

111 – AHCCCS PHARMACY AND THERAPEUTICS COMMITTEE

EFFECTIVE DATE: 04/16/19

APPROVAL DATE: 03/14/19

I. PURPOSE

The AHCCCS Pharmacy & Therapeutics (P&T) Committee (Committee) is advisory to AHCCCS 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 AHCCCS on the development and maintenance of a statewide drug list and prior authorization criteria as appropriate. Committee members shall not participate in matters in which they have a potential conflict of interest and they shall evaluate information regarding individual drugs and therapeutic classes of drugs in an impartial manner emphasizing the best clinical evidence and cost effectiveness consistent with Executive Order 2018-06.

II. DEFINITIONS

AHCCCS DRUG LIST	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.
BUSINESS DAY	A business day means a Monday, Tuesday, Wednesday, Thursday, or Friday unless a legal holiday falls on Monday, Tuesday, Wednesday, Thursday, or Friday.
COMMITTEE	The AHCCCS Pharmacy and Therapeutics Committee, as appointed by the Chief Medical Officer (CMO) or designee.
EFFECTIVENESS	The actual effects of a drug treatment under real life conditions.
EFFICACY	The ability of a treatment to achieve the desired results under ideal study conditions.
EVIDENCE-BASED MEDICINE	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 peer-reviewed articles in medical journals published in the United States.

SIMPLE-MAJORITY

Minimum number that is greater than 50%. With respect to approving a motion, a simple majority of the quorum present at the Committee meeting must vote in favor of the motion in order for the motion to be approved. Committee members who are AHCCCS staff do not have voting rights.

QUORUM

The minimum number of Committee members who must be present in order for the Committee to hold a Committee meeting and conduct business which, for the purposes of this Policy, shall be 50% of the membership plus one. Because the Committee is comprised of 23 members, 12 members must be present to constitute a quorum.

III. POLICY

The Committee shall be comprised of 23 individuals as described in this Policy. It is the intent of AHCCCS that the Committee be comprised of members from both urban and rural areas of the State of Arizona.

A. COMPOSITION

1. AHCCCS representatives consisting of:
 - a. Chief Medical Officer (CMO) or designee,
 - b. Office of Individual and Family Affair Administrator (OIFA) or designee, and
 - c. Pharmacy Administrator or designee.

2. 10 health care providers with active Arizona licenses in good standing and registered with AHCCCS (as applicable to the type of licensure) including one from each of the following disciplines and/or specialties:
 - a. Family practice,
 - b. Internal medicine,
 - c. Obstetrics and Gynecology,
 - d. Pain management,
 - e. Pediatrics,
 - f. Pharmacist,
 - g. Psychiatry, and
 - h. Registered nurse.

3. Public representatives from all of the following:
 - a. Inter-Tribal Council of Arizona (ITCA),
 - b. Medicaid member, and
 - c. Medicaid member advocate.

4. AHCCCS Managed Care Organizations (MCOs) and Tribal Regional Behavioral Health Authority (TRBHA) representatives:
 - a. Four MCO Medical Directors or Pharmacy Directors or their designees, and
 - b. Two TRBHA Medical Directors or Pharmacy Directors or their designees.
5. University representative
 - a. Researcher

B. COMMITTEE MEMBER APPOINTMENT PROCESS AND CONFLICT OF INTEREST

1. Committee members who are AHCCCS staff serve continuously and are non-voting members. AHCCCS staff are counted for the purposes of determining whether or not a Quorum has been met in order to proceed with the Committee meeting. The remaining Committee members shall be appointed by the AHCCCS CMO for a two-year term with the option of an additional single term renewal, for a four year maximum.
2. Recruitment and selection of Committee member vacancies:
 - a. The AHCCCS website <https://www.azahcccs.gov/PlansProviders/Pharmacy/> provides instructions for completion of the AHCCCS P&T Committee Application for Appointment and the Conflict of Interest Disclosure Form, Attachment A, to be submitted to AHCCCS for consideration, and
 - b. Factors considered in AHCCCS' selection of Committee members include but are not limited to: the position for which they are applying, Arizona Medicaid experience, and the submitted Conflict of Interest Disclosure Form.
3. AHCCCS has the sole discretion to appoint Committee members and may terminate the appointment of any member at any time.
4. Committee members shall not:
 - a. Be employed by, subcontract with, or directly or indirectly represent a pharmaceutical manufacturer,
 - b. Be employed by, subcontract with, or directly or indirectly represent a Pharmacy Benefits Management (PBM) company, or
 - c. Receive payments or compensation from the pharmaceutical industry in excess of the physician mean general payment amount for the most recent year as specified on openpaymentsdata.cms.gov.
5. Before a Committee member participates in his/her first Committee meeting, Committee members shall submit the completed Conflict of Interest Disclosure Form and disclose any potential conflicts of interest with respect to their participation in Committee business.
6. Committee members shall update their Conflict of Interest Disclosure Form no less

