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## **AHCCCS Pharmacy and Therapeutics Committee Operational Policy**

**May 9, 2016**

### **PURPOSE**

The AHCCCS Pharmacy & Therapeutics Committee (Committee) is advisory to the AHCCCS Administration and is responsible for evaluating scientific evidence of the relative safety, efficacy, effectiveness and clinical appropriateness of prescription drugs. The Committee shall make recommendations to the AHCCCS Administration on the development and maintenance of a statewide drug list and prior authorization criteria as appropriate. Committee members shall evaluate individual drugs and therapeutic classes of drugs in an unbiased manner emphasizing the best clinical evidence and cost effectiveness.

### **DEFINITIONS**

1. "AHCCCS Drug List" means a list of medications and related products supported by current evidence-based medicine. The primary purpose of the AHCCCS Drug List is to encourage the use of safe, effective, clinically appropriate and the most cost-effective medications.
2. "Committee" means the AHCCCS Pharmacy and Therapeutics Committee, as appointed by the Chief Medical Officer.
3. "Efficacy" means the ability of a treatment to achieve the desired results under ideal study conditions.
4. "Effectiveness" means the actual effects of a drug treatment under real life conditions.
5. "Evidence-based medicine" means the judicious use of the best scientific evidence including clinical expertise and member values when making decisions about healthcare. The scientific evidence is limited to information studied and available in the United States.
6. "Simple-majority" means the vote taken by the Committee where at least 51% of the members must approve the motion before it is accepted.

### **COMPOSITION**

The Committee shall be comprised of individuals described in numbers 1 thru 4 below. It is the intent of the AHCCCS Administration that the Committee be comprised of members from both urban and rural areas of the State of Arizona.

1. AHCCCS representatives shall include the:
  - a. Chief Medical Officer (CMO) or designee
  - b. Medical Management Administrator or designee
  - c. Office of Individual and Family Affair Administrator (OIFA) or designee
  - d. Pharmacy Administrator or designee

2. Eight health care providers, currently registered with the AHCCCS program, including but not limited to the following:
  - a. Psychiatrist
  - b. Obstetrician gynecologist
  - c. Pediatrician
  - d. Primary care provider
  - e. Registered nurse
  - f. Pharmacist
  - g. Other

In the case of pharmacists or others that are not registered with AHCCCS, the company employing the pharmacist or others must be a registered AHCCCS provider.

3. Members of the public:
  - a. Inter-Tribal Council of Arizona (ITCA) Representative
  - b. Medicaid member
  - c. Member advocate
4. AHCCCS Managed Care Organizations (MCOs) and Regional Behavioral Health Authority (RBHA) representatives:
  - a. Three MCO Acute Plan Medical Directors or Pharmacy Directors or designees
  - b. One MCO ALTCS Medical Director or Pharmacy Director or designee
  - c. One RBHA Medical Director or Pharmacy Director or designee
  - d. One TRBHA Medical Director or Pharmacy Director or designee

#### **MEMBER APPOINTMENT PROCESS AND LENGTH OF TERM**

1. The AHCCCS Chief Medical Officer (CMO), Pharmacy Administrator, Medical Management Administrator, and OIFA Administrator or their designees are ex-officio. The remaining Committee members shall be appointed by the AHCCCS CMO for 2 year terms with the option of term renewal, for a maximum of 4 years.
2. The Committee may submit to the AHCCCS CMO a list of nominees with to replace members whose term will be expiring within 6 months of the expiration of their term. The AHCCCS CMO may solicit or receive nominations from other sources.
3. AHCCCS has the sole discretion to appoint Committee members and may terminate the appointment of any member at any time.
4. The Committee application form is available on the AHCCCS Pharmacy website.

#### **CONFLICT OF INTEREST DISCLOSURE FORM**

1. The Conflict of Interest Disclosure Form provided by the AHCCCS Administration. Members must complete and submit the Form before attending their first Committee meeting. The Form must be submitted to the AHCCCS Administration annually by July 1st of each year.
2. Members must update their Conflict of Interest Disclosure Form any time their circumstances change in order to ensure their information is current. Updated information must be submitted within 30 days of the change.

