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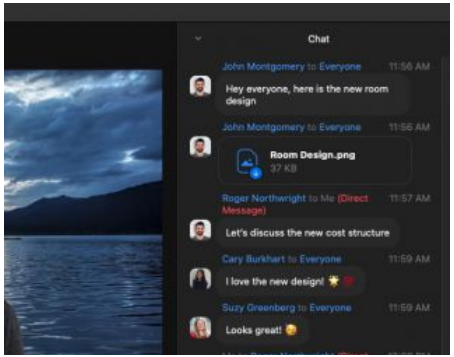

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AHCCCS PHARMACY BENEFIT OVERVIEW

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AHCCCS
Arizona Health Care Cost Containment System

Pharmacy Benefit Agenda

- Stakeholders
- AHCCCS Pharmacy Program Benefit
- AHCCCS Rules
- Pharmacy Terminology
- Pharmacy Benefit Managers
- AHCCCS Point-of-Sale Pharmacy Expenditures
- Prior Authorization Process
- Pharmacy & Therapeutics Committee
- CMS Medicaid Drug Rebate Program

AHCCCS Pharmacy Program Stakeholders

- Advocacy Groups
- AHCCCS Members
- The Arizona Legislature
- Arizona Taxpayers
- Centers for Medicare and Medicaid Services
- Governor's Office
- Managed Care Contractors
- Pharmacy Benefit Managers (PBMs)
- Pharmaceutical Manufacturers
- Provider Networks from Individual Providers to Large Hospital Systems
- Retail, Specialty, Long Term Care, Mail Order & Hospital Pharmacies

AHCCCS Pharmacy Benefit

- Basis of the AHCCCS Pharmacy Benefit is the Provision of:
  - Medically Necessary
  - Clinically Appropriate
  - Cost Effective Medications
- Coverage of Federally and State Reimbursable Drugs
  - Legend Prescriptions Medications
  - Specialty Medications
  - Over-the-Counter Medication
- The prescribing clinician and pharmacy must be AHCCCS registered.

Who Does The AHCCCS Pharmacy Benefit Serve?

- Eligible Members:
  - Title XIX (Medicaid)
  - Title XXI (KidsCare)
  - Non-Title XIX SMI
  - Non-Title XIX SED
- Dual Eligible Members
  - Members that have both Medicaid and Medicare Coverage
  - Medicare Part D – SMI/SED Cost Sharing (Copayments, Deductibles, Coverage Gap)
  - Medicare Part B Coordination of Benefits – up to 20% of the Medicare Payment
- Individuals in crisis or those seeking SUD treatment
- AHCCCS is the Payer of last resort unless the payer is Indian Health Service

AHCCCS Pharmacy Program Limitations
A.A.C. R9-22-209 Section D

The following limitations apply to pharmaceutical services:

1. A medication personally dispensed by a physician, dentist, or a practitioner within the individual's scope of practice is not covered, except in geographically remote areas where there is no participating pharmacy or if accessible pharmacies are closed.

2. A new prescription or refill in excess of a 30-day supply is not covered unless:

   a. The member will be out of the provider's service area for an extended period of time and the prescription is limited to the extended time-period, not to exceed a 90-day supply, or

   b. The Contractor authorizes the prescription for an extended time-period not to exceed a 90-day supply.

3. An over-the-counter medication, in place of a covered prescription medication, is covered only if the over-the-counter medication is appropriate, equally effective, safe, and less costly than the covered prescription medication.

AHCCCS Pharmacy Program Supply Limits in AHCCCS Medical Policy Manual Policy 310-V

- A new or refill prescription in excess of a 30-day supply is not covered unless:
  - The medication is prescribed for a chronic illness and the prescription is limited to no more than a 90-day supply,
  - The member will be out of the provider's service area for an extended period-of-time and the prescription is limited to the extended time-period, not to exceed 90 days, or
  - The medication is prescribed for contraception and the prescription is limited to no more than a 90-day supply.