than annually from the date of first completion, and additionally no later than 30 calendar days from any change to the information in the existing Conflict of Interest Disclosure Form. The form shall be submitted to AHCCCS at AHCCCSPharmacyDept@azahcccs.gov.

7. Committee members shall recuse themselves from any discussion, recommendation, or voting with respect to an individual drug and/or entire drug class if they have any potential conflict of interest concerning the individual drug or drug class under review.
8. Committee members shall complete annual conflict of interest training conducted by AHCCCS.

C. MEETINGS

1. The AHCCCS CMO or designee is the Committee's Chairperson and is responsible for setting meeting agendas. The Committee Chairperson may call special meetings. The Committee Chairperson shall preside at all meetings and shall facilitate discussion by the members.
2. The Committee shall meet at least three times annually and/or at other times at the discretion of the Committee Chairperson or AHCCCS. Advance notice shall be provided to Committee members of all meetings.
3. With the exception of Closed Session Committee meetings, the Committee meetings are open to the public. Committee Meetings and the Agendas are made available on the AHCCCS website: <https://www.azahcccs.gov/PlansProviders/Pharmacy/>
4. A teleconference line will be available for the public portion of the meeting.
5. Committee members shall physically attend all meetings in-person. Telephonic attendance by Committee members is not permitted.
6. Closed Sessions shall be held for the purpose of reviewing clinical information and proprietary financial information that pertain to preferred and non-preferred drug recommendations. Closed Sessions are confidential and are not open to the public. In addition, the Committee Chairperson is responsible for calling the Closed Session which shall be limited to Committee members and the AHCCCS supplemental rebate vendor staff. Closed Sessions are not controlled by A.R.S. §38-431.03.
7. The Committee shall:
 - a. Review the AHCCCS Drug List, at a minimum, biennially, or on an as needed basis,
 - 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, and
- 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. Review new drugs that are from a therapeutic class that is not currently listed as a supplemental rebate class with preferred drugs on the AHCCCS Drug List in accordance with the following schedule:

NEW DRUGS COMMERCIALY AVAILABLE IN:	EXPECTED COMMITTEE MEETING FOR REVIEW:
January, February, March or April	May
May, June, July or August	October
September, October, November or December	January

- d. Make recommendations to AHCCCS on the grandfathering status of each non-preferred drug for each therapeutic class reviewed by the Committee, and
 - e. Respond to requests for medication additions, deletions, or changes to the AHCCCS Drug List submitted to AHCCCS.
 - i. Requests for medication additions, deletions or changes to the AHCCCS Drug List shall be submitted to the AHCCCS Pharmacy Department using the email address: AHCCCSPharmacyDept@azahcccs.gov and shall include the following information:
 - 1) Medication requested (brand name and generic name),
 - 2) Dosage forms, strengths, and corresponding costs of the medication requested,
 - 3) Average daily dosage,
 - 4) FDA indication and accepted off-label use,
 - 5) Advantages or disadvantages of the medication over currently available products on the AHCCCS Drug List,
 - 6) Adverse effects reported with the medication,
 - 7) Specific monitoring requirements and costs associated with these requirements, and
 - 8) For deletions, a detailed clinical summary for the request which shall also include items as specified in this Policy.
8. On or about 60 days prior to the Committee meeting, AHCCCS shall post the therapeutic classes to be reviewed for non-supplemental and supplemental rebates on the AHCCCS website.