3. Members cannot be employed by a pharmaceutical manufacturer or a pharmacy benefits management company.
4. Members must disclose to AHCCCS any financial conflict of interest in any pharmaceutical company, including, but not limited to, the holding of stock options or the receipt of honoraria or consultant monies, receipt of any remuneration, grants, or other compensation from a pharmaceutical manufacturer or pharmaceutical benefits management company prior to becoming a member or participating on a subcommittee.
5. A member must recuse him/herself from any discussion and decision making of an individual and/or entire drug class if he or she has a conflict of interest concerning the individual drug or drug class under review.

### MEETINGS

1. The AHCCCS CMO or designee is the Committee's Chairperson and is responsible for setting meeting agendas. The Chairperson may call special meetings. The Chairperson shall preside at all meetings, and shall facilitate discussion by the members.
2. The Committee shall meet at least quarterly and may meet at other times at the discretion of the Chairperson or AHCCCS. Advance notice shall be provided to Committee Members of all meetings.
3. The Committee shall:
  - a. Review medications available through the outpatient drug benefit listed on the AHCCCS Drug List at a minimum annually.
  - b. Review new drugs and biosimilars on or about 180 days from the date the drug is commercially available. If the new drug is a new entry to a supplemental rebate class with preferred drug(s) listed on the AHCCCS Drug List:
    - i. The drug will be reviewed as a single agent if the supplemental rebate class' next review is scheduled for greater than 180 days from the date the new drug became commercially available.
    - ii. The drug will be reviewed at the next scheduled supplemental rebate class' review if the supplemental rebate class' next review is less than 180 days from the date the new drug became commercially available.
  - c. New drugs, only available through the retail pharmacy benefit, that are from a therapeutic class that is not currently listed as a supplemental rebate class with preferred drugs on the AHCCCS Drug List shall be reviewed in accordance with the following schedule:

New Drugs Commercially Available In:	Expected P&T Meeting For Review:
December, January, or February	May
March, April or May	August
June, July or August	November
September, October or November	February

- d. Make recommendations to AHCCCS on the grandfathering status of each non-preferred drug for each therapeutic class reviewed by the Committee.
- e. Respond to requests for medication additions, deletions or changes to the AHCCCS Drug

List submitted to AHCCCS; these requests must include the following information:

- i. Medication requested (brand name and generic name);
  - ii. Dosage forms, strengths and corresponding costs of the medication requested;
  - iii. Average daily dosage;
  - iv. FDA indication and accepted off-label use;
  - v. Advantages or disadvantages of the medication over currently available products on the AHCCCS Drug List;
  - vi. Adverse effects reported with the medication; and
  - vii. Specific monitoring requirements and costs associated with these requirements.
  - viii. For deletions, a detailed clinical summary for the request which shall also include items (i) thru (vii).
  - ix. Requests must be submitted to the AHCCCS Pharmacy Department using the email address: [AHCCCSPharmacyDept@azahcccs.gov](mailto:AHCCCSPharmacyDept@azahcccs.gov)
4. On or about 60 days prior to the Committee meeting:
    - a. AHCCCS shall post the therapeutic classes to be reviewed for supplemental rebates on the AHCCCS Pharmacy website.
    - b. The Committee members may obtain clinical information for therapeutic class reviews for supplemental rebates at the AHCCCS supplemental rebate vendor, Provider Synergies' website with a secure username and password.  
<http://www.providersynergies.com/services/medicaid/default.asp?content=Arizona>
  5. On or about 7 days prior to the Committee meeting:
    - a. The Committee members will be provided a final agenda and meeting materials.
    - b. AHCCCS shall post on the AHCCCS Pharmacy website the final agenda with the list of approved speakers.
  6. If a Committee member is unable to attend a meeting, the member is requested to notify the Chairperson of their absence.
  7. Other information related to the Committee meeting will be posted on the AHCCCS Pharmacy website.
  8. Meeting minutes of the Committee's deliberations will be distributed prior to the next meeting and a formal approval process will be used to accept the minutes at the beginning of each meeting. Approved Committee meeting minutes will be posted on the AHCCCS website.
  9. The AHCCCS supplemental rebate contractor may be present to assist the Chairperson during meetings when supplemental rebate is a topic on the agenda.
  10. The Committee meetings are open to the public.
  11. Executive sessions in which confidential information is discussed shall not be open to the public. Executive sessions shall be limited to Committee members and the AHCCCS Administration supplemental rebate vendor staff. The Chairperson shall adjourn to the executive session when discussing confidential information.
  12. Committee members must attend all meetings in person.
  13. A teleconference line will be available for the public portion of the meeting.