Experimental Services A.A.C. R9-22-203

Part A. Experimental services are not covered. A service is not experimental if:

1. It is generally and widely accepted as a standard of care in the practice of medicine in the United States and is a safe and effective treatment for the condition for which it is intended or used.
2. The service does not meet the standard in subsection (A)(1), but the service has been demonstrated to be safe and effective for the condition for which it is intended or used based on the weight of the evidence in peer-reviewed articles in medical journals published in the United States.
3. The service does not meet the standard in subsection (A)(2) because the condition for which the service is intended or used is rare, but the service has been demonstrated to be safe and effective for the condition for which it is intended or used based on the weight of opinions from specialists who provide the service or related services.

Part B. The following factors shall be considered when evaluating the weight of peer-reviewed articles or the opinions of specialists:

1. The mortality rate and survival rate of the service as compared to the rates for alternative non-experimental services.

2. The types, severity, and frequency of complications associated with the services as compared with the complications associated with alternative non-experimental services.

Common Pharmacy Terminology

- **Brand Name Drug** - A drug that has been FDA approved under a New Drug Application (NDA) and is a new chemical entity and is under a patent. CMS refers to these drugs as "Innovator Drugs"
- **Generic Drug** - A drug that contains the same active ingredient(s) as a brand name drug and the FDA has approved it to be manufactured and marketed after the brand name drug's patent expires. CMS refers to these drugs as "Non-Innovator Drugs"
- **Authorized Generic Drug** - Authorized generics are prescription drugs produced by company that manufactures the brand name product and can be marketed under a private label, at lower pricing than the branded product. AG drugs can be marketed before the patent expires.
- **Biosimilar** - A biological drug approved by the FDA based on a showing that it is highly similar, to a FDA-Approved biological drug, known as the reference product, and has no clinically meaningful differences in terms of safety and effectiveness from the reference product.
- **Specialty Drugs -** May require special handling & monitoring, have limited distribution, are generally self-administered and high cost.
- **National Drug Code –** also known as the NDC. Each drug name and strength has a unique 11-digit number. The first 5 digits identify the manufacturer, the next 4 identify the drug name & strength and the last 2 identify the package size.
- **Formulary** - A listing of medications covered or preferred by the plan.

Pharmacy Terminology – Biologics

- Slightly different from the broader term “Specialty” drug
- Characteristics of Biologics
  - Includes a wide range of products including vaccines, blood and blood components, allergenics, gene therapy, and recombinant therapeutic proteins
  - Isolated from a variety of natural sources
    - → Human, animal, or micro-organism
  - May be produced by cutting-edge biotechnology methods
    - → Gene-based and cellular biologics lead the science
      - → DEEP PIPELINE
  - Usually used to treat a variety of medical conditions where treatment options are or were previously severely limited

Pharmacy Pricing Terminology

- **AAC – Actual Acquisition Cost** – drug cost net of all discounts.
- **ASP – Average Sales Price** – Manufacturers submit sales price information to CMS Medicare which includes all discounts and is the basis for the Medicare Part B quarterly pricing file.
- **AWP – The Average Wholesale Price -**
  - The published drug and device pricing information is “based on data obtained from manufacturers, distributors, and other suppliers.
  - AHCCCS and it MCO Contractors use AWP in the PBM claims adjudication process.
- **MAC Pricing** – **Maximum Allowable Cost** (MAC) is maximum amount that will be paid per unit for a specific generic drug.
- **NADAC** – **National Average Drug Acquisition Cost** prepared for and posted weekly by CMS Medicaid.
- **U&C - Usual & Customary -** The dollar amount of a pharmacy's charge for a prescription to the general public that reflects all advertised savings, discounts, special promotions, or other programs including membership-based discounts.
- **WAC – Wholesale Acquisition Cost-** the price of a drug sold to pharmacies or prescribers by the wholesaler or manufacturer.

What is a Pharmacy Benefit Manager (PBM)?

- Organizations that **manage** pharmacy benefits for:
- Medicaid FFS
- Managed Care Organizations
- Medicare Part D Plans
- Employer Groups
- Other Providers
  - Veterans Administration
  - Union Groups

Examples of Current PBMs

PBMs' Core Functions

- **Benefit Administration**
  - Manage prescription drug benefits and act as vehicle between, the payer, the pharmacies, pharmaceutical manufacturers and the wholesalers.
  - Pharmacy Help Desk that Supports Member & Provider Networks
- **Claims Adjudication**
  - Process claims for prescription drugs
- **Utilization Management**
  - Perform clinical management services to oversee prescription drug utilization
  - Provide Drug List Development in conjunction with Prior Authorization
- **Monitoring and Reporting**
  - Coordinate development and delivery of reports (e.g., monthly, quarterly) to track drug expenditures
- **Rebate Negotiation**
  - Negotiate with pharmaceutical manufacturers to reduce drug prices and obtain rebates

