

ASES' Pharmacy Financial Committee

Policies and Procedures

**Puerto Rico Health Insurance Administration
September 24, 2020**

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1. Purpose

- 1.1. The ASES' Pharmacy Financial Committee (PFC) is authorized by the Puerto Rico Health Insurance Administration (known in Spanish as *Administración de Seguros de Salud* or ASES) and its Board of Directors to make formulary recommendations and include in the Formulary of Medications Covered(FMC) or List of Medication by Exception (LME) selections based on the Drug Review and Recommendations of the Pharmacy and Therapeutics (P&T) Committee to include or exclude drugs.
 - 1.1.1 Vote to select drugs for inclusion on the FMC based on the clinical recommendations from VITAL's P&T Committee. Before the meetings, PFC members must read P&T meeting minutes to become familiar with the clinical discussion of the topics to be covered.
- 1.2. The primary purpose of the Committee is to recommend which drugs are to be included on the FMC/LME. Specifically, the addition of medications that significantly impact pharmaceutical and/or premium costs may require the approval of the PRHIA Board of Directors.
- 1.3. The ASES' PFC will also review the FMC and LME from time to time and evaluate additional recommendations on potential cost-saving pharmacy initiatives, including the evaluation of the utilization of high-cost specialty medications and orphan drugs and the exceptions process through which such drugs are approved, under the direction and approval of ASES.
- 1.4. Selections must be based on cost-effectiveness evaluation of drug therapies.
- 1.5. At the request of either party, the Committee will evaluate any new treatment, including but not limited to new: technology, medical or surgical procedure, physical or behavioral therapy, drugs, Part B drugs and orphan drugs (collectively, "New Treatment"), that are medically necessary and are not expressly excluded from the Government Health Plan Program (GHP).

2. Responsibilities

- 2.1. The Pharmacy Program Administrator (PPA) is responsible for managing the logistics of the ASES' Pharmacy Financial Committee (PFC) with support and approval from ASES. These include, but are not limited to:
 - 2.1.1. Present to the PFC all recommendations made by the P&T Committee that require further decisions by the PFC.
 - 2.1.2. Presentations shall include manufacturer rebate opportunities to help in the decision process of selecting cost effective alternatives for inclusion on PDL.
 - 2.1.3. Developing and distributing the invitation and agenda for meetings.
 - 2.1.4. Reserving meeting rooms and/or providing numbers for virtual meetings.
 - 2.1.5. Keeping the meeting attendance list and keeping a registry of the Letters of Understanding and Confidentiality Agreements.
 - 2.1.6. Preparation, taking and disseminating meeting minutes, following every PFC

meeting. The minutes of the meetings shall be sent to PFC members no later than eighteen (18) business days after the meeting date. The meeting minutes shall include a record of all votes taken at the meeting.

- 2.1.7. Following-up on agreed upon action items and pending issues.
- 2.1.8. Maintaining copy of all the documentation listed above for ten (10) years from the date of issue.

2.2 The Pharmacy Benefits Administrator (PBM) is responsible for:

- 2.2.1. Providing the Summary of the Recommendations that were made by the P&T Committee meeting prior the FC meeting.

2.3 ASES' Pharmacy Financial Committee members are responsible for:

- 2.3.1 Participating in meetings and actively discussing the issues presented. Attendance is mandatory.
- 2.3.2 Evaluate Therapeutic Classes or drugs with manufacturer rebate and discount proposals in order to make decisions for inclusion/exclusion of products in the PDL, after the P&T Committee has made a favorable recommendation for inclusion.
- 2.3.3 Decide and select drugs for inclusion on the PDL based on the clinical recommendations from VITAL's P&T Committee.
- 2.3.4 When requested, presenting results of specific analysis, providing feedback on strategies/initiatives being implemented, and sharing recommendations for pharmacy benefit management continued improvement.
- 2.3.5 Providing feedback on draft normative letters, policies and other documents that will be disseminated with provider networks, beneficiaries, the media, and/or other audiences regarding FMCs.
- 2.3.6 In coordination with ASES, developing educational programs, informational, outreach and other interventions based on approved initiatives and support its implementation with providers and/or patients accordingly.
- 2.3.7 Maintain confidentiality of information that is protected by law as confidential, including, but not limited to, any financial, cost, or market analyses that may be presented to the Committee and information disclosed by manufacturers or wholesalers in a form that discloses the identity of a specific manufacturer or prices charged for drugs by such manufacturer.

3 Committee Composition and Membership

3.3 Members of the ASES' Pharmacy Financial Committee are appointed by ASES. Representatives from Managed Care Organizations (MCO) shall be appointed by each MCO. Representatives of pharmaceutical companies are not allowed. Members should not have worked for any pharmaceutical company during the last three (3) years prior to his/her nomination for this position.

