Policy for Medication Exception Requests of the Puerto Rico Health Insurance Administration

I. PURPOSE:

To define the Puerto Rico Health Insurance Administration (ASES, for its acronym in Spanish) policy and procedures to manage exception requests from prescribers under the Government Health Insurance Plan (GHIP) for medications that: (i) are not in the Formulary of Medications Covered (FMC, for its acronym in Spanish); or (ii) are covered with utilization management edits under the FMC such as step therapy, quantity or dose limits or prior authorization requirements and prescribers wish to bypass such restrictions.

II. POLICY:

The Managed Care Organizations (MCOs) will maintain a standardized procedure for making timely and appropriate Exception Request decisions in accordance with ASES requirements and in compliance with 42 C.F.R. § 438.210(d)(3) to avoid delays that may jeopardize the enrollee's life, health, or ability to regain maximum function.

An exception request may be used for (i) Non-FMC drugs, or (ii) Medications covered with utilization management edits under the FMC (such as step therapy, quantity or dose limits, or prior authorization requirements), when the prescriber wishes to bypass such restrictions. In those cases, the MCO must suggest that the prescriber first consider using drugs listed on the List of Medications by Exception (LME). If the prescriber demonstrates that none of the alternatives in the LME is clinically viable for the patient, then the MCO can consider approving coverage for drugs outside of the LME.
An Exception Request may also be used to bypass certain utilization management restrictions applicable to drugs that are listed on the FMC or LME, such as a step therapy requirement, quantity or dose limit, or prior authorization requirement.

III. SCOPE:

This policy applies to ASES' contracted pharmacy benefit management (PBM) organization, MCOs and their GHIP providers including, but not limited to, physicians, hospitals, behavioral facilities, ambulatory facilities, emergency rooms, and pharmacies prescribing and/or dispensing outpatient drugs.

IV. DEFINITIONS:

TERM	DEFINITION
Formulary of Medications Covered (FMC, for its acronym in Spanish)	FMC means "Formulario de Medicamentos en Cubierta" in Spanish. The FMC is the list of preferred and non-preferred medications covered by the GHIP, though ASES may assign different levels of cost-sharing within the FMC.
List of Medications by Exception (LME)	List of medications that are not included in the FMC, but that have been evaluated and approved by ASES' Pharmacy and Therapeutics (P&T) Committee to be covered only through an exception process if certain clinical criteria are met. Covered outpatient drugs that are not included on the LME may still be covered under an Exception Request, unless statutorily excluded.
Exception Request	A request to obtain coverage by exception of a drug that is not included in the GHIP's FMC, or to bypass utilization management restrictions that apply to drugs listed on the FMC. Exception Requests may be evaluated based on the MCO's own clinical criteria or through the standards set forth under this policy.

Medical Necessity	**As defined by Section 7.2 of the Contract with MCOs** 7.2.1 Based on generally accepted medical practices specific to the medical or behavioral health condition of the enrollee at the time of treatment, Medically Necessary Services are those that relate to (i) the prevention, diagnosis, and treatment of health impairments; (ii) the ability to achieve age-appropriate growth and development; or (iii) the ability to attain, maintain, or regain functional capacity. The scope of Medically Necessary Services must not be any more restrictive than that of Puerto Rico's Medicaid program. Additionally, Medically Necessary services must be: 7.2.1.1 Appropriate and consistent with the diagnosis of the treating provider and the omission of which could adversely affect the eligible enrollee's medical condition; 7.2.1.2 Compatible with the standards of acceptable medical practice in the community; 7.2.1.3 Provided in a safe, appropriate, and cost-effective setting given the nature of the diagnosis and the severity of the symptoms; 7.2.1.4 Not provided solely for the convenience of the enrollee or the convenience of the provider or hospital; and 7.2.1.5 Not primarily custodial care (for example, foster care). 7.2.2 In order for a service to be Medically Necessary, there must be no other effective and more conservative or substantially less costly treatment, service, or setting available.

V. BACKGROUND:

ASES' contract with the MCOs stipulates that certain medications, not otherwise covered under the GHIP, might be covered through an exception process by which the patient's health care provider must substantiate the clinical need for such exception.

Preferred and non-preferred medications covered by the GHIP are included in the FMC, though different levels of cost-sharing may apply. In addition, the GHIP has developed, through its Pharmacy & Therapeutics (P&T) Committee, a List of Medications by Exception (LME) that may be covered under special circumstances. The medications in the LME will be subject to the MCO's evaluation upon the participating physician's request for exception, on a case-by-case basis, to determine if it complies with the protocol established by ASES for said medication. If it is not in compliance, the medication will be denied; and if it complies, it will be approved.

