Policies and Procedures
PRHIA Pharmacy and Therapeutics Committee

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Aprobado por Lcdo. Jorge Galva, Director Ejecutivo

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2 Purpose

2.1 Outline the composition and responsibilities of the Pharmacy and Therapeutics Committee (P&T Committee) members of the Puerto Rico Health Insurance Administration (PRHIA; known as ASES for its Spanish acronym).
2.2 To outline the process for the P&T Committee meetings based on current best practice philosophies.

3 Scope

3.1 These policies and procedures apply to the Puerto Rico Health Insurance Administration (PRHIA) P&T Committee.

4 Definitions

4.1 **ASES** - Spanish acronym for Puerto Rico Health Insurance Administration ("Administración de Seguros de Salud"). *See Puerto Rico Health Insurance Administration below).*
4.2 **ASSMCA** - Spanish acronym for Mental Health and Addiction Services Administration ("Administración de Servicios de Salud Mental y Contra la Adicción").
4.3 **Executive Session** - A closed meeting in which extremely confidential and/or sensitive matters are discussed. Participation is limited to the Chairperson, Independent Members, designated PRHIA representatives and responsible PBM staff.
4.4 **Formulary of Medications Covered (FMC, for its acronym)** – A continually updated list of medications supported by current evidence based medicine covered by the Government Health Insurance Plan (GHIP). Drugs are categorized by therapeutic class, and by preferred and non-preferred status. Preferred status is reserved for the lowest net cost alternatives within the class and the Non-preferred status is for the highest net cost alternatives.
4.5 **Government Health Insurance Plan (GHIP)** - Health insurance for the medically-indigent (Medicaid) population, public employees and retirees of the civil service system of the Commonwealth of Puerto Rico.
4.6 **List of Medications by Exception (LME, for its acronym)** - List of medications that are not included in the FMC as covered by the GHIP, but that

have been evaluated and recommended by the PRHIA P&T Committee to be covered only through the exceptions process established in the *PRHIA Policy for Medication Exception Requests* if certain clinical criteria are met.

4.7 Majority Vote - The decision of greater than fifty percent of the Independent Members present for a vote.

4.8 Managed Care Organization (MCO) - Organization contracted by the Government of Puerto Rico to underwrite and administer the health care services for the GHIP.

4.9 Pharmacy and Therapeutics (P&T) Committee - A multidisciplinary, multispecialty group whose primary responsibility is to evaluate medications after Food and Drug Administration (FDA) approval and make recommendations to PRHIA for inclusion or exclusion in the Formulary of Medications Covered (FMC) or the List of Medications by Exception (LME) to be covered by the GHIP.

4.10 Pharmacy Benefits Manager (PBM) - An organization that manages pharmaceutical benefits for managed care organizations, other medical providers, or employers. PBMs contract with clients interested in optimizing the clinical and economic performance of their pharmacy benefit. PBM activities may include benefit plan design, creation/administration of retail and mail service pharmacy networks, claims processing and managed prescription drug care services such as drug utilization review, formulary management, generic dispensing, prior authorization and disease and health management.

4.11 Pharmacy Program Administrator (PPA) - An organization that negotiates rebate contracts for PRHIA, invoices rebates to Pharmaceutical Companies, makes rebate collection efforts on behalf of PRHIA, and supports the FMC and LME formularies management updating and maintenance processes. PPA also provides periodic drug cost and data utilization analysis to make changes to drug formularies and presentations to assure cost-effectiveness, among other responsibilities.

4.12 Puerto Rico Health Insurance Administration (PRHIA; ASES by its Spanish acronym) - Public corporation in charge of implementing, administering and negotiating through contracts with health insurance companies, the health insurance for the medically-indigent, public employees and retirees of the civil service system of the Commonwealth of Puerto Rico. This insurance is known as the Government Health Insurance Plan (GHIP). Exercising its express and implied powers granted by its charter, this public corporation created the P&T Committee to obtain professional and objective counseling regarding pharmaceutical products to be included in the drug formulary; as such term is defined herein.

5 Policy

5.1 Outline standards and provisions relevant to the PRHIA Pharmacy and Therapeutics (P&T) Committee to ensure that drug formularies are supported by

current evidence based medicine that will promote clinically appropriate, safe and cost-effective drug therapy.

5.2 Establish the composition, qualifications and credentials of the P&T Committee members.

5.3 Outline responsibilities and obligations of the P&T Committee members, conflict of interest and confidentiality provisions.

5.4 Establish formulary management policies on the use and review of drug products and therapies in light of new drugs and new indications, uses, or warnings affecting existing drugs and the process to follow to give access to non-formulary drugs.

6 Pharmacy and Therapeutics Committee Purpose and Functions

6.1 The Pharmacy and Therapeutics (P&T) Committee is a multidisciplinary, multispecialty group with the purpose to serve in an advisory capacity in order to assist the PRHIA in the selection of drugs to be included on the Formulary of Medications Covered (FMC) and the List of Medications by Exception (LME) .

6.2 The Committee will ensure that the FMC and LME are based on clinical evidence that is both safe and cost-effective and indications approved by the Food and Drug Administration (FDA).

7 Pharmacy and Therapeutics Committee Structure

7.1 Pharmacy and Therapeutics (P&T) Committee

7.1.1 The P&T Committee shall be composed of a Chairperson, Independent members, Ad hoc or non-permanent members and Advisory Panel, as defined in this policy.

7.1.2 Chairperson

7.1.2.1 The Chairperson of the P&T Committee is appointed by the PRHIA Executive Director. The Chairperson may, but not necessarily, be appointed from within the P&T Committee Independent members.

7.1.2.1.1 If the appointed Chairperson is an independent member of the P&T Committee, he/she may act as Chairperson for a maximum of two (2) terms of two (2) years each.

7.1.2.1.2 If the appointed Chairperson is not a P&T Committee independent member, the PRHIA will establish the terms of his/her tenure.

7.1.2.2 The Chairperson shall provide leadership for the Committee at the Committee meetings.

7.1.2.3 The Chairperson is responsible of conducting P&T Committee meetings. The P&T Chairperson presides over the meeting to ensure that participants are following the conventions of the meeting, that there is full participation during meetings, and that all relevant matters are discussed and acted upon.

7.1.2.4 Considers the views and opinions of all members of the Committee and tries to maintain an atmosphere at meetings that encourages members to express their views.

7.1.2.5 The Chairperson shall determine whether there is quorum.

7.1.2.6 The Chairperson provides the PRHIA Executive Director with a P&T Committee Summary Report containing information on the P&T Committee recommendations and activities. Such report, along with meeting minutes, must be submitted to the Executive Director within thirty (30) working days after the P&T Committee meeting has taken place.

7.1.2.7 The Chairperson will participate in the voting process only as a tiebreaker (refer to section 8.6.1).

7.1.2.8 The Chairperson will be required to sign a Letter of Understanding, which includes confidentiality and conflict of interest attestation statements (Appendix I, page 30). The Letter of Understanding will remain in effect for one (1) year.

7.1.3 Independent Members

7.1.3.1 The independent members group will include practicing pharmacists and physicians.

7.1.3.2 Core medical specialties are established based on practice standards and drug utilization patterns among GHIP beneficiaries.

7.1.3.3 One independent member from each of the following core medical areas will be appointed:

7.1.3.3.1 Geriatric Medicine
7.1.3.3.2 Family Practice
7.1.3.3.3 Internal Medicine
7.1.3.3.4 Pediatrics
7.1.3.3.5 Obstetrics and Gynecology
7.1.3.3.6 Psychiatry
7.1.3.3.7 Child and Adolescent Psychiatry
7.1.3.3.8 Pharmacist
7.1.3.3.9 Board Certified Geriatric Pharmacist

7.1.3.4 Candidates for independent membership will be requested from each participating MCO, from the PBM, and from the PRHIA.

7.1.3.5 The PRHIA reserves the right to establish other medical specialties to be represented in the P&T Committee to respond to a particular need as identified by the PRHIA and/or in response to the healthcare system evolution. Furthermore, the PRHIA can appoint an independent member, provided the candidate complies with all credentials and qualifications established herein.

7.1.3.6 Independent members and the Chairperson are the only voting members of the P&T Committee (see section 8.6.1).

7.1.3.7 Qualifications, Evaluation and Appointment

7.1.3.7.1 Independent members:

7.1.3.7.1.1 Cannot be employees, officers, directors or agents of, and may not have a financial interest in an MCO, PBM, PPA, pharmaceutical manufacturer or distributor, or governmental agencies, excluding public state universities and academic institutions.