Additional Services Offered By PBMs

- Develop alternative reimbursement and discount programs
- Coordination of Third-party Liability issues
- Patient Safety Quality Management
- Provider Education
- Pharmacy Fraud, Waste, and Abuse audit services
- Pharmacy and Therapeutics (P&T) Committee
- Drug Utilization Review (DUR) Board Support
- Population Health Programs

FFS PBM Services

- Process Prescription Claims Electronically
- Drug List Management
- Develop and Implement Various Plan Set-ups as Required by FFS
- Drug Utilization Review
- Contract with the Pharmacy Network
- Provide Audit Services
- Provide Customer Service to Members, Prescribers & Pharmacy Providers
- Implement Clinical Programs
- Develop all prior authorization criteria
- Provide input CMS Drug Utilization Report and Initiatives

FFS PBM Plan Set-Ups

- Multiple Plan System Programming Set-ups
  - American Indian Health Plan Title XIX
  - KidsCare Title XXI
  - Dual Eligible OTC Plan
  - Medicare Part B Plan
  - TRBHA Plan for Non-Title XIX SMI or SED Individuals
  - 340B FQHC Reimbursement
  - Prior Quarter Coverage
  - IHS/638 Tribal Pharmacies
    - AIR & Specialty Medications
  - All dispensed medications must be state and federally reimbursable.

FFS PBM Management Services

- Drug Utilization Review (DUR)
  - Concurrent – edits in the system at the point-of sale, for example, drug is for sulfa and patient is allergic.
  - Prospective – refers in general to the PA Process.
  - Retrospective – Review of utilization reports.
  - CMS Annual DUR Report – Due June 30th
    - FFS PBM- Two clinical retrospective reviews approved by the P&T Committee for the CMS DUR report.
    - MCOs must submit the CMS DUR Report on the CMS DUR website by May 31 annually.

AHCCCS Pharmacy Program Drug Lists

- AHCCCS Drug List
- AHCCCS FFS Acute & Long-Term Care Drug List
- Dual Eligible Over-the-Counter Drug List for FFS
- Federal Emergency Services Dialysis Drug List
- MCO Behavioral Health Contractors:
  - For Title XIX - AHCCCS Drug List
  - For Non-Title XIX SMIs - A behavioral health drug list
  - For Non-Title XIX SED - A behavioral health drug list
  - Substance Abuse Block Grant Drug List (SABG)
  - Crisis Drug List

How Are Prescription Claims Paid?
Point-Of-Sale Reimbursement Methodologies

AHCCCS FFS PBMs' Claims Pricing

- **Brand Name Drugs:**
  - Lesser of Logic
    - Average Wholesale Price (AWP) minus % Discount or
    - NADAC or Usual and Customary (U&C) or Submitted Ingredient Cost
    - Whichever is Less Plus a Professional/Dispensing Fee (DF)
- **Generic Drugs** -
  - Lesser of Logic
    - AWP-%;
    - U&C, NADAC, Submitted Ingredient Cost; or
    - The Maximum Allowable Cost, aka MAC Price
    - Plus a Professional/Dispensing Fee (DF)

MCO & FFS Pharmacy Point-of-Sale Expenditures For 2020, 2021 & 2022

Year	MCO	FFS	Total Expenditures
2020	1.564B	191M	1.76B
2021	1.729B	304M	2.03B
2022	1.921B	401M	2.32B

Total FFS & MCO Pharmacy Point of Sale Expenditures for Calendar Years 2020 thru 2022

$6.11B

PBM Prior Authorization Services

The Prior Authorization Criteria Development:

Utilizes **clinical** and **scientific evidence.**

Supports the **appropriate use** of medications.