9. On or about 30 days prior to the Committee meeting, the Committee members may obtain clinical information for therapeutic class reviews from the website of the AHCCCS supplemental rebate vendor, Provider Synergies, at <http://www.providersynergies.com/services/medicaid/default.asp?content=Arizona>. A secure username and password is required.
10. On or about seven days prior to the Committee meeting:
 - a. The Committee members will be provided an agenda and meeting materials, and
 - b. AHCCCS shall post on the AHCCCS website, the agenda with the list of approved speakers.
11. If a Committee member is unable to attend a meeting, the member is required to send email notification of the absence as soon as possible prior to the meeting to AHCCCSPharmacyDept@azahcccs.gov.
12. Meeting minutes of the prior Committee meeting will be distributed in advance of the subsequent 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.
13. The AHCCCS supplemental rebate vendor may be present to assist the Committee Chairperson during meetings.
14. Individuals described in Section III., G are prohibited from contacting AHCCCS P&T Committee members to discuss individual drugs or therapeutic classes to be reviewed at AHCCCS P&T Committee meetings. However, those individuals are permitted to submit written testimony as described in Section III., G.

D. SUBCOMMITTEES

1. The Committee Chairperson or AHCCCS may designate and appoint one or more subcommittees.
2. A minimum of two Committee members shall serve on each such subcommittee.
3. Other persons may participate as designated by the Committee Chairperson.
4. Subcommittee members shall meet all Conflict of Interest requirements.
5. No subcommittee shall have authority to amend, alter, or repeal this Policy, adopt any action contrary to the Committee, or 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 Committee Chairperson or

AHCCCS whenever the best interests of the Committee or the State will be best served by such removal.

E. VOTING AND QUORUM

1. A Quorum is necessary for the Committee to hold a meeting and transact business. A minimum of 12 of the 23 Committee members shall be present to constitute a Quorum to conduct Committee business.
2. Actions of the Committee shall be transacted by motion, which may be proposed by any Committee member in attendance, including the Committee Chairperson, and shall require a second. Voting on all motions shall be by hand vote unless a Committee member asks that the roll be called and that the vote of each Committee member be recorded.
3. Voting Committee members shall have one vote on each matter submitted to vote to the Committee. AHCCCS staff on the Committee are non-voting members.
4. If a Quorum is present to conduct committee business, a Simple-Majority of the voting Committee members present at the Committee meeting are required to vote in favor of a motion in order for the motion to be accepted and recommended to AHCCCS. For example, if 12 committee members are needed for a Quorum, and 17 Committee members are present, then eight Committee members who are permitted to vote are required to vote in favor of the motion in order for it to be accepted.
5. For any matter in which a Committee member has been recused from participating or acting on any matter, that Committee member shall not be counted for the purposes of determining a Quorum, for conducting the Committee meeting, and for determining the minimum number of votes necessary to pass a proposal related to any matter for which the Committee member has been recused. Any Committee member who has been recused shall not participate in voting with respect to the matter for which the member has been recused.
6. Committee members shall be physically present, in-person, to vote on each matter submitted for a vote to the members.

F. PUBLIC TESTIMONY PROVIDED TO THE COMMITTEE BY INDIVIDUALS NOT DESCRIBED IN SECTION III., G

1. Individuals who are not Committee members and who are not described in Section III., (G) are permitted to present testimony to the Committee as representatives of the public as set forth below. In order to present testimony, the representative of the public shall not be directly or indirectly employed by, contracted with, or speaking on