7.1.3.7.1.2 Must be duly certified by the pertinent licensure board of the Government of Puerto Rico.

7.1.3.7.1.3 Physicians who are Independent members must be serving GHIP population.

7.1.3.7.1.4 The members will be chosen by specialty, board certification, prior P&T experience, experience treating GHIP recipients, absence of conflicts of interest and number of years in practice.

7.1.3.7.2 Candidates must meet other qualification criteria as established in this policy (Appendix IV in page 41 and V, page 33*)*.

7.1.3.7.3 The PBM will review each candidate's curriculum vitae based on the selection criteria established by PRHIA and will submit the qualified potential candidate(s) to the PRHIA with its recommendation for appointment.

7.1.3.7.4 A PRHIA representative will review the candidate's curriculum vitae and the PBM recommendation and will determine if a final recommendation for appointment is in order. If so, the recommendation for selection and appointment will be submitted to the PRHIA Executive Director for consideration. All independent member appointments require the approval of the Executive Director.

7.1.3.7.5 Each Independent member is appointed for a two (2) year term. The appointment may be extended for additional successive terms provided PRHIA's approval.

7.1.3.8 Reasons for Termination

7.1.3.8.1 Independent members may be removed from the Committee if there is evidence of breach of any of the terms and conditions stated in the Letter of Understanding, such as the presence of a conflict of interest, or poor meeting attendance, defined as two (2) consecutive absences from scheduled meetings, with or without reasonable cause.

7.1.3.9 Documentation and Credentials

7.1.3.9.1 All Independent members will be required to sign a Letter of Understanding, which includes confidentiality and conflict of interest attestation statements (Appendix I, page 30). The Letter of Understanding will remain in effect for one (1) year.

7.1.3.9.2 Licenses and certifications must be verified upon initial appointment and thereafter at least every three (3) years.

7.1.4 Ad Hoc Members (Non-Permanent)

7.1.4.1 Ad hoc or non-permanent members are healthcare professionals and physicians specialized in medical areas other than those represented by the independent members.

7.1.4.2 An Ad hoc member cannot act simultaneously as a Permanent Independent Member.

7.1.4.3 Ad hoc medical specialties or consultants may be invited to attend a P&T Committee meeting to provide subject matter expertise whenever there is a particular therapy or drug class for which the P&T Committee members, the PBM or PRHIA consider critical the input of a certain medical specialty area.

7.1.4.4 Ad hoc members serve in a consultant capacity in order to assist the PRHIA in the development of clinical protocols and may also make recommendations regarding the prior authorization criteria of any prescribed drug.

7.1.4.5 Ad hoc members are not voting members of the Committee.

7.1.4.6 Candidates for Ad hoc membership will be requested from each participating MCO, PPA, PBM and PRHIA.

7.1.4.6.1 Ad hoc members may not be employees, officers, directors, or agents of, and may not have a financial interest in a MCO, PBM, PPA, pharmaceutical manufacturer or distributor, or governmental agencies, excluding public state universities and academic institutions.

7.1.4.7 Candidates Qualifications, Evaluation and Appointment

7.1.4.7.1 Ad hoc members will be chosen by expertise in a particular medical specialty, board certifications, experience and absence of conflicts of interest.

7.1.4.7.2 Physicians who are Ad hoc members must be serving GHIP beneficiaries.

7.1.4.7.3 Candidates must meet other qualification criteria as established in this policy (Appendix VI, page 434).

7.1.4.7.4 The PBM will review each candidate's curriculum vitae based on the selection criteria established by PRHIA and will submit the qualified potential candidate(s) to the PRHIA with its recommendation for appointment.

7.1.4.7.5 A representative from PRHIA will review the candidate's curriculum vitae and the PBM recommendation and will determine if a final recommendation for appointment is in order. If so, the recommendation for selection and appointment will be submitted to the PRHIA Executive director for consideration. All Ad hoc member appointments require the approval of the Executive Director.

7.1.4.7.6 Ad hoc members will serve as such for as long as necessary, unless cause for termination arises, as stated in the Letter of Understanding.

7.1.4.8 Reasons for Termination

7.1.4.8.1 Ad hoc members may be removed from the P&T Committee if there is evidence of breach of any of the terms and conditions stated in the Letter of

Understanding, such as conflict of interest or confidentiality items.

7.1.4.9 Documentation and Credentials

7.1.4.9.1 All Ad hoc members will be required to sign a Letter of Understanding, which includes confidentiality and conflict of interest statements. The Letter of Understanding will remain in effect for one (1) year.

7.1.5 Advisory Panel Members

7.1.5.1 The Advisory Panel members are employees, officers, directors, or agents of, and may have a financial interest in an MCO, PBM, PPA or the Government of Puerto Rico. The Advisory Panel also includes representatives from ASSMCA and PRHIA.

7.1.5.2 Advisory Panel members, although not voting members of the P&T Committee may participate in the committee discussions.

7.1.5.3 Attendance of the Medical Directors of each MCO or a representative is mandatory.

7.1.5.4 The Advisory Panel members will attend P&T Committee meetings and review and comment on formulary management issues, but will not vote upon Committee decisions.

7.1.5.5 Advisory Panel Members advises the Independent Members on development and administration of drug formularies.

7.1.5.6 All Advisory Panel members will be required to sign a Confidentiality Agreement, which includes confidentiality and conflict of interest statements (Appendix II, page 34). The Confidentiality Agreement will remain in effect for one year.

7.1.6 Guests

7.1.6.1 Guests consist of other participants previously approved by the P&T Committee or by PRHIA 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.

7.1.6.2 Guests are required to sign a Non-Disclosure Agreement which includes confidentiality and conflict of interest statements (Appendix III, page 378).

7.1.7 Product sponsor representatives are excluded from P&T Committee membership and are not allowed to attend P&T Committee meetings.

7.2 Ad hoc (Special) Committees

7.2.1 Ad hoc or special committee(s) may be established by the P&T Committee and/or by PRHIA to attend a particular issue or objective.

7.2.2 The structure, functions and responsibilities of the ad hoc committees will be approved by PRHIA.

7.2.3 Recommendations for special committees' membership will be requested from each MCO, PBM, ASSMCA and the PRHIA.

7.2.3.1 Special Committee members may not be employees, officers, directors, or agents of, and may not have a financial interest in an MCO, PBM, PPA, pharmaceutical manufacturer or distributor, or governmental agencies, excluding public state universities and academic institutions.

7.2.4 The P&T Committee Chairperson, the PBM and a representative from PRHIA will review each candidate's curriculum vitae, based on selection criteria, and submit a final recommendation for appointment to the PRHIA Executive Director.

7.2.5 Appointments to such Ad Hoc Committees shall be subject to review and approval by PRHIA Executive Director.

7.2.6 An Ad hoc committee will operate for as long as the P&T Committee members and/or PRHIA deem necessary.

7.2.7 All Special Committee members will be required to sign a Letter of Understanding, which includes confidentiality and conflict of interest statements. Unless cause for termination arises, the Letter of Understanding signed by the Special Committee members will remain in effect for one (1) year.

8 Pharmacy and Therapeutics (P&T) Committee Meetings

8.1 Frequency of Meetings

8.1.1 Ordinary Meetings

8.1.1.1 P&T Committee ordinary meetings will be held at least on a quarterly basis.

8.1.2 Extraordinary Meetings

8.1.2.1 Whenever necessary but no more than once a month the P&T Committee's Chairperson and/or PRHIA may convene an extraordinary meeting.

8.1.2.2 Reasons to convene such a meeting include emergent issues, such as, but not limited to:

8.1.2.2.1 Significant new safety concerns that pose a risk to insured patients that may result in harm and requires an expedite review for additions of restrictions or removal from the formularies.

8.1.2.2.2 To address issues when it is determined by the PRHIA that waiting until the next scheduled meeting is suboptimal.

8.1.3 The P&T Committee reserves the right to move to an Executive Session at the request of any of its members and after a majority vote of the independent members has been obtained, thereby closing the Committee meeting to all individuals except for the Chairperson, Independent members, designated PRHIA representatives and PBM staff.

8.1.4 The PBM is responsible of the P&T Committee meetings coordination, including the development of the meeting agenda, in coordination with PRHIA, the presentation of therapeutic classes/drugs during the P&T Committee meeting, and the preparation and distribution of the meeting minutes as stipulated, among others.