3.4 Membership will be as follows:

- 3.4.1 Three (3) representatives from each Managed Care Organization (MCO) with one vote for each MCO

- 3.4.2 At least three (3) representatives from the PPA (voice right, no vote rights)
 - 3.4.3 Two (2) representatives from the PBM (voice right, no vote right)
 - 3.4.4 Three (3) representatives from ASES Pharmacy Department with one vote in case of tie on decision.
 - 3.4.5 Two (2) Medical representatives from the IPAs with one vote.
 - 3.4.6 The P&T Committee Chairperson (voice right, no vote right)
- 3.5 PFC Members from the MCOs include:
- 3.5.1 The Medical Directors which are allowed to send another physician from the health plan with decision-making authority.
 - 3.5.2 A senior level staff with pharmacy and/or clinical expertise relevant for the PFC.
 - 3.3.3 A Financial expertise person
- 3.6 Guests:
- 3.5.1 Guests consist of other participants previously approved by the PFC or by ASES whose attendance is necessary to discuss a particular issue or topic. Their participation in the meeting will be limited to the time allotted for the specific topic or issue needed to be addressed.
 - 3.5.2 Guests are required to sign the Letter of Understanding and Confidentiality Agreement which includes confidentiality and conflict of interest statements.
- 3.7 Representatives and Guests will be appointed by each organization and notified in writing to ASES' Executive Director with copy to ASES' Director of Pharmacy.
- 3.8 Each organization will be responsible for their representative's attendance to meetings and performance of their duties and responsibilities as members of the PFC.
- 3.9 To ensure consistency, maximize time spent in the discussions, and achieve the best integration of clinical and administrative / operational procedures it is strongly recommended by ASES that the same representative participate in all the meetings.
- 3.10 To ensure the Committee will operate in a manner that protects the impartiality and credibility of its recommendations, each Committee member will be required to sign a Letter of Understanding and Confidentiality Agreement (Appendix 1), which also include a conflict of interest statement. Unless cause for termination or change of representative arises, the Letter of Understanding and Confidentiality Agreement will remain in effect for one (1) calendar year starting from the date of signature. New members will be required to sign the Letter of Understanding and Confidentiality Agreement.
- 3.11 If a PFC member cannot attend to a meeting, a designee or representative should be appointed by the participating entity. In order to be able to attend the PFC meetings, then he/she will be required to sign the Letter of Understanding and Confidentiality Agreement.

4 Meetings

4.3 Frequency and Place of Meetings

- 4.3.1 PFC's meetings, including conference calls and virtual meetings, will be held every two months and may meet at other times at the discretion of ASES and when requested by the Committee members.
- 4.3.2 Unless otherwise scheduled in advance by ASES, the date of the next meeting of the Committee will be scheduled by the end of the last scheduled meeting.
- 4.3.3 APFC's members are responsible to submit any item that should be included in the agenda at least three (3) to five (5) days in advance of each meeting. ASES will decide whether or not to include. PPA will follow up with PFC's members three (3) to five (5) days in advance of each meeting to remind them about the scheduled session and the agenda. This notification could be done by phone or email and always confirmed by email to the members of the Committee.
- 4.3.4 Meetings will be:
 - 4.3.4.1 Scheduled based on the availability of all ratified members and/or the entity's designee representative.
 - 4.3.4.2 Held at an accessible location that will be announced by ASES to all PFC members at least three days prior to each meeting. A telephone number and a pin number and/or access code will be provided as well for conference call meetings.
- 4.3.5 Meeting Attendance
 - 4.3.5.1 PFC members are expected to attend all committee meetings or assign a designee representative with decision-making authority. Representatives will be bound by all applicable duties and responsibilities of regular members.
 - 4.3.5.2 Meeting sessions can be virtual meetings, as needed.
 - 4.3.5.3 The invitation and agenda of all PFC meetings will be prepared and distributed by PPA.
- 4.3.6 Quorum
 - 4.3.6.1 There must be a quorum of the PFC Committee present for the Committee to conduct business. If less than a quorum of the PFC is present, there shall be no meeting.
 - 4.3.6.2 Quorum is reached when simple majority of voting members are present for the meeting.
 - 4.3.6.3 If quorum is not reached within thirty (30) minutes of the scheduled meeting time, the meeting will be cancelled. All attendees will be excused and they will propose a new meeting date. ASES will send by

email the invitation to this new meeting including the date, time and location where it will be held.

