111 – AHCCCS PHARMACY AND THERAPEUTICS COMMITTEE

EFFECTIVE DATES: 04/16/19, 10/30/19, 09/01/21, 04/15/22, 08/13/24

APPROVAL DATES: 03/14/19, 10/01/19, 07/15/21, 02/02/22, 06/03/24

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. Committee members shall not participate in matters in which they have an actual or potential conflict of interest. Committee members 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 Arizona Executive Order 2018-06.

II. DEFINITIONS

For purposes of this Policy the following terms are defined as:

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 medications that are also cost-effective.
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 then that day shall not be considered a business day.
COMMITTEE	Committee refers to the AHCCCS Pharmacy and Therapeutics Committee. Members of the Committee are appointed by the Chief Medical Officer (CMO) of AHCCCS or by a 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.

EXECUTIVE SESSION	The Executive Session shall be held for the purpose of reviewing presented clinical information and proprietary financial information that pertains to preferred and non-preferred drug recommendations. The Executive Sessions are confidential and not open to the public.
QUORUM	The minimum number of Committee members who must be present in order for the Committee to hold a Committee meeting and conduct business. A quorum shall be 50% of the membership plus one. Because the Committee is comprised of 20 members, 11 members must be present to constitute a quorum. Members who are employed by AHCCCS shall be considered for the purposes of determining a Quorum.
SIMPLE MAJORITY	A Simple Majority is the minimum number of Committee members 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. Members who are employed by AHCCCS shall not have voting rights and shall not be considered part of the simple majority.

Additional definitions are located on the AHCCCS website at: AHCCCS Contract and Policy Dictionary

III. POLICY

The Committee shall be comprised of the following individuals as specified in this Policy.

A. COMPOSITION

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

2. Health care providers with active Arizona licenses in good standing and registered with AHCCCS (as applicable to the type of licensure) consisting of individuals from the following disciplines and/or specialties (maximum of 10 members in this category):
   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 consisting of:
   a. Inter-Tribal Council of Arizona (ITCA),
   b. Medicaid member, and
   c. Medicaid member advocate.

4. The AHCCCS Contractors and Tribal Regional Behavioral Health Authority (TRBHA) consisting of:
   a. Four MCO Medical Directors or Pharmacy Directors or their designees, and
   b. Two TRBHA Medical Directors or Pharmacy Directors or their designees.

B. COMMITTEE MEMBER APPOINTMENT PROCESS AND CONFLICT OF INTEREST

1. Committee members who are employed by AHCCCS shall serve continuously and are non-voting members. AHCCCS employees 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 or Designee for a two-year term with the option of term renewal.

2. Recruitment and selection of Committee member vacancies:
   a. The AHCCCS Pharmacy website provides instructions for completion of the 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 arenot 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 involved with or 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 Centers for Medicare and Medicaid Services (CMS) Open Payments database US Mean, including the Specialty Mean, if available, for the most recent year.

5. Receive payments or compensation from the pharmaceutical industry in excess of the Centers for Medicare and Medicaid Services (CMS) Open Payments database US Mean, including the Specialty Mean, if available, for the most recent year. Before a Committee member participates in their 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.

   Committee members shall update their Conflict-of-Interest Disclosure Form no less than 12 months 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. If a Committee meeting takes place before a member can submit the form, the member shall notify the Committee of such conflict at the start of such meeting. The Form shall be submitted to AHCCCS at: AHCCCSPharmacyDept@azahcccs.gov.

6. 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 conflicts of interest concerning the individual drug or drug class under review.

7. 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 shall preside at all meetings and shall facilitate discussion by the Committee members.

2. The Committee shall meet virtually at least three times annually. Other Committee meetings may be scheduled at the discretion of AHCCCS. Advance notice shall be provided of all meetings as further detailed in this Policy.

3. With the exception of the Executive Session portion of the Committee meeting, the AHCCCS P&T Committee meetings are open to the public. Committee meetings and agendas are made available on the AHCCCS Pharmacy website.

4. The Executive Session of the meeting shall be held for the purpose of reviewing proprietary financial information that pertains to preferred and non-preferred drug recommendations. The Executive Session is confidential and is not open to the public. The Committee Chairperson is responsible for initiating the Executive Session, which shall be limited to Committee members and the AHCCCS supplemental rebate vendor staff. Executive Sessions are not regulated by ARS 38-431.03.

5. The Committee shall:
   a. Review the AHCCCS Drug List approximately every two years or on an as needed basis,
   b. Review biosimilars in accordance with the AMPM Policy 310-V, and
   c. Review new chemical entity drugs on or about 180 days from the date the drug is commercially available.
   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 DrugList 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) Food and Drug Administration (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 alsoinclude items as specified in this Policy.

6. New formulations of a current medication with the same chemical entity are not reviewed as a new drug at the P&T Committee meeting.