8.1.4.1 The PBM will send the call to meeting notice at least fourteen (14) business days prior to the scheduled meeting date.

8.1.4.2 If an ad hoc member is to be invited to participate at a P&T Committee meeting, the call to meeting notice will be sent at least five (5) business days prior to the scheduled meeting date.

8.1.5 Ad hoc or Special Committee Meetings

8.1.5.1 Special Committee meetings will be held as deemed necessary to accomplish the designated task at hand (see section 7.2).

8.1.5.2 The PBM is responsible of the Special Committee meetings coordination, including the development of the meeting agenda, in coordination with PRHIA, the preparation of materials to be presented, and the preparation and distribution of meeting minutes.

8.2 Place of Meeting

8.2.1 Meetings will be held at a location to be announced at the end of each P&T Committee meeting. In case of unanticipated circumstances, changes in place of meeting should be notified to P&T members at least five (5) calendar days in advance of the scheduled meeting.

8.2.2 Ad hoc or extraordinary meetings, and executive session meetings can be held face to face, by telephone, conference service or other electronic means.

8.2.3 When unforeseen events do not allow all P&T Committee members to be gathered at once, P&T Committee members can be contacted through other available communication means at the time.

8.3 Meeting Attendance

8.3.1 Independent members are expected to attend all Committee meetings. Failure to attend two (2) consecutive scheduled meetings, with or without cause, is a reason for P&T membership termination.

8.3.1.1 Independent Members must notify the PBM, in writing or by telephone, of an excused absence at least three (3) business days prior to a scheduled meeting, unless the absence responds to an unforeseen, last-minute event.

8.3.1.2 Substitutions are not allowed.

8.3.2 Advisory Panel members are expected to attend all Committee meetings.

8.3.2.1 MCO's and PPA are allowed a maximum of two representatives per meeting.

8.3.2.2 One of the MCO representatives must be from the Pharmacy Department and the other must be its Medical Director or a representative.

8.4 Meeting Agenda & Materials

8.4.1 The meeting agenda (Appendix VII: Pharmacy and Therapeutics Committee Agenda, page 46) is prepared by the PBM, and submitted to PRHIA for approval.

8.4.1.1 The first items of the agenda are the quorum confirmation and conflict of interest disclosure.

8.4.1.2 The next item of the agenda is the distribution of the approved minutes of the previous meeting.

8.4.1.3 Other agenda items may vary based on the specific objectives of each meeting, but overall, will include the following:

8.4.1.3.1 Annual or biannual revision of therapeutic classes included in the FMC or LME

8.4.1.3.2 Evaluation of new drugs or new approved indications of existing drugs

8.4.1.3.3 Evaluation of new and existing prior authorization (PA) protocols and other drug utilization management edits

8.4.1.3.4 Pending business from previous P&T Committee meetings

8.4.1.3.5 Safety Issues Reports

8.4.1.3.6 Formulary Review Requests

8.4.2 The PBM staff is responsible of preparing/providing materials to support the topics to be evaluated by the P&T Committee.

8.4.3 The PBM will distribute the approved agenda, the approved minutes of the previous P&T Committee meeting, and the evaluation materials for the agenda items to all Independent and Advisory Panel members no later than five (5) business days prior to the scheduled meeting. Distribution is made via an FTP secure site or other secure electronic application.

8.4.3.1 If an ad hoc member will be invited to participate in a P&T Committee meeting, the PBM will provide him/her with evaluation materials pertinent to the topic on which they are being consulted no later than five (5) work days prior to the scheduled meeting. Minutes from previous P&T Committee meetings are not provided to ad hoc members.

8.4.4 It is expected of all members to adequately prepare themselves in advance of the meeting to allow for a thorough discussion and informed decision-making process of the agenda topics. Members shall review the agenda and study the supporting documents and materials distributed prior to the meeting.

8.4.5 The PBM will meet with the Chairperson prior to the P&T scheduled meeting to review the agenda topics and the specific evaluation objectives for each agenda item.

8.5 Quorum Requirements

8.5.1 There must be a quorum of the P&T Committee present in order for the Committee to conduct business. P&T Committee quorum is reached when more than half of the Independent members are present.

8.5.1.1 Quorum requirements apply to ordinary and extraordinary meetings.

8.5.1.2 If a special consultation meeting (see 8.2.3) is convened, quorum will be met when at least more than half of the independent members respond to the consult.

8.5.2 If quorum is not reached within thirty (30) minutes after the scheduled meeting time, the meeting will be cancelled. All attendees will be excused. The PBM, in coordination with PRHIA, will set a new meeting date. All efforts will be made to reschedule the meeting as soon as possible.

8.5.3 PBM staff will have five (5) business days to inform the new meeting date, time and place to Independent members, Advisory Panel, invited Ad hoc members, special committee members and guests.

8.5.4 If an ordinary or extraordinary meeting cannot be held as scheduled, the Chairperson will include in his/her report to the PRHIA the specific reason for this occurrence.

8.6 Right to Vote

8.6.1 P&T Committee Chairperson and Independent members are the only members who have the right to vote. The Chairperson will participate in the voting process only as a tiebreaker.

8.6.1.1 Ad hoc members, members of the Advisory Panel, and guests are encouraged to express their opinions and expertise during the P&T Committee meetings, but are not allowed to vote.

8.6.2 The voting process will be closed-off to individuals not officially recognized at the meeting.

8.6.3 The voice method will be used for voting unless a different method is requested and approved by a majority of the Independent members.

8.6.4 Each Independent member will have the right to cast one vote for each decision to be made by the P&T Committee.

8.6.5 Approval of recommendations will require a simple majority vote of the Independent members present at the moment.

8.6.6 Proxies are not allowed in the P&T Committee meetings.

8.7 P&T Committee Meeting Minutes

8.7.1 Every committee meeting and/or official activity shall be summarized into minutes using a standard established format (Appendix VIII: Pharmacy and Therapeutics Committee Minutes, page 467).

8.7.2 The PBM is responsible for preparing, editing the meeting's minutes, following every P&T Committee meeting.

8.7.3 P&T Committee Meeting Minutes Approval Process

8.7.3.1 Eighteen (18) business days after meeting - PBM sends the drafted minutes to all P&T Committee members. The drafted minutes may be sent by secure email, or may be placed in a shared FTP secure site or other secure electronic application.

8.7.3.2 P&T Committee members have five (5) business days to review the document and submit corrections, changes and suggestions to the PBM, or to approve the minutes as distributed. P&T members are responsible of reviewing the minutes to ensure the appropriateness and accuracy of the P&T Committee decisions.

8.7.3.3 The PBM has two (2) business days to review the document to incorporate corrections, modifications and changes submitted by the P&T members, if any.

8.7.3.3.1 If the PBM does not receive a response from the P&T Committee members, it will assume that they agree with the minutes as presented.

8.7.3.3.2 If the PBM receives a request for a significant change or an objection to any of the decisions as recollected on the minutes, the proposed change along with the revised minutes will be forwarded again to all Independent Members for review and commenting.

8.7.3.4 The PBM will send the revised document to the PRHIA within two (2) working days after receiving the changes suggested by P&T members.

8.7.3.5 PRHIA has five (5) working days to review the minutes and approve and forward the minutes to the PBM.

8.7.3.5.1 If the PBM does not receive a response from the PRHIA within said period, it will consider the minutes to be approved by the PRHIA and will proceed to distribution.

8.7.3.5.2 The minute's approval date is equal to the date on which PRHIA's response is due.

8.7.3.6 An electronic copy of the approved minutes will be sent by the PBM to the PRHIA Executive Director, MCO's, PPA and ASSMCA within three (3) working days after its approval date.

8.7.3.7 Approved minutes are distributed as part of the materials for the next Committee meeting.

8.7.3.8 Minutes of Extraordinary Meetings

8.7.3.8.1 The PBM will prepare and send the drafted minutes to all P&T Committee members who participate in such meeting within three (3) working days after the meeting has taken place. The drafted minutes may be sent by secure mail, or placed in a shared FTP secure site or other secure electronic application.

8.7.3.8.2 P&T Committee members will have two (2) working days to review the document and submit corrections, changes and suggestions to the PBM, or to express they are in agreement with the document as presented.

8.7.3.8.3 The PBM will work on the modifications and corrections presented, if any.

8.7.3.8.3.1 If the PBM does not receive a response from P&T members, it will

assume they agree with the minutes as presented.