5 Authority of the Committee

- 5.3 ASES' Executive Director or its representative, MCOs and IPAs are the only voting members. ASES' Executive Director or its representative will participate in the voting process only as a tiebreaker.
- 5.3.1 The remaining PFC members and guests are encouraged to express their opinions and expertise during the PFC meetings, but are not allowed to vote.
- 5.3.2 If there is a quorum, a majority vote of the voting members present shall be the act of the PFC. ASES will have the authority to validate this decision.
- 5.4 If a matter poses a substantial conflict of interest to a member, the member shall recuse himself or herself and shall not participate in the voting process regarding such matter.
- 5.5 Members are encouraged and expected to share their opinions, evidence, and insight openly.
- 5.4 Whenever there is disagreement, clear and transparent debate is welcomed to understand the reasoning behind each position or point.
- 5.5 Members are also welcomed to provide feedback on the meeting minutes sent by the PPA.

6 Appendix 1

6.1 Letter of Understanding and Confidentiality Agreement

ASES' PHARMACY FINANCIAL COMMITTEE (PFC)

LETTER OF UNDERSTANDING AND CONFIDENTIALITY AGREEMENT

This Letter of Understanding and Confidentiality Agreement (“the Letter”) is to confirm our mutual understanding with respect to the terms and conditions under which _____ (hereinafter referred as “Member”), of legal age, , resident of _____, Puerto Rico, who serves as the _____ of _____, agrees to serve in ASES’ Pharmacy Financial Committee (hereinafter referred as “PFC”).

It is understood and agreed that as Member you will, among other things, provide the ASES’ PFC with the benefit of your knowledge and experience relevant for the development, implementation, and evaluation of pharmacy strategies to improve the cost-effective, access, and efficiency of this service provided by VITAL and managed by the Puerto Rico Health Insurance Administration (herein referred by its Spanish acronym “ASES”). In addition, you will provide advice and recommend changes that will improve the outcomes of VITAL patients needing and/or taking prescription drugs and other related treatments and technologies.

Member agrees to be part of ASES’ PFC with all the rights and obligations as set forth in this Letter.

Member shall participate in all meetings and/or activities of ASES’ PFC. If Member cannot attend to a scheduled meeting, he/she will inform ASES and should appoint a substitute to that meeting.

It is expressly understood by the Member that he/she shall not be an employee or provide professional services on a regular basis nor possess shares or stocks of any pharmaceutical corporation during his/her tenure under ASES’ PFC.

Any violation from a Member to the covenants stated in this Letter shall constitute a material breach of the obligations under this Agreement and would constitute cause for its removal of the Committee.

As a Member, you agree to hold and maintain confidential, and shall exercise all reasonable care to prevent the disclosure of confidential information received from ASES, the PBM and PPA hereunder; shall not provide it to any independent third party, and shall not use it for any purpose other than that indicated in this Letter or in the Standard Operating Procedures’ Manual.

“Confidential Information” shall include, but not be limited to, ASES, the PBM and PPA’s know-how, business development data, business activities, specifications and all other intellectual property, including any information disclosed by other Members and Guests from ASES’ PFC, provided, however, that the foregoing obligations of non-use and non-disclosure shall not apply to any such confidential information which:

(i) is known to the Member before receipt thereof under this Letter (except information previously disclosed to the Member by ASES, the PBM or PPA, or information gained by the Member as a result of prior services performed by the Member for ASES, the PBM or PPA, under an ongoing obligation of confidentiality), or is independently developed by or for the Member without benefit of ASES, the PBM or PPA's confidential information, as evidenced by the Member's written records;

(ii) is disclosed to the Member without restriction after the effective date of this Letter by a third party having a legal right to make such disclosure;

(iii) is or becomes part of the public domain through no breach of this Letter by the Member;
or

(iv) is required by law, court, order, a judicial or administrative agency of competent jurisdiction to be disclosed, after maximum practicable notice by the Member to ASES provided that in each case the Member shall use its best efforts to limit such disclosure and maintain the confidentiality of such confidential information to the extent possible.

All drawings, papers and records of any kind relating to the business of ASES, the PBM or PPA in the possession of the Member, are and shall be the property of ASES. The Member will return the information in its possession to ASES at any time upon request by them.

ASES will not use any statement, contribution, or opinion of the Member in favor or against future contractual relationships or negotiations between ASES and the represented entity, related or not to the GHP. Additionally, ASES will maintain the confidentiality of any statement, contribution, or opinion expressed by the Member during Committee meetings.

Either party reserves the right to cancel this agreement at any time for any reason or no reason.

If the foregoing terms and conditions meet your understanding and approval, please show your acceptance and agreement by executing this Letter in duplicate in the space provided below and returning one executed duplicate to ASES, whereupon this Letter shall constitute the agreement between you and ASES with respect to the services as a committee member.

Puerto Rico Health Insurance
Administration (ASES)

Accepted and Agreed:

Signature

Signature

Name: _____

Name: _____

Title: _____

Title: _____

Date: _____

Date: _____ Phone: _____