## **SUBCOMMITTEES**

1. The Chairperson or AHCCCS may designate and appoint one or more subcommittees.
2. A minimum of 2 Committee members shall serve on each such subcommittee.

3. Other persons may participate as designated by the Chairperson.
4. Sub-committee members must complete a Conflict of Interest disclosure form provided by AHCCCS prior to attending their first sub-committee meeting and annually as needed.
5. No subcommittee shall have authority to amend, alter, or repeal this Policy, adopt any action contrary to the Committee, remove any member or take any action on behalf of the Committee or AHCCCS.
6. Any member of any subcommittee may be removed by the Chairperson or AHCCCS whenever the best interests of the Committee or the State will be best served by such removal.

### **VOTING AND QUORUM**

1. All business of the Committee shall be transacted by motion or resolution, which may be proposed by any member in attendance, including the Chairperson and shall require a second. Voting on all motions and resolutions shall be by voice vote unless a member asks that the roll be called and that the vote of each member be recorded.
2. Each member of the Committee shall have one vote on each matter submitted to a vote to the Committee.
3. A Simple-majority of voting members shall be required for all matters. A majority of the quorum must vote in favor for a motion in order for the motion to be adopted.
4. When a member must recuse him/herself from acting on any matter, that person shall not be counted for the purposes of determining a quorum.
5. Members must be present to vote on each matter submitted for a vote to the members.

### **IN-PERSON ORAL PUBLIC TESTIMONY**

1. Public representatives presenting testimony to the Committee must register to present at the meeting no later than 14 days prior to the meeting.
2. The registration form is interactive and will be available on the AHCCCS Pharmacy website.
3. Registration is available on a first-come, first-serve basis and is limited to 15 presenters.
4. Registration to testify will include the name of the person wishing to testify, address, organization represented, the drug that will be the subject of the testimony, and if a drug manufacturer requested them to appear and testify in a paid or unpaid capacity.
5. In order to accommodate testimony from a variety of organizations and individuals, testimony is limited to one individual per organization on each agenda item.
6. Individuals who present must sign in at least 10 minutes prior to the start of the meeting; otherwise the individual may not be permitted to present comments.
7. Individuals presenting may not be employed by, speak on behalf of, or represent a pharmaceutical manufacturer.
8. The Committee Chairperson will recognize the speakers in alphabetical order of the medications listed in the therapeutic class being reviewed.
9. Speakers may provide comments verbally and through written handouts provided to Committee members at the meeting.
10. Speakers are limited to comments that do not exceed 3 minutes per drug.
11. Questions or comments from the Committee will not be entertained unless the Chairperson grants approval for questions or comments from the Committee members. The Chairperson

may suspend or eliminate the comment process for reasons including, but not limited to, speaker noncompliance with the comment process, time constraints, and/or the quality of information presented.

#### WRITTEN PUBLIC TESTIMONY

1. Public representatives sending written testimony to the Committee must submit letters no later than 14 days prior to the meeting.
2. In order to accommodate testimony from a variety of organizations and individuals, testimony is limited to one individual per organization on each agenda item and shall not exceed 2 pages.
3. Written testimony must include the name of the person wishing to testify, address, organization represented, the drug that will be the subject of the testimony, and if a drug manufacturer requested them to testify in a paid or unpaid capacity.
4. Individuals submitting written testimony may not be employed by, speak on behalf of, or represent a pharmaceutical manufacturer.
5. Written testimony must be submitted to AHCCCS pharmacy office at:  
[AHCCCSPharmacyDept@azahcccs.gov](mailto:AHCCCSPharmacyDept@azahcccs.gov)

#### PHARMACEUTICAL COMPANY TESTIMONY

Pharmaceutical representatives presenting clinical information to the Committee must register to present at the meeting no later than 30 days prior to the meeting. The registration form is interactive and will be available on the AHCCCS Pharmacy website. The chairperson may limit the number of presenters.