8.7.3.8.3.2 If the PBM receives a request for a significant change to the minutes, the document will be forwarded again to P&T members for review and commenting.

8.7.3.8.4 An electronic copy of the approved minutes will be sent by the PBM to all advisory panel P&T members within the next two (2) working days.

8.7.3.8.5 The minute's approval date is equal to the date on which P&T Committee members' response is due.

8.8 P&T Committee Document Retention

8.8.1 The PBM and the PRHIA must keep all meeting materials in a secured area for a period of ten (10) years.

8.8.2 All meetings will be audio recorded. The recordings will be stored by the PBM in a secured area for a ten (10) years period.

9 Responsibilities

9.1 Pharmacy and Therapeutics (P&T)

9.1.1 Evaluates the clinical use of medications and develops guidelines for managing access to them to ensure safe drug use and administration.

9.1.2 Make recommendations to the PRHIA for the inclusion/exclusion of medications in the FMC and the LME to be covered by the GHIP of Puerto Rico using criteria established for efficacy, safety, and quality.

9.1.3 The P&T Committee use clinical effectiveness data that may integrate overall costs and offer comparisons among therapies to make recommendations.

9.1.4 Recommends to PRHIA and PBM the development of administrative and educational programs to promote the appropriate use of medications.

9.1.5 Recommends to the PRHIA utilization protocols for individual medications or for therapeutic categories to promote appropriate medication use based on current clinical guidelines. These protocols include, but are not limited to pre-authorization, step therapy, quantity limits, specialty limit, age limit, and other utilization management tools.

9.1.6 Review and approval of policies and procedures for the use of and access to non-formulary drug products when medically need is justified by physician.

9.2 Pharmacy Benefits Manager (PBM)

9.2.1 The PBM is responsible for all administrative support and coordination of the activities of the P&T Committee, as assigned by the PRHIA. The PBM will:

9.2.1.1 Assume reasonable costs and expenses of the P&T Committee, including stipends paid to Independent and Ad hoc members. Other non-voting members are not compensated.

9.2.1.2 Prepare a yearly schedule for regular meetings

9.2.1.3 Prepare agenda and supporting materials for each meeting. Medication monographs and previous meeting minutes to all Committee members five (5) working days prior to a scheduled meeting. Medication monographs will include, but are not limited to, Average Wholesale Price (AWP) cost and Maximum Allowable Cost (MAC) for reference purposes.

9.2.1.4 Maintain P&T committee meeting records

9.2.1.5 Arrange meetings and meeting sites for P&T Committee meetings.

9.2.1.6 Prepare and submit copies of the ratified P&T Committee meeting minutes to the PRHIA following every committee meeting, and maintain written and electronic records of such materials for ten (10) years from the date of issue.

9.2.1.7 Maintain tracking report of recommendations made, actions taken and issues raised by the Committee;

9.2.1.8 Update the processing and adjudication system according to the most recent PRHIA determinations on P&T Committee recommendations, as per instructions sent by the PPA. The PBM will have a maximum of seven (7) calendar days to make the changes after receiving the instructions.

9.2.1.9 Act as a liaison between members of the P&T and the PRHIA.

9.2.1.10 Assist in the selection and appointment of Independent, Ad hoc and Special Committee members.

9.2.1.11 Administer the Letters of Understanding, Confidentiality and Non-Disclosure Agreements and submit signed documents to the PRHIA for safekeeping.

9.2.1.12 Support the PRHIA in the credentialing process of Independent members at the contracting time and then at least every three (3) years.

9.2.1.13 Develop clinical protocols to be evaluated by the PRHIA, and to be discussed with the P&T Committee for their recommendation and approval. Those protocols should be reviewed and revised at least every two (2) years.

9.2.1.13.1 The PBM will maintain an updated list of all medication protocols available. This list, as well as the protocols, will be available to the PRHIA, and the MCOs at any moment.

9.2.1.13.2 Upon meeting minute's approval, the PBM will place PA clinical protocols referred to in the approved minutes in a predefined electronic location for access from the ASES web page and is responsible of performing ongoing maintenance to ensure current PA protocols are always available.

9.2.1.13.3 The PBM will notify the MCOs and PPAs when PA protocols are available on the web.

9.2.1.14 Monitor the market for adverse events, warnings and contraindications related to existing medications included in the FMC and the LME, to update PA and step therapy protocols, quantity limits and other related edits or formulary changes.

9.2.1.15 Perform the following activities with respect to pharmaceutical companies:

9.2.1.15.1 Coordinate internal clinical presentation meetings with pharmaceutical companies, if needed, for those products to be evaluated by the P&T Committee. Such meetings should be held at least one month prior to the scheduled P&T meeting to present and discuss clinical data available on the drug (see section 10.3.1, page 23).

9.2.1.15.2 Review materials submitted by pharmaceutical companies.

9.2.1.15.3 Send a notification letter to pharmaceutical companies acknowledging the receipt of requested information (Appendix IX: Submission of Requested Product Information, page 478).

9.2.1.16 Provide PRHIA a list identifying the companies' contact persons' name and telephone numbers for scheduling of meetings, requests for materials and any other required information or communications from PRHIA.

9.2.1.17 Coordinate and facilitate meetings to follow up on P&T recommendations, upon request.

9.3 Managed Care Organization (MCO)

9.3.1 Submit, when requested, beneficiaries data related to therapeutic classes or products to be evaluated by the P&T Committee.

9.3.2 Implement drug protocols as developed and approved by the P&T Committee.

9.3.3 Follow policies established by PRHIA for the management of medication exceptions requests from providers.

9.3.4 Implement the exception process established by PRHIA using the clinical protocols for those products included in the List of Medications by Exception (LME).

9.3.5 Distribute to network providers all communications prepared by PRHIA regarding the FMC and the LME.

9.3.6 When requested, provide to PRHIA the pre-authorization procedures and coverage determinations results.

9.3.7 Submit other required reports to the PRHIA, as needed.

9.3.8 Collaborate in the development and implementation of educational programs in cooperation with the PRHIA and the PBM, as needed.

9.4 Pharmacy Program Administrator (PPA)

9.4.1 Evaluate and make pharmaco-economic recommendations regarding medications requiring a Request for Proposal for rebates and discounts.

9.4.2 Help control the rising expenditures of covered medications by establishing cost containment methods (e.g. Pre-Authorization, Step Therapy, Specialty Limit, Age Limit, Gender Limit, among others) as applicable.

9.4.3 Collaborate in monitoring the market for adverse events, warnings and contraindications related to existing medications included in the FMC.

9.4.4 Provide to the PBM the pharmacy utilization data related to the products or therapeutic classes to be reviewed by the P&T Committee.

9.4.4.1 The request for utilization data will be submitted by the PBM at least eighteen (18) working days prior to the P&T Committee meeting, and the PPA must provide the requested information at least eight (8) working days prior to the meeting.

9.4.5 Identify needs and opportunities for formulary improvement based on existing P&T Committee recommendations and changes in the pharmaceutical market conditions.

9.4.6 Evaluate manufacturer rebate and discount proposals for medications included in the FMC by the P&T Committee.

9.4.7 Develop and maintain the FMC based on clinical recommendations from the P&T Committee and the total net cost of available therapies.

9.4.8 After pharmacoeconomic evaluations, and based on P&T Committee recommendations, prepare and send notifications of outcomes to pharmaceutical companies (Appendix XIII: Favorable LME Evaluation, Appendix XIV: Non-Favorable FMC Evaluation, Appendix XIV: Non-Favorable FMC Evaluation Notification Letter).

9.4.9 Update and maintain the FMC and the LME documents (in Excel format) based on PRHIA accepted recommendations and other P&T Committee recommendations, and submit them to the PBM and MCO's on a quarterly basis, or whenever necessary.

9.4.10 Refer to PRHIA all FMC and LME updates in an electronic format for publication in the PRHIA web page.

9.4.11 Publish FMC and LME in the PPA web page, as applicable.

9.4.12 Submit to the PBM the complete instructions to set up medications in the claims adjudication system (EXCEL format).

10 Formulary Management Policies

10.1 The P&T Committee will provide input for the development and maintenance of the FMC and LME of the GHIP taking into consideration the objective parameters of indications, effectiveness, safety, clinical guidelines and costs according to current clinical evidence available in the scientific literature.

10.2 The P&T Committee will provide input for the development and maintenance of the FMC and LME of the GHIP taking into consideration the objective parameters of indications, effectiveness, safety, clinical guidelines and costs according to current clinical evidence available in the scientific literature.

