POLICY AND PROCEDURE

DEPARTMENT: Pharmacy Operations	REFERENCE NUMBER: OH.PHAR.12
EFFECTIVE DATE: 02/10	POLICY NAME: Specialty Pharmacy Program
REVIEWED/REVISED DATE: 02/11, 02/12, 02/13, 02/14, 08/14, 08/15, 08/16, 11/16, 11/17, 10/18	RETIRED DATE: N/A
PRODUCT TYPE: Medicaid	PAGE: 1 of 7

SCOPE:
Centene Corporate Pharmacy Solutions, Centene Health Plan Pharmacy Departments, AcariaHealth Specialty Pharmacy and Envolve Pharmacy Solutions. This policy only applies to those claims adjudicated through Envolve Pharmacy Solutions.

PURPOSE:
The Specialty Pharmacy Program is designed to provide the Centene Health Plan Pharmacy Departments, Acaria Health Specialty Pharmacy Specialty Pharmacy Services and Envolve Pharmacy Solutions with guidance on the approval and denial process for provision of biopharmaceuticals or other high cost drug therapy where preferred contract pricing may apply. AcariaHealth Specialty Pharmacy is the preferred Specialty Pharmacy provider for Centene Health Plans.

POLICY:
AcariaHealth Specialty Pharmacy is the current preferred provider for specialty drugs for Centene Health Plans. A Health Plan may choose to have providers direct specialty drug requests directly to them as a first step. In such cases, Health Plans should have established written work flows noted in the Centene Health Plan's local policy and a corresponding workflow established to ensure timely reviews.

Specialty medications, for which the provider has been contractually approved for use of office supplies, may also require prior authorization. These requests are not adjudicated through Envolve Pharmacy Solutions and are considered 'buy and bill'. All such requests should be faxed directly to the Centene Health Plan. Upon receipt, the Health Plan Referral Specialist will forward the 'buy and bill' requests to clinical review nurses in Medical Management. A Health Plan may choose to have the Pharmacy Department handle the 'buy and bill' requests. In such cases, Health Plans should have established written work flows noted in the Centene Health Plan's local policy and a corresponding workflow established to ensure timely reviews.

Centene or its subsidiaries does not discriminate on the basis of race, color, national origin, sex, age or disability, nor exclude from participation in, deny the benefits of, or otherwise subject to discrimination under any applicable Company health program or activity.

PROCEDURE:

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1. Envolve Pharmacy Solutions' Pharmacy Services staff 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 Envolve Pharmacy Solutions for eligible plan members by telephone or facsimile transmission utilizing the Health Plan's Prior Authorization Request 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.

   a. Verbal PA requests will be received by a Pharmacy Technician (PT) and transcribed into the Pharmacy Benefit Management (PBM) system for subsequent review by a pharmacist. A clinical decision will be communicated by facsimile to the prescriber.

2. Prior authorization requests are tracked and triaged by Pharmacy Technicians (PT) into the PBM system for review. PT may send a response to the prescriber, after tracking is complete, if the request falls into one of the following categories: duplicate PA request, member is not eligible for service due to expired eligibility, individual is not identified as listed in the PBM system as a member, or the request is for a specialty medication that is not delegated for review by Envolve Pharmacy Solutions staff.

   a. If major elements of information, such as diagnosis, medication history, or rationale, are missing from the PA request form, the PT may send a response to the prescriber indicating that the request cannot be reviewed due to insufficient information available to make a clinical decision. Only information necessary to certify the prescription will be collected. Clear documentation of the prescriber's original requests and any negotiation or agreement to accept an alternative treatment will be maintained. The prescriber is not required to submit the member's entire medical record but only data relevant to the clinical parameters of the prescription. The prescriber will not be coerced by Envolve Pharmacy Solutions or its reviewers in the negotiation or agreement to accept an alternative treatment.

3. The pharmacist holding an unrestricted license will review an electronic copy of the

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PA request from the PBM queue. In order to review and determine a prior authorization request, all pharmacists will be appropriately licensed as required by the state boards of pharmacy and/or state utilization management (UM) requirements (i.e. New Hampshire). Prior to reviewing cases for those states with specific requirements, pharmacists who review and determine requests for these states will obtain a license from that state board of pharmacy. The pharmacist will make a clinical decision regarding the requested medication or for other pharmacy benefit limitations and restrictions based on the diagnosis, previous medication history, including trial and failure of Preferred Drug List (PDL) medications, and the rationale provided by the prescriber or his/her designee.

a. The pharmacists will take into consideration a number of factors to determine whether to approve or not approve a PA request. These factors include, but are not limited to:

1) Medical necessity criteria, including prior authorization or step therapy criteria, are created by the Clinical Pharmacy Advisory Committee (CPAC) and approved by the Corporate P&T Committee, as well as, the Health Plan's Pharmacy and Therapeutics (P&T) committee. Reviews are done based on clinical appropriateness and to assure timely access to both PDL and non-PDL drug products.

2) FDA approved indications with dose and age specifications.

3) Evidence-based medicine supported in peer-reviewed journal articles.

4) Published National or Professional Societies' standards of practice.

5) FDA alerts, market withdrawals or news that provides updated information on market availability, treatment of a condition/disease or adverse events of medications.

6) National Institute of Health and/or Centers for Disease Control recommendations or guidelines.

7) Clinical judgment based on the clinical information available to the prescriber during the time of the review.

8) Member's medication claim history available in the PBM system.

9) Request is for experimental or investigational medication and is otherwise allowed under CP.PMN.53 Off-Label Use.