Medications not included in the FMC will be not be paid for by the GHIP unless an Exception Request is granted. If an Exception Request is submitted, drugs listed on the LME will be preferred over non-FMC drugs. or LME covered outpatient drugs. An Exception Request may also be used to bypass certain utilization management restrictions applicable to drugs that are listed on the FMC, such as a step therapy requirement, quantity or dose limit, or prior authorization requirement. A patient may appeal a decision to deny an Exception Request.

Certain drugs are considered excluded from coverage and will not be paid for by the GHIP even if an Exception Request is submitted. For example, under Section 1927(d)(2) of the Social Security Act, the GHIP will not cover drugs used to promote fertility, drugs used for cosmetic purposes or hair growth, drugs used for the symptomatic relief of cough and colds, most prescription vitamins and mineral products, non-prescription drugs or over-the counter-medication unless specifically included in GHIP coverage, and drugs which the manufacturer seeks to require as a condition of sale that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee. Drugs that are not prescribed for a medically accepted indication are also excluded and will not be covered. These drugs are considered "statutorily excluded." Also excluded are drugs prescribed for the purpose of treating a condition not covered under the GHIP. In addition, the Puerto Rico Medicaid State Plan excludes certain drugs such as those to treat hepatitis C from coverage, as these drug therapies are covered under other non-Medicaid government health programs.

VI. PROCESSING OF REQUESTS FOR EXCEPTION

If a medication not included on the FMC, but included on the LME, is submitted to the Pharmacy Benefit Manager (PBM) for adjudication, the pharmacy will receive the following message at the point of sale: *Non Formulary/Validate other alternatives in FMC.* If a medication not included on the LME is submitted to the PBM for adjudication, the pharmacy will receive the following message at the point of sale: *Non-Formulary Drug*.

To request an exception, the physician must complete a request and submit it to the MCO along with the necessary medical documentation (described in Section D.1.b below) showing compliance with ASES protocol for said medication. If the request or additional documentation or evidence (described in Section D.1.b below) is included with the prescription, the pharmacy will send the case to the MCO to process the request for exception.

A. Receipt of Exception Requests:
   1. Exception Requests will only be accepted from the patient's health care provider and shall be received in the MCO's Pharmacy Clinical Unit via regular mail, e-mail, telephone or fax.
      i. Regular mail requests will be stamped with the date and time it is received by the MCO and will serve as the starting time for evaluation period. For e-mail, telephone or fax requests, the receipt date and time will be used.
   2. Exception Requests shall include the following standard information: the prescription, a supporting statement setting forth the clinical justification and medical necessity for the prescribed medication that meets all the requirements described in Section D.1.b below, and expected duration of treatment, as required by the protocol for the medication.
   3. Incomplete requests that do not include all of the information listed in Section A.2 above will be returned by the MCO or pharmacy receiving the request to the prescribing physician or health care provider by fax or e-mail, for completion as soon as practicable, and within 24 hours. The processing time starts when the information required in Section A.2 above is received.

B. Timeframes:
   1. The outcome of the MCO's determination to approve or deny the Exception Request shall be communicated in accordance with Section E below to the enrollee, pharmacy and prescribing physician within 24 hours after the request is received and the MCO receives the standard information necessary in Section A.2 above to make a determination.
   2. In an emergency situation, the MCO must authorize at least a 72-hour supply of the requested drug as long as the drug is not statutorily excluded. An emergency situation means that a lack of access to the requested drug may seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function. Terms that may indicate that a request should be treated as an emergency situation include, but are not limited to, "rush," "stat," "immediately," "patient's life is in danger," "urgent," or "expedite." If a requested drug cannot be dispensed in a quantity, dose or form limited to a 72-hour emergency supply, e.g. injection vials or drugs infused by a pump or other device, the emergency dispense must be authorized in the minimum necessary form or increment that exceeds the 72-hour supply.
   3. If additional time is needed to process a request, the MCO shall determine whether to grant the extension as soon as practicable, and within 24 hours. ASES's authorization to grant an extension is delegated to the MCOs, as long as the MCOs comply with the intent and purpose set forth in ASES Contract Section 7.5.12.4.2.2. governing Prior Authorization, and as also applied to Exception Requests.
      "ASES may, in its discretion, grant an extension of the time allowed for Prior Authorization decisions where:
         i. The Enrollee, or the Provider, requests the extension; or
         ii. The MCO justifies to ASES a need for the extension in order to collect additional information, such that the extension is in the Enrollee's best interest."
      The maximum time allowed when granting an exception must be no more than 72 hours. However, the MCO must still authorize the required 72-hour supply of the requested drug in an emergency situation as set forth in Section B.2 above, even if an extension is granted.