10.3 The recommendations of a medication for inclusion in the FMC and LME must be based on scientific evidence that takes into consideration pharmacoeconomic issues in order to achieve appropriate, safe and cost effective drug therapy in relation to other medications within the therapeutic class. Formulary management and medication evaluations shall be performed utilizing specific criteria, such as:

10.3.1 Therapeutic Use

10.3.1.1 Epidemiology/risk factors for disease

10.3.1.2 Pathophysiology

10.3.1.3 Clinical presentation

10.3.1.4 Approaches to treatment: principal options/practice patterns

10.3.1.5 Description of alternative treatment options (both drug and non-drug)

10.3.1.6 The place in treatment and the anticipated uses of the proposed therapy (i.e. first line, second line)

10.3.1.7 Expected outcomes of therapy

10.3.2 Product Description

10.3.2.1 Generic, brand name and therapeutic class of the product
10.3.2.2 Dosage forms
10.3.2.3 FDA approved and other studied indications
10.3.2.4 Pharmacology
10.3.2.5 Pharmacokinetics / Pharmacodynamics
10.3.2.6 Contraindications
10.3.2.7 Warnings / precautions
10.3.2.8 Adverse effects
10.3.2.9 Interactions
10.3.2.10 Dosing and administration
10.3.2.11 Access
10.3.2.12 Comparisons with pharmacokinetic/pharmacologic profile of other agents in the therapeutic area.
10.3.2.13 Supporting clinical and economic information
10.3.2.14 Product value and overall cost
10.3.2.15 PRHIA will determine priorities on products to be presented in the P&T meeting based on the agenda of the scheduled PBM and according to identified needs.

10.3.3 Therapeutic class reviews are subject to any of the following criteria or conditions:

10.3.3.1 Physician requests submitted to MCO, PBM or PRHIA
10.3.3.2 Requests submitted by MCO, PBM, PRHIA or PPA
10.3.3.3 Projected high utilization of a specific new medication
10.3.3.4 New medication (refer to section 10.3.5)
10.3.3.5 Recall or withdrawal of a medication from the market
10.3.3.6 Line extension products (refer to section 10.3.7)
10.3.3.7 Length of time that the product has been on the market (refer to sections 10.3.5 and 10.3.7).

10.3.4 Requests for changes to the FMC will be submitted using the Formulary Review Request Form (Appendix X: Formulary Review Request Form, page 489).

10.3.4.1 Upon receiving the Formulary Review Request Form, the PBM will send a confirmation letter to the requester (Appendix XI: Formulary Review Request, page 512).
10.3.4.2 Medication reviews: A medication will be recommended for inclusion in FMC or LME based upon the review of the entire therapeutic class. A physician's or MCO request for review of a medication will be coordinated with the next scheduled

review of the entire therapeutic class, if possible. Efforts will be made to allow for a prompt evaluation within P&T Committee schedule constraints.

10.3.5 The P&T Committee may review a new medication within twelve (12) months after its release into the Puerto Rico market, subject to the PRHIA P&T Committee's priorities. A different timeframe may apply for the review of new indications of products already included in the formulary. Earlier reviews will be scheduled at the discretion of the P&T Committee and PRHIA.

10.3.6 Review of Medications Used to Treat Human Immunodeficiency Virus (HIV).

10.3.6.1 P&T Committee shall review new HIV drugs and make recommendations to PRHIA for inclusion or not in the "Collaborative Agreement by and between PRHIA and Department of Health" to cover these drugs through the Aids Drugs Assistance Program (ADAP).

10.3.6.2 The PBM must make reasonable efforts to schedule these products for P&T Committee to conduct a prompt review that should not exceed ninety (90) days after FDA approval.

10.3.7 Products Line Extensions

10.3.7.1 The P&T Committee will evaluate line extensions when such line extension has a different indication and cost of the medication already included in the FMC or LME.

10.4 Once a drug is evaluated by the P&T Committee and not recommended for inclusion in the FMC or LME, it cannot be evaluated again until after one (1) year of the initial evaluation, unless other uses or new indications are approved, or new scientific evidence that supports a new evaluation becomes available.

10.5 At the discretion of the P&T Committee, therapeutic classes and the applicable medication protocols will be reviewed every two years. This applies to drugs currently listed in the FMC and LME, as well as non-formulary drugs.

10.6 In the event that a patient requires a medication not included in the FMC, the medical provider may select a drug from within the List of Medications by Exception (LME). All claims for drugs not included in the FMC, but available in the LME, will require a clinical evaluation by the MCO to determine medical necessity based on the established PA criteria.

10.7 In the event that a prescribed medication is neither included in the FMC nor in the LME, the MCO must consider this medication as an exclusion from

coverage. The insured or the attending physician may follow the exception process as established by the PRHIA in its Policy for Medication Exception Requests for non-covered drugs.

10.8 The P&T Committee will establish the protocols for those medications requiring prior authorization, step therapy, quantity limits or any other drug utilization management tool. The MCO will be responsible for implementing and executing these clinical protocols according to FDA approved recommendations, while the PBM will handle administrative protocols regarding high cost (≥$500.00) or prior authorizations for drug supply due to upcoming patient's traveling plans.

10.9 P&T Committee recommendations regarding any changes to the FMC and LME shall be forwarded, along with the approved minutes, to PRHIA for further evaluation by the PPA.

11 PRHIA Board of Directors Approval Process

11.1 The PRHIA Board of Directors ("Board of Directors") will approve the structure, function and responsibilities of the P&T Committee, thereby authorizing its members to carry out the business of effective formulary management and cost containment.

11.2 The Board of Directors will delegate the authority to provide oversight to the Committee activities to the PRHIA Executive Director.

11.3 The P&T Committee, in consultation with the PRHIA Executive Director, may submit specific recommendations regarding the formulary that require approval of the PRHIA Board of Directors. Specifically, the addition of medications that significantly impact pharmaceutical and/or premium costs shall require the approval of the PRHIA Board of Directors.

11.4 Minutes from the P&T Committee meetings will be made available to the PRHIA Board of Directors upon request.

12 Conflict of Interest and Confidentiality Policies

12.1 Although it is assumed that all P&T Committee Independent members acting on behalf of PRHIA act honestly and with integrity when making recommendations concerning evaluations of pharmaceutical products for inclusion or exclusion to the FMC or LME, there are potential and real conflicts of interest which may impact an individual opinion or may appear to make that opinion self-serving.

12.2 Potential conflicts of interests are situations which might not allow for impartial or objective determinations. Independent members may not be employees, officers, directors, or agents of, and may not have financial interests in an MCO, PBM, PPA, pharmaceutical manufacturer or distributor or governmental agencies excluding public state universities and academic institutions. This would include the receipt of research or lecture honoraria from such companies.

12.3 PRHIA does not wish to exclude individuals who are experts in given fields from participating in the P&T Committee, merely because they have conflicts of interest due to their expertise. However, the validity of the P&T Committee and its reputation are based on the confidence in its integrity and the belief by PRHIA and the public alike that recommendations are unbiased and based only on concerns for the best interests of the beneficiaries of the GHIP.

12.4 Independent members will make decisions based on the available evidence in the scientific literature or other non-commercial sources of information, with disregard to interests of third parties.

12.5 Independent members will not accept contributions or payments from persons or organizations attempting to obtain preferential consideration or exert influence in the decisions of the committee. Independent members will inform the Chairperson of any attempt of undue influence.

12.6 Independent members will inform the PBM in writing of any former or present financial contract or affiliation with companies. The PRHIA will determine if a conflict of interest exists.

12.7 Independent members will inform the PBM in writing of any former or present financial contract or affiliation with companies that manufacture, package or distribute medications, or with health insurers, benefit administrators or providers that participate in the GHIP. The PRHIA will determine if a conflict of interest exists.

12.8 Independent, Ad hoc and Special Committee members are not allowed to reveal, disclose or publish any matters related to the information and documentation necessary to perform the functions of the P&T Committee, nor any decisions or comments of the Committee, without the written consent of the PRHIA Executive Director.

12.9 Independent, Ad hoc and Special Committee members are required to sign a Letter of Understanding, which includes confidentiality and conflict of interest statements.

12.10 Advisory Panel members are required to sign a Confidentiality Agreement before they can attend and participate at a P&T Committee meeting.

12.11 All other participants are required to sign a Non-Disclosure Agreement before they can attend and participate in a P&T Committee meeting.