7. Drugs solely administered via intravenous infusion are not reviewed at the P&T Committee meeting.

8. On or about 60 days prior to the Committee meeting, AHCCCS shall post the expected therapeutic classes to be reviewed for non-supplemental and supplemental rebates on the AHCCCS website. The list of therapeutic classes or individual drugs may change at the discretion of AHCCCS.

9. On or about 30 days prior to the Committee meeting, the Committee members shall be provided clinical information for new drugs and the therapeutic class reviews to be discussed at the next meeting. The clinical information is provided by the AHCCCS supplemental rebate vendor, MagellanRx/Prime Therapeutics, at: https://www1.magellanrx.com/preferred-drug-list-programs/manufacturer-hub/single-state-programs/

10. A secure username and password may be required to access the clinical materials.

11. On or about seven days prior to the Committee meeting AHCCCS shall:
    a. Post the meeting agenda to the AHCCCS website, and
    b. Provide the following to Committee member:
       i. The agenda,
       ii. Meeting minutes from the prior P&T meeting,
       iii. Approved written public testimony, and
       iv. Other materials as appropriate.

12. If a Committee member is unable to attend a meeting, the member is required to send an email notification of the absence as soon as possible prior to the meeting to: AHCCCSPharmacyDept@azahcccs.gov.

13. 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 amend the minutes, if necessary, and approve the minutes at the beginning of each meeting. Approved Committee meeting minutes will be posted on the AHCCCS website.

    The AHCCCS supplemental rebate vendor's clinical pharmacist and staff shall present clinical and financial information to Committee members. Clinical information shall be presented during the public virtual meeting and any financial information shall be presented in the Executive Session.

14. Individuals specified in Sections F and G are prohibited from contacting Committee members to discuss individual drugs or therapeutic classes that may be reviewed or are scheduled to be reviewed at the AHCCCS P&T Committee meetings. However, those individuals are permitted to register to give oral or written public testimony as specified in Sections F and G.
    a. Pharmaceutical manufacturers whose representative(s) or other related entities that contact AHCCCS P&T Committee members to discuss individual drugs or therapeutic classes that may be reviewed at the AHCCCS P&T meeting shall be prohibited from giving public testimony for two years. Individuals described in Section F that contact AHCCCS P&T Committee members to discuss individual drugs or therapeutic classes that may be reviewed at the AHCCCS P&T meeting shall be prohibited from giving public testimony for 2 years.

15. Approximately 30 days after the AHCCCS P&T meeting date, the following documents shall be posted on the AHCCCS website:
    a. The P&T presentation slides,
    b. The P&T recommendation slides,
    c. Prior P&T approved meeting minutes,
    d. Accepted written public testimony,
    e. Preferred Drugs National Drug Code file, and
    f. Contractor P&T Meeting Summary Memo.

D. SUBCOMMITTEES

1. The AHCCCS Committee Chairperson may designate and appoint 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 Conflicts 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 bestserved 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 11 of the 20 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 at the meeting. A member shall attend the meeting virtually. Any Committee actions, including those proposed by the Committee Chairperson, shall require a second. Voting on all motions shall be conducted electronically 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 for a vote to the Committee. Committee members who are AHCCCS employees 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 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 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 present virtually to vote on each matter submitted for a vote to the members.

F. PUBLIC TESTIMONY PROVIDED TO THE COMMITTEE BY INDIVIDUALS WHO ARE NOT SPECIFIED IN SECTION III. G.

1. Individuals who are not Committee members and who are not specified in Section III., G are permitted to present testimony to the Committee as public representatives as set forth below. To present testimony, the public representative shall not be directly or indirectly employed by, contracted with, or speaking on behalf of pharmaceutical manufacturers, PBMs, advocacy organizations/foundations, lobbyists, or subcontractors of these entities. The public representative may provide comments orally at the meeting to Committee members or through written testimony as outlined in this policy.

2. For individual health care providers who receive payments or compensation from manufacturers that are listed for the most recent available year in the CMS Open Payments database:
   a. Oral testimony is permitted if the most recent payments or compensation received by the provider on the CMS Open Payments database is equal to or less than the US Mean or the Specialty Mean for the provider,
   b. Written testimony may only be provided when the most recent payments or compensation received by the provider is greater than the US Mean or the Specialty Mean but less than two times the US Mean or the Specialty Mean whichever is greater, on the CMS Open Payments database, and
   c. Testimony will not be permitted for any individual health care provider, who received payments or compensation in excess of two times the US Mean or Specialty Mean, whichever is greater, as noted in the CMS Open Payments database.

