Additions and Removals to PAL: Louisiana Medicaid

Original Date:	01/01/2023	Accountable Dept.:	HPS (Humana Pharmacy Solutions) Clinical Strategies, 73284
Last Reviewed Date:	08/28/2023		

Summary of Changes:

- Change to existing policy

Scope:

The purpose for this document is to define how Humana identifies and assesses physician administered drugs (PADs) for addition to or removal from the HCPR Medical preauthorization list (PAL) of its Louisiana Medicaid plan. This document applies to the following business areas:

- Clinical Drug Evaluation & Policy Strategies (CDEPS)
- Clinical Drug Policy Management (CDPM)
- Clinical Formulary Administration (CFA)
- Clinical Formulary & Medical Strategies (CFMS)
- Clinical Trend & Pipeline (CTP)
- Oncology Quality Management (OQM) Vendor
- Pharmacy Analytics & Consulting (PAC)

Procedures:

Procedure Overview:

- Humana may make updates to the HCPR Medical PAL **on January 1** of a new plan year or mid-year.
- Updates to the HCPR Medical PAL are driven by:
  - **Internal decisions finalized by Humana's Pharmaceutical & Therapeutics (P&T) Committee (e.g. additions/removals based on strategy or edit performance)**
  - **State direction**
  - New to market drugs or new drug indications
  - ~~**New plan year additions/removals**~~
  - ~~**Mid-year updates (e.g., intentional additions/removals based on strategy or edit performance)**~~
- **PADs that are also included on Louisiana Department of Health's (LDH) Preferred Drug List (PDL) will have the same preferred status and prior authorization criteria as the PDL (except Antiemetic/Antivertigo Agents therapeutic class).**

- ~~LDH will provide Humana with a Medicare Part B Drugs List each quarter that contains PADs that must be covered on the medical/professional outpatient benefit. Humana will evaluate the drug list for potential PAL additions using internal rules of the road.~~
- ~~If a drug on the Medicare Part B Drugs list could be covered as a pharmacy or medical/professional benefit, Humana will not implement utilization management (UM) criteria that leads to site of care steerage.~~[JS1][BP2]
- Humana will apply UM requirements that align with the manufacturer's package insert and FDA approved indications but will not apply any UM requirement that would indicate a drug is covered under the FFS pharmacy benefit.
- Humana is responsible for coverage of all drugs included in any high-cost or gene therapy risk pool.
- Humana will internally evaluate PADs for addition and removal to the PAL using rules of the road, utilization, and cost data.
- **Rules of the Road for PAL Addition**:
  - Drugs that are billed to the medical benefit OR ~~**B vs. D determination**~~
  - Drugs that are **administered** in the physician's office, clinic, outpatient, or home setting AND
  - One or more of the following apply:
    - High-cost therapy (≥ $10,000/treatment or month)
    - Potential for off-label use
    - Potential for fraud, waste, and abuse
    - Potential safety concerns
    - ~~**Candidate for UM Dosing OR Site of Care opportunities OR Specialty Medication Sourcing**~~
    - Supports a medical strategy
    - **Drug included in state's risk pool**
  - Exclusion(s):
    - Drugs indicated for acute or emergent use (to prevent access to care barriers)
- **Rules of the Road for PAL Removal**:
  - Edit process is no longer needed (e.g., more cost-effective management strategy identified)
  - **Drug is no longer on the market**

Detailed Procedure:

1. **Identify drug opportunities for PAL addition and removal**
   - 1.1. **CFMS: Obtain current fee schedule for the state. Identify potential PAL additions that meet the following criteria:**
     - **Drug is on the state's fee schedule**

- **Drug is not on the state's PAL**
- **Drug meets Rules of the Road for PAL addition**

1.2. CFMS: Obtain state's risk pool drug list and identify drugs not on the state's PAL for addition.

1.3. CFMS: Compare potential additions to the state's PDL to identify and align preferred/non-preferred status.

1.4. CFMS: Identify potential PAL removals based on Rules of the Road for PAL removal.

1.5. CFMS: Request and receive savings modeling of PAL additions/removals from PAC team.

2. Obtain approval of PAL additions and removals

2.1. CFMS: Present recommendations for PAL additions and removals at Formulary Build forum and Medical Strategies forum, with formal document, for discussion and alignment amongst strategic partners: CFA, CFMS, CTP, OQM vendor team, PAC.

2.2. CFMS: Share recommendations for PAL additions/removals with state pharmacy director and obtain feedback.

2.3. CFMS: Present target drug additions and removals to the PAL at PMCS and P&T meetings for final approval.

3. Distribute planned PAL changes to impacted teams

3.1. CFMS: Share approved list of drug additions and removals with CDEPS, CDPM, CFA, CFMS, and OQM vendor teams.

3.2. CFMS: Add changes to HCPR Medical Drug List Change Request tracker

3.3. CFMS: Ensure prescriber and enrollee notification process is initiated for negative PAL changes.

4. Complete PAL updates and operational updates

4.1. CDEPS: Create, update, or archive clinical policies based on specific PAL changes.

4.2. CDPM: Create or update operational product build based on specific PAL changes.

4.3. CDPM: Update and publish internal and external PAL documents.

4.4. CFMS: Confirm all updates complete on effective date of change.

Definitions:

- **Healthcare Common Procedure Coding System (HCPCS) Drug Code: A standardized code to identify drug products for claim submission.**
- **Humana Clinical Pharmacy Review (HCPR) Medical PAL (i.e., PAD PAL): A list of physician administered drugs for which preauthorization is required.**
- **Humana Pharmaceutical and Therapeutics (P&T) Committee: Responsible for reviewing and approving changes to the PAL.**
- **Negative PAL Change: Eliminating or further restricting access to a covered physician administered drug product by adding utilization management requirements where none were present before**
- **Preauthorization (i.e., Prior Authorization): The process of determining medical necessity for specific drugs or services before they are rendered.**
- **Preferred Drug List (PDL): A list maintained by LDH indicating which drugs are covered without the need for Prior Authorization, with the exception that some preferred drugs require Prior Authorization to validate clinical criteria.**

- **State: The state of Louisiana.**
- **Utilization Management (UM): Refers to the process to evaluate the medical necessity, appropriateness, and efficiency of the use of health care services, procedures, and facilities.**

References:

Louisiana Department of Health and Magellan Medicaid Administration Inc. Contract: 2. Definitions and Acronyms

Louisiana Medicaid Managed Care Organization Model Contract: 2.2.3.12.3.2.2

Louisiana Medicaid Managed Care Organization Model Contract: Glossary

Louisiana Medicaid Managed Care Organization (MCO) Manual

Communication and Training Plan:

- N/A

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