13 Effective Date and Amendments

13.1 The Policies and Procedures contained in this document will be approved by the PRHIA Board of Directors, and will be effective on the date stated in section 14.

13.2 These Policies and Procedures may be amended as deemed necessary by the P&T Committee and PRHIA and must be revised at least once a year.

14 Review and Approvals Log

Review History Log
June 2008
August 2012
April 2015
August 2016
April 2017
August 2017
November 2018
January 2019
June 2019
January 8, 2020
September 17, 2020

Approved by:

Jorge E. Galva, JD, MHA
Executive Director
Puerto Rico Health Insurance Administration (PRHIA)

Date: 09/17/2020

15 Appendixes

Appendix I: Letter of Understanding

PUERTO RICO HEALTH INSURANCE ADMINISTRATION
PBM NAME

LETTER OF UNDERSTANDING

PHARMACY AND THERAPEUTICS COMMITTEE

Advisor Information	
Name:	
Address:	
Of Legal Age: ☐ YES ☐ NO	Social Security Number:

This Letter of Understanding ("the Letter") is to confirm the mutual understandings with respect to the terms and conditions under which the Advisor agrees to serve the **Puerto Rico Health Insurance Administration** (hereinafter referred to as "the Administration", **PBM** (hereinafter referred to as "the PBM"), by becoming an **Independent Member** (hereinafter referred to as "the Advisor") of the Pharmacy and Therapeutics Committee (hereinafter referred to as the "P&T Committee) for the Health Insurance Plan of the Commonwealth of Puerto Rico.

It is understood and agreed that as an **Independent Member** you will, among other things, provide the PBM and THE ADMINISTRATION with the benefit of your knowledge and experience relevant for evaluating and recommending the inclusion or exclusion of pharmaceutical products to the Formulary of Medications Covered (FMC) and the List of Medications by Exception (LME) that promotes the clinical and cost-effective use of medications. In addition, you will provide advice and comment on promotional and educational materials.

1. RIGHTS AND OBLIGATIONS

A. The Advisor agrees to become an independent member of the P&T Committee with all the rights and obligations as set forth in this Letter and as stated in the Policies and Procedures Manual.

1. The Advisor shall participate in all meetings and/or activities of the P&T Committee as described in the Policies and Procedure Manual, or as required from time to time by the PBM and THE ADMINISTRATION. In the event that Advisor fails to attend any particular meeting he/she shall contact the PBM's Clinical Services Department to inform of his/her absence, as described in Policies and Procedures Manual. In the event that the Advisor fails to attend two (2) consecutive scheduled meetings, with or without reasonable cause, he/she will be removed from the Committee.

2. Conflict of Interest

A. Although it is assumed that all committee members acting on behalf of PRHIA act honestly and with integrity when making recommendations concerning evaluations of pharmaceutical products for inclusion or exclusion to the FMC or LME of PRHIA, there are potential and real conflicts of interest which may impact on an individual opinion or may appear to make that opinion self-serving.

B. Potential conflicts of interest are situations which might not allow for impartial or objective determinations. Independent members may not be employees, officers, directors, or agents of, and may not have financial interests in a Managed Care organization (MCO), Pharmacy Benefit Manager (PBM), Pharmacy Program Administrator (PPA), pharmaceutical manufacturer or distributor, or governmental agencies excluding public state universities and academic institutions. This would include the receipt of research or lecture honoraria from such companies.

C. PRHIA does not wish to exclude individuals who are expert in given fields from participating in the P&T Committee, merely because they have conflicts of interest due to their expertise. However, the validity of the P&T Committee and its reputation are based on the confidence in its integrity and the belief by PRHIA and the public alike that recommendations are unbiased and based only on concerns for the best interests of the Government Health Insurance Plan beneficiaries.

D. Independent Members will make recommendations based on the available evidence in the scientific literature or other noncommercial sources of information with disregard to interests of third parties.

E. Independent Members will not accept contributions or payments from persons or organizations attempting to obtain preferential consideration or exert influence in the recommendations of the committee. Independent Members will inform the Chairperson of any attempt of undue influence.

F. Independent Members will inform the PBM in writing of any former or present financial contract or affiliation with companies detailed in section 2.B. above. PRHIA will determine if a conflict of interest exists.

G. Independent members are not allowed to reveal, disclose or publish any matters related to the information and documentation necessary to perform the functions of the P&T Committee, nor any recommendation or comments of the Committee, without the written consent of the PRHIA Executive Director.

H. It is expressly understood by the Advisor that he/she shall not be a member of or participate in any other health insurance company Pharmacy and Therapeutic Committee. Also, the Advisor represents and warrants that he/she is not an employee, shall not provide professional services on a regular basis, and shall not possess shares of stock of any pharmaceutical corporation during his/her tenure under the P&T Committee, including the receipt of research or lecture honoraria from such companies.

I. Any violation to the covenants stated in this Letter shall constitute a material breach of the obligations under this Agreement and would constitute cause for termination.

3. Confidentiality

A. The Advisor agrees to hold and maintain confidential, and shall exercise all reasonable care to prevent the disclosure of confidential information received from the PBM and THE ADMINISTRATION 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 P&T Committee Policies and Procedures Manual. "Confidential Information" shall include, but not be limited to the PBM's know-how, business development data, business activities, specifications and all other intellectual property, plus any information disclosed by other participants in the P&T Committee, provided, however, that the foregoing obligations of non-use and non-disclosure shall not apply to any such confidential information which:

1. is known to the Advisor before receipt thereof under this Letter or is independently developed by or for the Advisor without benefit of the PBM and THE ADMINISTRATION confidential information, as evidenced by the Advisor's written records; except information previously disclosed to the Advisor by MC-21 and THE ADMINISTRATION, or information gained by the Advisor as a result of prior services performed by the Advisor for the PBM and THE ADMINISTRATION, under an ongoing obligation of confidentiality,
2. is disclosed to the Advisor without restriction after the effective date of this Letter by a third party having a legal right to make such disclosure;
3. is or becomes part of the public domain through no breach of this Letter by the Advisor; or
4. is required by law or court order or a judicial or administrative agency of competent jurisdiction to be disclosed, after maximum practicable notice by the Advisor to the PBM and THE ADMINISTRATION, provided that in each case the Advisor shall use his/her best efforts to limit such disclosure and maintain the confidentiality of such confidential information to the extent possible.

B. All drawings, papers and records of any kind relating to the business of the PBM and THE ADMINISTRATION in the possession of Advisor, are and shall be the property of the PBM and THE ADMINISTRATION at any time upon request.

4. This agreement will remain in effect for one year from the date of the signature, at which time parties may renew their understanding by signing a new Letter of Understanding. Either party reserves the right to cancel this agreement at any time for any reason, or for no reason.
5. As full and complete compensation for the services rendered by the Advisor, the PBM will pay a stipend for each P&T Committee meeting attended in the amount described in the amount of _____ ($_____) per P&T Committee meeting attended as full and complete compensation for services rendered to the P&T Committee.
6. It is understood and agreed that the Advisor's status shall be that of an independent contractor and not that of an employee of the PBM and/or THE ADMINISTRATION and will not, therefore, be entitled to any of the benefits available to MC-21 and/or ADMINISTRATION employees.
7. If the foregoing terms and conditions meets the Advisors' understanding and approval, he/she will show his/hers acceptance and agreement by executing this letter where indicated below and by returning the executed letter to the PBM, whereupon this Letter shall constitute the agreement between the Advisor, the PBM and THE ADMINISTRATION with respect to the services in an advisory capacity.

Accepted and agreed upon:

Advisor	
Signature:	
Name:	
Title:	
Date:	

Puerto Rico Health Insurance Administration	
Signature:	
Name:	
Title:	
Date:	

PBM	
Signature:	
Name:	
Title:	
Date:	

Appendix II: Confidentiality Agreement

PUERTO RICO HEALTH INSURANCE ADMINISTRATION
PBM Name

CONFIDENTIALITY AGREEMENT

Advisory Panel Member (the "Advisor) Information
Name:
Address:
Of Legal Age: ☐ YES ☐ NO
Representing (select one): ☐ MCO ☐ PRHIA ☐ ASSMCA ☐ PBM ☐ PPA ☐ Other (Please Specify):

This Agreement entered into this ___ **of** _____, _____, by and between the **Puerto Rico Health Insurance Administration** (hereinafter referred to as "the Administration", **the PBM** (hereinafter referred to as "the PBM"), and the **Advisory Panel Member** (hereinafter referred to as "the Advisor").