10) Implemented clinical edits that have been approved by the State's P&T committee when using a State's directed formulary.

b. The pharmacist holding an unrestricted license will make a decision to approve or

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not to approve a request. If the request does not contain sufficient clinical information to make a decision, the request will not be approved due to insufficient information.

1) If the request is not approved due to insufficient information, the response to the prescriber and member must specify which information is missing that is required to complete a review of the request.

2) If the request is not approved and the "PA status type" selected is "Unable to Approve", the reason(s) for not approving the request must be specified. Specific criteria or reason(s) must be cited to give the practitioner and the member sufficient information to understand and decide whether to appeal a decision to deny coverage.

3) If the request does not contain sufficient clinical information to make a decision, the request will not be placed in pending status.

4. For clients that reside in a State that do not allow pharmacists to deny a prior authorization request, the requesting prescriber will be notified that the request will be forwarded to the health plan or delegate for further review, evaluation and a decision, for requests that cannot be approved based on the information presented and PDL alternatives that have not been tried.

5. Medicaid prior authorization or exception requests received are responded to within one business day (24 hours) or 72 hours, depending on the status of request. This is inclusive of written notification to the member and physician. Call Center staff will provide weekend and holiday coverage for the Prior Authorization department. They will respond to prior authorization requests by providing access to a 72 hour supply of medication, or as specified by state requirement (refer to plan benefit summary sheet for additional information).

   a. Medicaid prior authorization requests are processed within 24 hours (one business day). These include requests that are either "urgent" or "non-urgent" as defined by the various relevant states.

6. A 72 hour emergency supply of medication, or as specified by state requirement, is available by request for Medicaid plan members to allow the provider reasonable time to submit a PA request. Prescribers or pharmacies may request an emergency supply of medication for members by calling Envolve Pharmacy Solutions' Call Center or Pharmacy Services Prior Authorization department.

7. Envolve Pharmacy Solutions will fax an approval or denial notification to the prescriber. Medicaid members will receive a denial letter notification. The denial notifications will include the following:

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    a. Denial reason;

    b. Denial rationale including a reference to the PA guideline used to make the determination;

    c. How to request a copy of the clinical criteria used to make the determination;

    d. Ability to request a peer-to-peer or reconsideration;

    e. Instructions for initiating an appeal of a non-approval decision (adverse determination);

    f. Name and title of the individual who made the determination;

      Notifications will be mailed to the member or the above information will be sent to the health plan for inclusion into the member letter.

8. Acaria is sent notification of approvals in cases where Acaria is the exclusive or preferred pharmacy, any willing provider states where there is no specialty PA pharmacy designation on the PA request, and/or cases in any willing provider states where member is new to therapy.

9. A prescriber may request a peer-to-peer review or reconsideration when a PA is not approved (denial) by contacting the Prior Authorization department by telephone or resubmitting the prior authorization with additional clinical information. The notification of a prescriber's right is included in the notification response to the provider. The prescriber may present significant additional clinical information to have a previous denial of coverage overturned.

10. Envolve Pharmacy Solutions does not deny a previously approved prior authorization for prescription coverage to a covered person. However, Envolve Pharmacy Solutions reserves the right to adjust the approval date to the date when the following circumstances have been identified so that the member can no longer receive the medication;

    a. Prior authorization was obtained based upon fraudulent, materially inaccurate, or misrepresented information submitted by the covered person, authorized person, or the provider, or

    b. The approved medication was not provided consistent with the prescriber's submitted plan of care (medical information) and/or any restrictions included in the prior authorization (i.e. quantity limits, step-therapy).

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NOTE: Any local deviation from this process due to state regulations or customized process must be clearly noted in the Centene Health Plan's local policy and a corresponding workflow established.

REFERENCES:
CC.UM.05 Timeliness of UM Decisions CP.PMN.53 Off-Label Use Drug Use for Prior Authorization Approval EPS.PHARM.54 Specialty Drug List Management CC.COMP.42_ACA 1557 Nondiscrimination in Health Programs Activities

ATTACHMENTS: N/A

DEFINITIONS:
Specialty Drug - Drugs categorized as biopharmaceuticals or drugs that have preferred contract pricing arrangements for provision by a specialty supplier.

REVISION LOG

REVISION	DATE
Made clerical changes to clarify work flow. Defined "specialty drugs".	02/11
No substantive changes.	02/12
Changed "CCMS" references to "case management application".	02/12
Removed Attachment A: Centene Health Plan and CVS Caremark Program Flow. It no longer followed all the flow logic in the P&P language.	02/13
Overall review of the procedure to obtain pharmacy benefit prior authorization review for drugs provided via a retail/specialty pharmacy.	02/14
Updated references to CVS Caremark and replaced with AcariaHealth Specialty Pharmacy as Centene's preferred specialty pharmacy.	02/14
No changes deemed necessary.	08/14
Changed $500 to $600 based on CMS threshold.	08/15
Annual Review; changed threshold to $670; updated PA requests process flow.	08/16
Changed US Script to Envolve Pharmacy Solutions, added CPAC to the process. Exchanged the USS.07 Off-Label Drug Use for Prior Authorization Approval and replaced with Centene CP.PMN.53 Off-Label Use.	11/16
Added EPS.PHARM.54 Specialty Drug List Management policy to references; Added discrimination statement; Updated references.	11/17
Updated template. Removed statement "Most drug therapy with costs in excess	10/18

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of $670 per dose, or in excess of $670 per treatment regimen (consisting of more than one dose), requires prior authorization."	

POLICY AND PROCEDURE APPROVAL

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