclerosis agents (e.g., Copaxone, Interferons, etc.) or psoriatic conditions (e.g., Cosentyx).

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)

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REFERENCES:

Louisiana Medicaid Managed Care Organization Statement of Work
1/1/2020
LDH Contract Amendment #1
LDH Contract Amendment #2

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LA.UM.05 Timeliness of UM Decisions
LA.PHAR.08 Pharmacy Prior Authorization and Medical Necessity

ATTACHMENTS:

N/A

DEFINITIONS:

N/A

REVISION LOG

REVISION	DATE
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"	10/13
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.	4/14
LA Procurement 2015 Policy Update	11/14
Under Scope, changed Centene Corporate Pharmacy Department to Corporate Pharmacy Solutions Group	10/15
Annual Review; changed threshold to \$670; updated PA requests process flow; updated references Changed DHH to LDH	09/16
Changed US Script to Envolve Pharmacy Solutions, added CPAC to the process; Added process of Verbal PA request	1/17
No revisions to Policy	8/17
Annual review. No revisions.	8/18
Updated State Contract language	10/18

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Changed Product Type from Louisiana Healthcare Connections to Medicaid	
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	01/19
Corporate Annual Review: No changes deemed necessary	01/20
<u>Updated language to be in compliance with Louisiana Medicaid Managed Care Organization Statement of Work 7.17.4</u>	10/20
<u>Annual Review – Updated language to correspond with LDH Contract Amendment 1 & 2</u>	12/21
<u>Updated: the statewide universal prior authorization form</u>	03/22

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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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