WHEREAS: The PBM is engaged in the business of providing Pharmacy Benefits Management Services to insurance companies and to the Health Insurance Plan of the Commonwealth of Puerto Rico.

WHEREAS: The Advisor provides consultative services in the area of Pharmacy Benefits Management, among others.

WHEREAS: THE ADMINISTRATION and the PBM possess certain confidential, proprietary information concerning Pharmacy Benefits Management, the public disclosure of which would harm its business interest.

WHEREAS: THE ADMINISTRATION and the PBM desire to engage the Advisor to perform consulting services related to the activities of the Pharmacy and Therapeutic Committee and/or the Pharmacy Benefits Financial Committee for the Health Insurance Plan of the Commonwealth of Puerto Rico.

WHEREAS: THE ADMINISTRATION, the PBM and the Advisor wish to establish a confidential relationship that will allow either party to disclose confidential information to the other, solely for its use as described hereunder.

NOW THEREFORE, in consideration of these premises and the mutual covenants and obligations contained in this Agreement, and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, THE ADMINISTRATION, the PBM and the Advisor do hereby agree as follows:

1. During the term of this Agreement, including any extension thereof, the Receiving Party shall exercise all reasonable care to prevent the disclosure of Confidential Information received from the Disclosing Party hereunder. As used hereunder, the term "Confidential Information" refers to all information disclosed hereunder, as well as, all information materially developed hereunder, from the respective disclosure of the Confidential Information by the Receiving Party, except any portion thereof which:

    a. is known to the Receiving Party before receipt thereof under this Agreement, except information previously disclosed to the Receiving Party by the Disclosing Party, or information gained by the Receiving Party as a result of prior services performed by the Receiving Party for the Disclosing Party, under an ongoing obligation of confidentiality), or is independently developed by or for the Receiving Party without benefit of the Disclosing Party's Confidential Information, as evidenced by the Receiving Party's written records;
    b. is disclosed to the Receiving Party without restriction after the effective date of this Agreement by a third party having a legal right to make such disclosure;
    c. is or becomes part of the public domain through no breach of this Agreement by the Receiving Party; or
    d. is required by law or court order or a judicial or administrative agency of competent jurisdiction to be disclosed, after maximum practicable notice by the Receiving Party to the Disclosing Party, provided that in each case the Receiving Party shall use its best efforts to limit such disclosure and maintain the confidentiality of such Confidential Information to the extent possible.

2. If applicable, the Receiving party shall not disclose the other's Confidential Information to any more than the minimum number of the Receiving Party's responsible employees, who are directly engaged or are essential for the evaluation and/or consultation with respect to the Confidential Information. The Receiving party shall take all reasonable steps to ensure that such employees shall keep such information confidential. Neither party shall disclose the existence and nature of this Agreement.

    a. Neither party shall use the name of the other party in any publicity, advertising or disseminated information without the prior written approval of that party.
    b. Neither this Agreement, nor the relationship between the parties hereunder shall be deemed to constitute by implication or otherwise grant to the Receiving Party

by the Disclosing Party of any license or other rights under any patent, patent application or other intellectual property right or interest in the other party's.

c. Confidential Information and any information and products and services materially derived or developed there from. No agency or partnership relationship is created by this Agreement.
d. Once the relationship between the parties is concluded, and upon the request of the Disclosing Party, the Receiving Party shall promptly deliver to the Disclosing Party all Confidential Information including, if applicable, all samples and other tangible materials belonging to the Disclosing Party.
e. The parties shall indemnify and hold each other, including, if applicable, its officers, directors, shareholders, employees and ad agents, harmless from and against any third party claims, liabilities, damages, judgments or other losses (including reasonable attorneys' fees) imposed upon, incurred, arising out of or as a result of any negligent act, omissions or breaches in connection with the performance of any of their respective obligations under this Agreement.
f. Each party warrants and represents that: (i) it has the legal right to make any disclosures under this Agreement, and, that it will not disclose to the other any information which is confidential and/or proprietary to a third party; and (ii) the terms of this Agreement are not inconsistent with other contractual and/or legal obligations it may have, or with the policies of any institution with which it is associated.
g. This Agreement shall remain in effect for one year from the date of the signature, at which time parties may renew their understanding by signing a new Confidentiality Agreement. Termination or expiration of this Agreement shall not affect any rights or obligations, which have accrued prior thereto.
h. This Agreement shall be binding upon and inure to the benefit of the parties and their respective legal representatives, successors and assigns.
i. This Agreement and all rights and obligations of the parties shall be governed by and construed in accordance with the laws of The Commonwealth of Puerto Rico.

Advisor	
Signature:	
Name:	
Title:	
Date:	

Puerto Rico Health Insurance Administration	
Signature:	
Name:	
Title:	
Date:	

PBM	
Signature:	
Name:	
Title:	
Date:	

Appendix III: Non-Disclosure Agreement

PUERTO RICO HEALTH INSURANCE ADMINISTRATION,
PBM Name

NON – DISCLOSURE AGREEMENT – GUEST

GUEST Information
Name:
Address:
Of Legal Age: ☐ YES ☐ NO
Representing (select one): ☐ MCO ☐ PRHIA ☐ ASSMCA ☐ PBM ☐ PPA ☐ Other (Please Specify):

As a Guest you agree to hold and maintain confidentiality, and shall exercise all reasonable care to prevent the disclosure of confidential information received from THE ADMINISTRATION and/or the PBMs hereunder, shall not provide it to any independent third party, and shall not use it for any purpose other than that indicated in this NDA.

"Confidential Information" shall include, but not limited to THE ADMINISTRATION and the PBMs know-how, business development data, business activities, specifications and all other intellectual property, plus any information disclosed by other participants in the P&T Committee, 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 Guest before receipt thereof under this NDA (except information previously disclosed to the Guest by THE ADMINISTRATION and/or the PBMs, or information gained by the Guest as a result of prior services performed by the Guest for THE ADMINISTRATION and/or the PBMs, under an ongoing obligation of confidentiality, or is independently developed by or for the Guest without benefit of THE

ADMINISTRATION and/or the PBMs confidential information, as evidenced by the Guest's written records;

(ii) is disclosed to the Guest without restriction after the effective date of this NDA 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 NDA by the Guest; or

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

All drawings, papers and records of any kind relating to the business of THE ADMINISTRATION and/or the PBMs in the possession of Guest, are and shall be the property of (PBM's Acronyms). Guest shall deliver all if any of the same in his possession to THE ADMINISTRATION and/or the PBMs employees.

If the foregoing terms and conditions meet Guest's understanding and approval, please show acceptance and agreement by executing this NDA below whereupon this NDA shall constitute the agreement between Guest, THE ADMINISTRATION and the PBMs with respect to his/her participation.

Guest	
Signature:	
Name:	
Organization Representing:	
Date:	
Puerto Rico Health Insurance Administration	
Signature:	
Name:	
Title:	
Date:	

PBM - **Administrative**	
Signature:	
Name:	
Title:	
Date:	

Appendix IV: Selection Criteria for Independent Members: Physician

Candidates' Name:	
Recommended by:	Name: _____ From: ☐ MCO ☐ ASSMCA ☐ PBM ☐ PRHIA ☐ Other
Date Evaluated:	
Evaluated by:	

Criteria	Points	Score
Medical Doctor degree from an accredited medical school	**1**	
Accredited Residency training in: ☐ Family Practice ☐ Geriatrics ☐ Internal Medicine ☐ Pediatrics ☐ Ob/Gyn ☐ Psychiatry (Adults) ☐ Psychiatry (Children And Adolescents)	**1 each**	
Board Certification	**1 each**	
Is candidate an active practicing Physician? Does he/she provide medical services to the GHIP beneficiaries? If evaluating a Psychiatrist, does he/she have experience providing medical services to ASSMCA?	**1**	
Active License in Puerto Rico?	**1**	
Minimum five (5) years of experience?	**1**	

Experience in clinical pharmacy, formulary management or drug utilization?	**3**	
Academic experience?	**2**	
No professional relationship with the pharmaceutical industry?	**1**	
Total		

Comments:

Appendix V: Selection Criteria for Independent Members: Pharmacists

Candidates' Name:	
Recommended by:	Name: _____ From: ☐ MCO ☐ ASSMCA ☐ PBM ☐ PRHIA ☐ Other
Date Evaluated:	
Evaluated by:	