3. Oral Testimony - Representatives of the public may present oral testimony virtually as set below:
   a. Oral testimony shall be presented virtually at all Committee meetings,
   b. The public representative shall complete and submit the Public Testimony Registration and the Conflict-of-Interest Forms no later than 15 business days prior to the meeting. The forms are available at the MagellanRx/Prime Therapeutics website:
   c. https://www1.magellanrx.com/preferred-drug-list-programs/manufacturer-hub/single-state-programs/ Registration is available on a first-come, first-serve basis and shall be limited to no more than 20 total presenters per Committee meeting. At the discretion of the Committee Chairperson, the total number of public representatives 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 public representative per organization, per drug, even when the organization has multiple sites,
   e. The Committee Chairperson or designee will recognize public representatives in alphabetical order of the drugs listed in the therapeutic classes being reviewed,
   f. Public representatives are limited to comments that do not exceed three minutes in length per drug,
   g. Questions or comments from the Committee for the Representative will be entertained by the Committee Chairperson and are not subject to the three-minute limit, and

h. 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.

4. Written testimony - Public representatives may present written testimony as setforth below:
   a. The public representative requesting to provide written testimony shall complete and submit the Public Testimony Registration and the Conflict-of-Interest Forms and written testimony no later than 15 business days prior to the meeting. The forms are available at the MagellanRx/Prime Therapeutics website: https://www1.magellanrx.com/preferred-drug-list-programs/manufacturer-hub/single-state-programs/
   b. Written testimony is limited to one individual per organization on each agenda item and shall not exceed two pages, single spaced and a font size not less than 12 font.

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

1. Representatives are individuals who are directly or indirectly employed by, or contracted with, or speaking on behalf of pharmaceutical manufacturers, PBMs, advocacy organizations/foundations, lobbyists for these entities, or subcontractors of these entities. The representative may provide comments orally at the meeting to Committee members or through written testimony as outlined in this policy.

2. Public testimony requests from or on behalf of advocacy organizations, foundations or other similar groups, shall be limited to written testimony. At the discretion of AHCCCS, the advocacy organization or foundation or similar groups, may be required to submit the amount of grants, funding, or other support that has been received from pharmaceutical manufacturers or entities related to pharmaceutical manufacturers. Public testimony shall not be permitted if the requests for the grants, funding, or other supportive funding is not submitted or the AHCCCS request is denied by the advocacy organization, foundation or similar groups.

3. Oral Testimony - Representatives may present oral testimony virtually as setforth below:
   a. Oral testimony shall be presented virtually at all Committee meetings,
   b. The representative shall complete and submit the Public Testimony Registration Form no later than 30 business days prior to the meeting. The forms are available at the MagellanRx/Prime Therapeutics website: https://www1.magellanrx.com/preferred-drug-list-programs/manufacturer-hub/single-state-programs/
      Registration is available on a first-come, first-serve basis and shall be no more than 20 total presenters per Committee meeting. At the discretion of the Committee Chairperson, the total number of representatives who are permitted to provide oral testimony may be adjusted based on the Committee meeting agenda and time constraints,
   c. The Committee Chairperson will recognize the representatives by therapeutic class under review at the Committee meeting,
   d. Testimony is limited to one representative per organization, per drug,
   e. Representatives are limited to oral comments that do not exceed three minutes per drug,

f. Questions or comments from the Committee for the Representative will be entertained by the Committee Chairperson and are not subject to the three-minute limit, and
g. 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.

4. Written Testimony - Representatives may present written testimony as setforth below:
   a. The representative shall complete and submit the Testimony Registration Form no later than 30 business days prior to the meeting. The forms are available at the MagellanRx/Prime Therapeutics website: https://www1.magellanrx.com/preferred-drug-list-programs/manufacturer-hub/single-state-programs/
   b. Written testimony will not be permitted for any health care provider, representing a pharmaceutical manufacturer, PBM or a related entity, who received payments or compensation in excess of two times the US Mean or Specialty Mean, whichever is greater, as reported for the most recent available year, on the CMS Open Payments Database (openpaymentsdata.cms.gov),
   c. 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,
   d. Written testimony is limited to drugs that are part of therapeutic drug classes or individual drugs specified in the meeting agenda, and
   e. Written testimony is restricted to new studies released since the last AHCCCS P&T 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). 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, or
      vi. Product monographs and dossiers,
      vii. The 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, devices or other products scheduled for review at Committee meetings, upon request from AHCCCS.

2. Manufacturers responding to the request shall submit their offer on the *Offer Form* located on the AHCCCS supplemental rebate vendor's website and within the requested timeframe as noted in the AHCCCS P&T manufacturer letter provided by the supplemental rebate vendor.

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,
   c. AHCCCS P&T Committee Operational Policy,
   d. Public Testimony Registration Form, and
   e. Conflict-of-Interest Form.

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.

1. Such contract(s) include, but are not limited to:
   a. Engagements of independent legal,
   b. Actuarial,
   c. Clinical,
   d. Research, and/or
   e. Other consultants.