Enhances **patient** and **population health outcomes.**

Optimizes the use of **limited health care resources.**

FFS Pharmacy Benefit Management Services
Prior Authorization Services

Considerations when developing PA criteria:

- To ensure clinically and safe appropriate use of the medication.
- Use is for off-label, unproven or unsafe indications.
- Use when certain populations have been shown not to benefit from therapy.
- Drug is used as a first-line therapy when other equally safe and effective but less costly drugs are available.
- Drug is prescribed for a time-period the exceeds the recommended duration or when therapy ceases to provide benefit.
- Drug is prescribed at dosages exceeding the recommended dosing regimen.
- Drug is indicated for certain gene mutations.

Alignment with:

- ✔ AHCCCS plan design
- ✔ Standards of medical practice
- ✔ P&T Committee Recommendations
- ✔ Operational standards

FFS PBM Prior Authorization Criteria Development Process

Scientific evidence used to develop prior authorization criteria:

1. Food and Drug Administration (FDA) approved indications and limits,
2. Published practice guidelines and treatment protocols,
3. Comparative data evaluating the efficacy, type and frequency of side effects and potential drug interactions among alternative products as well as the risks, benefits, and potential member outcomes,
4. Drug Facts and Comparisons, American Hospital Formulary Service Drug Information,
5. United States Pharmacopeia – Drug Information,
6. DRUGDEX Information System, UpToDate, MicroMedex,
7. Peer-reviewed medical literature, including randomized clinical trials, outcomes, research data and pharmacoeconomic studies.

FFS PBM Prior Authorization Criteria Development Process

- Development of Prior Authorization (PA) Criteria
  - OptumRx dedicated clinical pharmacist to develop prior authorization criteria
  - MCOs are required to use the FFS PA Criteria
    - MCO's may send questions or requests for changes to current criteria or the development of new criteria to our dedicated OptumRx clinical pharmacist.
  - All changes are tracked on an excel spreadsheet.
    - New drugs needing PA criteria.
    - Changes in indications, packaging, shortages or other issues that must be added to an existing PA.
    - All MCO questions are responded to during the monthly meeting.
  - Our OptumRx clinical pharmacist meets with the MCOs monthly.
  - Updated criteria is posted monthly for FFS on the AHCCCS website.
  - MCOs are given an additional 30 days to make system changes and then post to their websites.

Required Information for Submitting a Prior Authorization Request

Provider

- Ordering Provider Name
- Tax ID
- Address
- Office Telephone Number
- Office Fax Number

Member

- Member Name
- Date of Birth
- ID Number
- Height
- Weight

Medication

- Place of Service
- Requested Drug Name or HCPCS Code
- Dosage
- Frequency
- Anticipated Start Date of Treatment

Clinical

- Clinical notes supporting the medical necessity of the request
- Pathology Reports
- Relevant Test Results

Prior Authorization Process Timeline for FFS & MCOs

- Prior Authorization (PA)
  - Response must be sent within 24 hours of receipt of the request.
  - If supporting documentation is not complete, a response for additional information is sent to the submitting provider and the provider is allowed 7 days to submit the additional information.
  - If the PA is denied, the Notice of Adverse Determination along with the Grievance and Appeals process must be sent no later than 14 days from the submitted date of the PA.

AHCCCS Pharmacy & Therapeutics (P&T) Committee

- P&T Committee is advisory to AHCCCS
  - P&T Operational Policy - ACOM Policy 111
  - Meeting schedule is on the AHCCCS website
    - January, May & October
- Committee Members are:
  - Practicing physicians, nurse practitioners, pharmacists, OIFA representative and a member & member advocates
    - P&T Application & Conflict of Interest Form
    - Members are chosen by computerized random selection process
- The Committee reviews & makes recommendations on the preferred status of medications within therapeutics drug classes, new drugs, new indications or other FDA approved changes.

AHCCCS Pharmacy & Therapeutics Committee Recommendation Considerations

AHCCCS Pharmacy & Therapeutics Committee

- Meetings are virtual and open to the public except for the executive session.
- Purpose is to Evaluate Clinical Evidence that is provided and presented by the AHCCCS Supplemental Rebate Vendor.
- Make recommendations on safe and effective drug use and promote cost-effective drug therapy.
- Oral and Written Public Testimony is accepted in accordance with the ACOM P&T Operational Policy 111:
  - Individuals from the public
  - Individuals from pharmaceutical, PBM or related companies
  - All individuals submitting public testimony are checked against the CMS Sunshine Database.
- Executive Session
  - Clinical and Financial information is evaluated
  - Committee formulates recommendations
  - Voting on the recommendations is completed in public
- AHCCCS reviews all P&T recommendations and renders a final determination to accept, modify or reject the recommendations.