Criteria	**Points**	**Score**
Pharmacy Doctorate from an accredited school of pharmacy?	**1**	
Residency or Fellowship training?	**1 each**	
Board Certification?	**1 each**	
Active Practicing Pharmacist?	**1**	
Active License in Puerto Rico?	**1**	
Minimum five (5) years of experience?	**1**	
Experience in formulary management or drug utilization?	**3**	
Academic experience?	**2**	
Experience in Psychopharmacology, Geriatrics?	**1**	
No professional relationship with the pharmaceutical industry?	**1**	
Total		

Comments:

Appendix VI: Selection Criteria for Ad Hoc Members

Specialty Area: _____

Candidates' Name:	
Recommended by:	Name: _____ From: ☐ MCO ☐ ASSMCA ☐ PBM ☐ PRHIA ☐ Other

Criteria	Points	Score
Degree from an accredited school: ☐ MD ☐ Pharm D ☐ Masters in _____ ☐ B.S. in _____ ☐ Other _____	**1 each**	
Residency or fellowship training in (if applicable): ☐ Medical specialty: _____ ☐ Clinical Pharmacy: _____ ☐ Other: _____	**1 each**	
Board Certification?	**1 each**	
Is candidate an active practicing Physician? Does he/she provide medical services to the GHIP beneficiaries?	**1**	

Criteria	Points	Score
Active License in Puerto Rico (if applicable)	**1**	
Minimum 5 years of experience?	**1**	
Experience in clinical pharmacy, formulary management or drug utilization?	**3**	
Academic experience?	**2**	
Total		

Comments

Date Evaluated:	
Evaluated by:	

Appendix VII: Pharmacy and Therapeutics Committee Agenda

Puerto Rico Health Insurance Administration
Government Health Plan (GHP) of Puerto Rico

Pharmacy and Therapeutics Committee Meeting
Date / Time / Place

----- Agenda -----

I.	**Quorum and Conflict of Interest Disclosure**	Chairperson
II.	**Distribution of Minutes from Previous Meetings**	Chairperson
III.	**Therapeutic Classes / Products Evaluation**	
	A.	PBM
	B.	
IV.	**Drug Utilization Management Tools Evaluation**	PBM
V.	**Pending Issues**	Chairperson
VI.	**Other Issues**	Chairperson
	A. Safety Issues Report	
	B. Formulary Review Requests	
VII.	**Adjournment**	Chairperson

Notes:

Appendix VIII: Pharmacy and Therapeutics Committee Minutes

Date

Location

Attendance (Members Present, Members Excused, Members Absent, Guests)

I. Quorum and Conflict of Interest Disclosure

II. Distribution / Ratification of Minutes from Previous Meetings

III. Evaluation of Therapeutic Classes / New Products / New Indications

A. Therapeutic Class / Product Name

Therapeutic Class / Drug:	Name				
Product Name	Current Status		Recommendations		Comments
	Formulary of Medications Covered (FMC)	List of Medications by Exception (LME)	Formulary of Medications Covered (FMC)	List of Medications by Exception (LME)	

PA – Pre-authorization / ST – Step Therapy / SP – Specialty Pharmacy / SL - Specialty Limit / AL – Age Limit / QL - Quantity Limit / LA – Limited Access / MF-MC – Maintain in FMC / IF-MC – Include in FMC/ EX-MC – Exclude from FMC / M-LME – Maintain in LME / IF-LME – Include in LME / EX-LME – Exclude from LME

IV. Drug Utilization Management Tools Evaluation

V. Pending Issues

VI. Other Issues

A. Safety Issues Report

B. Formulary Review Requests

VII. Meeting Adjournment

Appendix IX: Submission of Requested Product Information

Date:

To: Pharmaceutical Company

From: PBM Name

c: Puerto Rico Health Insurance Administration

Re: Submission of Requested Product Information

Thank you for the submission of the requested product information for (product name) in the Formulary of Medications Covered (FMC) or List of Medications by Exception (LME) of the Government Health Insurance Plan (GHIP).

This information will be forwarded to the P&T Committee for evaluation.

On behalf of the PRHIA and the Government of the Commonwealth of Puerto Rico, we appreciate your collaboration and continued support.

Appendix X: Formulary Review Request Form

FORMULARY REVIEW REQUEST FORM

This form must be duly completed and signed by the requesting physician and returned to (PBM). Please use additional sheets, if necessary.

Request For:	☐ Inclusion	☐ Exclusion

Generic Drug Name:	
Trade Drug Name:	
Dosage and Strength:	

1. Indication(s) for use: (Please provide supporting literature)

2. List other products currently in the Formulary of Medications Covered (FMC) which are considered similar to the proposed addition/deletion in terms of their chemical, microbiological or pharmacological characteristics and/or comparable in terms of their indicated use.

3. Explain the rationale for requesting the inclusion or exclusion of this product. (Provide supporting literature)

4. List the advantages and/or disadvantages of the proposed inclusion/exclusion compared to the available FMC alternative(s) (Provide supporting literature; improved outcomes, cost etc.)

5. Which agent(s) would you recommend to remove from the FMC? (Explain)

6. Should there be any restrictions placed on the use of this product (if yes, please explain; i.e., restriction to physician specialty)

7. List any requirements for specific drug monitoring, if applicable:

In signing this Formulary Review Request form I represent that I do not have an economic interest in, or act as an officer, a director of, or a speaker of any entity whose financial interests would reasonably appear to be affected by the inclusion/exclusion of the proposed drug in the FMC.

Individuals with a conflict of interest should refrain from proposing a drug for inclusion/exclusion from the drugs list.

Requesting Physicians Name	
Requesting Physicians Signature	
Requesting Physicians Specialty	
Date:	

Puerto Rico License #	DEA License #
Office Telephone	Fax Number

Mailing Address	

For PBM Use Only

Date/Time form was received	
Received by	

Appendix XI: Formulary Review Request Notification Letter

Date: _____

To: Requesting Party

From: PBM Name

CC: Pharmacy and Therapeutics Committee

Re: Request for Formulary Review

On behalf of the PRHIA, (PBM name) has received your request for the review review of _____ (product name). The request was received on _____ (date).

This information will be forwarded to the P&T Committee for evaluation.

PRHIA and the Government of the Commonwealth of Puerto Rico appreciate your collaboration and continued support.

Appendix XII: Favorable FMC Evaluation Notification Letter

Date

Name and Address

Pharmaceutical Company

Re: Formulary Review

Dear Mr. / Mrs. / Ms. _____:

The product _____ was evaluated on _____ (date) for inclusion in the

Government Health Insurance Plan (GHIP) Formulary of Medications Covered (FMC). Clinical and pharmacoeconomic information was carefully reviewed by the GHIP designated Consulting Entities.

We inform you that the referenced product has been recommended for inclusion in the GHIP FMC.

PRHIA and the Government of Puerto Rico appreciate your collaboration and continued support.

Sincerely,

(To be signed by the PRHIA Executive Director)

c: PPA, PBM, PRHIA

Appendix XIII: Favorable LME Evaluation Notification Letter

Date

Name and Address

Pharmaceutical Company

Re: Formulary Review

Dear Mr. / Mrs. / Ms. _____:

The product _____ was evaluated on _____ (date) for inclusion in the

Government Health Insurance Plan (GHIP) List of Medications by Exception (LME). Clinical and pharmacoeconomic information was carefully reviewed by the GHIP designated Consulting Entities.

We inform you that the referenced product has been recommended for inclusion in the GHIP LME.

PRHIA and the Government of Puerto Rico appreciate your collaboration and continued support.

Sincerely,

(To be signed by the PRHIA Executive Director)

c: PPA, PBM, PRHIA

Appendix XIV: Non-Favorable FMC Evaluation Notification Letter

Date

Name and Address

Pharmaceutical Company

Re: Formulary Review

Dear Mr. / Mrs. / Ms. _____:

The product _____ was evaluated on _____ (date) for inclusion in the

Government Health Insurance Plan (GHIP) of Puerto Rico Formulary of Covered Medications (FMC). Clinical information was carefully reviewed by the GHP designated Consulting Entities.

We inform you that the referenced product has not been recommended for inclusion in the GHIP FMC.

This product will not be reconsidered for formulary review until one year after this evaluation, subject to PRHIA P&T Committee's priorities.

PRHIA and the Government of Puerto Rico appreciate your collaboration and continued support.

Sincerely,

(To be signed by the PRHIA Executive Director)

c: PPA, PBM, PRHIA