- behalf of pharmaceutical manufacturers, PBMs, lobbyists for these entities, or subcontractors of these entities.
2. Any physician who receives payments or compensation in excess of the physician national mean for their specialty as reported for the most recent available year, on the CMS Open Payments Database at openpaymentsdata.cms.gov is limited to providing written testimony. Oral testimony is not permitted.
 3. Individuals, who receive payment(s) or compensation from pharmaceutical manufacturers, PBMs, or lobbyists for these entities or subcontractors of these entities, are limited to providing written testimony. Oral testimony is not permitted.
 4. In-person oral testimony by representatives of the public may present testimony as set forth below.
 - a. In order to present oral testimony the individual shall be physically present at the committee meeting,
 - b. The representative shall complete the Public Testimony Registration Form and the Conflict of Interest Form on the AHCCCS website at:
<https://www.azahcccs.gov/PlansProviders/Pharmacy/> no later than 14 business days prior to the meeting,
 - c. Registration is available on a first-come, first-serve basis and shall be no more than 20 total presenters per meeting. At the discretion of the Committee Chairperson, the total number of individuals who are permitted to provide oral testimony may be adjusted based on the Committee meeting agenda and time constraints,
 - d. Testimony is limited to one individual per organization per drug,
 - e. Individuals who present testimony shall sign in at least 10 minutes prior to the start of the meeting. Failure to do so may result in the individual not being permitted to present comments,
 - f. The Committee Chairperson will recognize the speakers in alphabetical order of the drugs listed in the therapeutic class being reviewed,
 - g. Speakers may provide comments orally and through written handouts provided to Committee members at the meeting,
 - h. Speakers are limited to comments that do not exceed three minutes in length per drug,
 - i. Questions or comments from the Committee will not be entertained unless the Committee Chairperson grants approval for questions or comments from the Committee members, and
 - j. The Committee Chairperson may suspend or elect to not offer the comment process for reasons including, but not limited to, speaker noncompliance with the comment process, time constraints, and/or quality of the information presented.

5. Written testimony
 - a. The individual requesting to provide written testimony shall complete and submit the Public Testimony Registration Form and the Conflict of Interest Form on the AHCCCS website at <https://www.azahcccs.gov/PlansProviders/Pharmacy/> no later than 14 business days prior to the meeting, and
 - b. Written testimony is limited to one individual per organization on each agenda item and shall not exceed two pages.

G. TESTIMONY PROVIDED TO THE COMMITTEE BY REPRESENTATIVES OF PHARMACEUTICAL MANUFACTURERS, PBMS, AND RELATED ENTITIES

1. Testimony provided to the Committee by representatives of pharmaceutical manufacturers, PBMs, and related entities is limited to written testimony. Oral testimony by these representatives is not permitted. For purposes of Section III., G, representatives are individuals who are directly or indirectly employed by, or contracted with, or speaking on behalf of pharmaceutical manufacturers, PBMs, lobbyists for these entities, or subcontractors of these entities.
2. Representatives of pharmaceutical manufacturers, PBMs, and related entities who wish to submit written testimony to the Committee shall submit information to the AHCCCS Supplemental Rebate Vendor at: pswebmail@magellanhealth.com no later than 30 business days prior to the meeting.
3. All clinical information submitted shall 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 shall be cited.
4. Written content submitted by representative of pharmaceutical manufacturers, PBMs, and related entities is limited to drugs relevant to the drug classes specified in the meeting agenda.
5. Written testimony submissions are restricted to new studies released since the last AHCCCS Committee review. Testimony is limited to randomized double-blinded active control studies, and information that is published, or accepted for publication, in a peer-reviewed journal(s).
 - a. The following information will not be accepted:
 - i. online publications,
 - ii. poster presentations,
 - iii. placebo controlled,
 - iv. observational,
 - v. open-label and non-randomized studies,
 - vi. product monographs and dossiers,
 - vii. P&T Committee briefs,

- viii. extensive bibliographies, or
- ix. similar inclusions.

H. SUPPLEMENTAL REBATE OFFERS

1. The AHCCCS supplemental rebate vendor 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 shall submit their offer on the *Offer Form* located on the AHCCCS supplemental rebate vendor's 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* located on the AHCCCS supplemental rebate vendor's website.
4. The following documents are also available on the AHCCCS supplemental rebate vendor's website:
 - a. Manufacturer's Letter Request for Supplemental Rebate Offer,
 - b. Classes and Products to be reviewed, and
 - c. AHCCCS P&T Committee Operational Policy.

I. CONTRACTS

The Committee shall not enter into contracts but may recommend that AHCCCS enter into contracts as 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.

J. UPDATES TO THE P&T COMMITTEE OPERATIONAL POLICY

Updates to this Policy will be managed through the AHCCCS Policy Committee (APC) process.