1. Pharmaceutical representatives shall submit clinical information to be presented at the meeting to the AHCCCS Pharmacy Department for review prior to the meeting at:  
[AHCCCSPharmacyDept@azahcccs.gov](mailto:AHCCCSPharmacyDept@azahcccs.gov)
2. All clinical information submitted must include a one-page cover sheet that summarizes the key points and directs the Committee members to the key areas of the submitted information for consideration. Page number, paragraphs and line numbers must be cited.
3. Presentation content by commenters is limited to drugs relevant to the drug classes specified in the meeting agenda.
4. **Information submitted is restricted to new studies released since the last review, and is limited to randomized double-blinded active control studies. Studies must have been published or accepted for publication in a peer-reviewed journal(s).**
5. **Online publications, poster presentations and placebo controlled, observational, open-label and non-randomized studies are not accepted for consideration.**
6. **Product monographs and dossiers, Pharmacy and Therapeutic (P&T) Committee briefs, extensive bibliographies, or similar inclusions will not be considered.**
7. Individuals who present must sign in at least 10 minutes prior to the start of the Committee meeting; otherwise the individual may not be permitted to present comments.
8. The Chairperson or designee will recognize the speakers in alphabetical order of the medications listed in the therapeutic class being reviewed.

9. Speakers may provide comments verbally and through written handouts provided to Committee members at the meeting.
10. Speakers are limited to comments that do not exceed 3 minutes per drug, per class, per manufacturer only when specific to supplemental rebates.
11. Questions or comments from the Committee will not be entertained unless the Chairperson grants approval for questions or comments from the Committee members. The Chairperson may suspend or eliminate the comment process for reasons including, but not limited to, speaker noncompliance with the comment process, time constraints, and/or the quality of information presented.

### **SUPPLEMENTAL REBATE OFFERS**

1. The AHCCCS supplemental rebate vendor, Provider Synergies, may request supplemental rebate offers from manufacturers for therapeutic class drugs or other products scheduled for review at Committee meetings.
2. Manufacturers responding to the request for must submit their offer on the Offer Form located on the Provider Synergies website.
3. Manufacturers that have a preferred drug/product on the AHCCCS Drug List may submit a new dosage formulation as a line item extension using the Arizona Line Item Extension Form found on the Provider Synergies website:  
<http://www.providersynergies.com/services/medicaid/default.asp?content=Arizona#>
4. The following documents are available on the Provider Synergies website:
  - a. Manufacturer's Letter Request for Supplemental Rebate Offer
  - b. Classes and Products to be reviewed.
  - c. Offer Form
  - d. Arizona Line Item Extension Form
  - e. AHCCCS Pharmacy & Therapeutics Committee Operational Policy

### **CONTRACTS**

The Committee shall not enter into contracts, but may recommend that AHCCCS enter into such contracts as are necessary or proper to carry out the provisions and purposes of the work of the Committee. Such contract(s) include, but are not limited to, engagements of independent legal, actuarial, clinical, research or other consultants.

### **SUGGESTED CHANGES TO COMMITTEE OPERATIONAL PROCEDURES**

Changes to the operational procedures may be suggested at any Committee meeting by a vote of two-thirds majority of the members present, provided that written notice of the proposed changes is sent to AHCCCS at least 10 business days prior to the meeting. AHCCCS will distribute this notice to the Committee members.



**REFERENCES**

[Academy of Managed Care: Managed Care Terms](#)

AHCCCS Medical Policy Manual: [Policy 310-V](#)

AHCCCS Drug List

**EFFECTIVE DATE**

This AHCCCS Pharmacy and Therapeutics Committee Operational Policy was approved by the AHCCCS Policy Committee on the \_\_\_\_\_ day of \_\_\_\_\_, \_\_\_\_\_ at the AHCCCS Policy Committee meeting.

This AHCCCS Pharmacy and Therapeutics Committee Operational Policy was duly adopted at the meeting of the Pharmacy and Therapeutics Committee on the \_\_\_\_\_ day of \_\_\_\_\_, \_\_\_\_\_.