AHCCCS Pharmacy & Therapeutics Committee

- Documents posted on the AHCCCS website under Pharmacy Section:
  - Prior to the meeting
    - Meeting Dates and Drug Classes
    - Agenda
  - After the P&T Meeting
    - Contractor Meeting Overview Memo
    - Meeting Minutes Approved from Prior Meeting
    - P&T Presentation & Recommendations
    - Preferred/Non-preferred Drug List NDC File
    - Written Public Testimony
- MCO must follow the P&T Recommendations & Preferred Agents
- Actuary Staff Involvement

Pharmacy - Rebates

- **Federal Rebates** – Rebates are paid by manufacturers to States based on the OBRA 90 regulation and the ACA regulations.
  - A drug is a CMS Covered Outpatient Drug that is eligible for coverage after the manufacturer signs the CMS Federal Rebate Agreement.
  - States collect the federal rebate on all CMS Covered Outpatient Drugs.
  - Vaccines and Devices are not rebated under the Federal Rebate Agreement.
  - AHCCCS contracts with a vendor to process the federal rebate for the state.
- **Supplemental Rebates** – Rebates obtained from pharmaceutical or device manufacturers that are in addition to the Federal Rebates.
  - Supplemental Rebates are managed by the AHCCCS Federal Rebate Vendor.

Questions?

Thank You.

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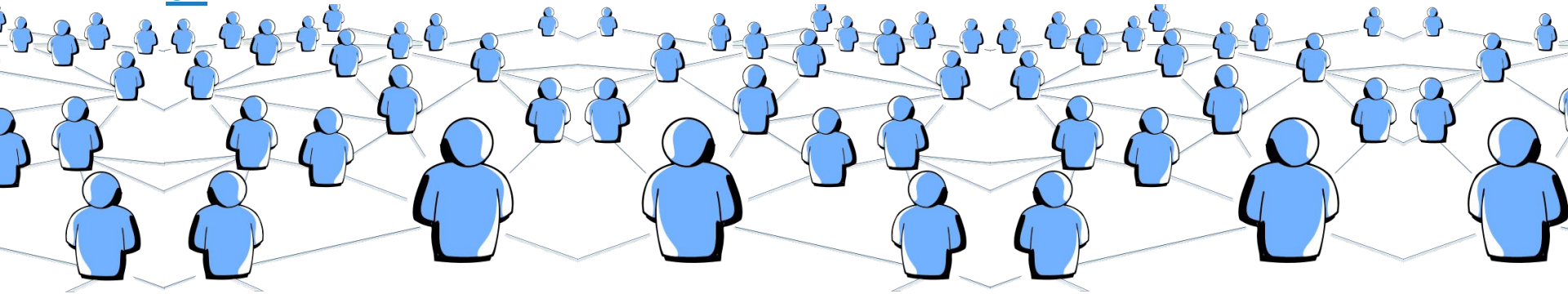
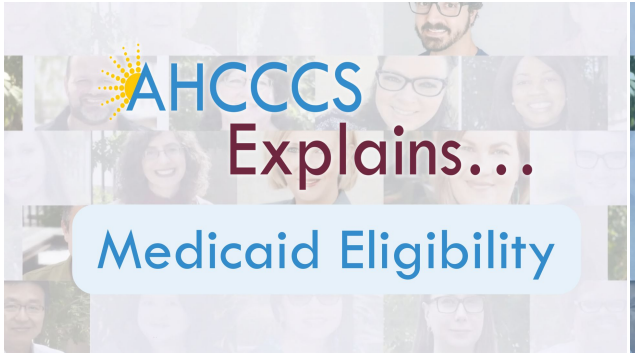


Learn about AHCCCS' Medicaid Program on YouTube!



YouTube

Watch our Playlist:

[Meet Arizona's Innovative Medicaid Program]

Other Resources - Quick Links

- AHCCCS Waiver
- AHCCCS State Plan
- AHCCCS Grants
- AHCCCS Whole Person Care Initiative (WPCI)
- AHCCCS Office of Human Rights
- AHCCCS Office of Individual and Family Affairs