C. Additional Information:

1. If a request is received, but additional information is needed to complete the evaluation, the request will be placed in a status of Need More Information (NMI) in the PA-Hub. Required information will be requested through fax, email or by contacting the prescribing physician, notifying the prescriber that the MCO will allow 72 hours for its submission. While in NMI status, the 24-hour timeframe specified in Section B.1 above will be tolled and reset once the additional information necessary to complete the evaluation is received.

    a. Examples of appropriate additional information requests include, but are not limited to:
        1) Diagnosis
        2) Relevant patient medical history or data
        3) Documentation of prior use of other alternative therapies (including the specific therapies, times used, and clinical results)
        4) Medical justification for the requested drug such as: alternative drugs on the FMC which are contraindicated, patient has experienced or would experience an adverse reaction to FMC drugs, evidence of therapeutic failure after available alternatives on FMC were attempted, drug is not covered in the FMC for a particular diagnosis
        5) Laboratory results, if requested on protocol

2. If the additional information needed to complete the evaluation is not submitted to the MCO within 72 hours after the request for additional information is sent, the request will be denied unless the MCO, prior to the expiration of the seventy two (72) hours, confirms that the available information is sufficient for an approval. If denied for lack of information, a notification letter will be sent to the pharmacy, patient, and provider.

D. Evaluation and Determination:

1. The MCO shall first verify that:
    a. The request is for a drug:
        i. That is included on the FMC with certain clinical or other utilization management restrictions that the prescriber seeks to bypass through an exception, not included in the FMC but it is included LME, or is not included on the LME but is a covered prescription drug that is not statutorily excluded, and
        ii. That has been prescribed for a medically accepted indication as defined by Section 1927(k)(6) of the Social Security Act, meaning that the use of the drug is approved by the FDA or is supported by one or more citations included or approved for inclusion in the American Hospital Formulary Service Drug Information, the United States Pharmacopeia – Drug Information (or its successor publications), or the DRUGDEX Information System, and
        iii. That complies with the clinical criteria and protocols established by ASES for drugs included in the LME, or is consistent with general medically accepted guidelines for non-LME drugs or where the Exception Request seeks to bypass applicable clinical criteria and protocols.
    b. The prescribing physician must provide a written and signed supporting statement setting forth the clinical reason or reasons that the requested prescription drug is medically necessary to treat the patient's disease or medical condition. His or her supporting statement must indicate that the requested prescription drug is medically necessary because:

        If the physician is requesting an LME alternative:

        i. All FMC alternatives for the requested drugs are contraindicated with drugs that the patient is already taking. The MCO must request that the patient's medical records show such contraindication, or that the prescribing physician provide scientific literature showing the strong possibility of serious adverse health effects as a result of taking the FMC alternatives; or
        ii. Patient has experienced a serious adverse reaction to the alternative drugs that appear in the FMC; or

iii. Therapeutic failure of all available alternatives on the FMC, either because these alternatives were ineffective or would adversely affect the health or condition of the patient.

If the physician is requesting an alternative not listed on FMC or LME:

i. All FMC and LME alternatives for the requested drugs are contraindicated with drugs that the patient is already taking. The MCO must request that the patient's medical records to show such contraindication, or that the prescribing physician provide scientific literature showing the strong possibility of serious adverse health effects as a result of taking the FMC and LME alternatives; or

ii. Patient has experienced a serious adverse reaction to the alternative drugs that appear in the FMC and LME; or

iii. Therapeutic failure of all available alternatives on the FMC and LME, either because these alternatives were ineffective or would adversely affect the health or condition of the patient.

2. If a physician provides an oral supporting statement to set forth the medical necessity of the drug, the MCO shall require the physician to submit this oral statement in writing. This written supporting statement must be submitted within 72 hours.

3. During the evaluation process, the MCO clinical reviewer will conduct an in-depth review of all available documentation submitted as part of the exception request including, but not limited to:
   a. The supporting statement and other documentation submitted with the exception request by the prescribing physician
   b. Internal information such as medication utilization history from PBM's adjudication system
   c. Diagnosis reported for the condition the requested drug is treating, from the claims system
   d. Any special condition(s) the patient may have which may have qualified him or her for special coverage.

4. If a discrepancy in the available documentation is found during the review of the information indicated in Section D.3 above, the prescribing physician shall be contacted by phone to clarify the discrepancy. The MCO clinical reviewer must document this contact, including the content of what was discussed and the results of that discussion.

5. The MCO clinical reviewer should also consider whether other utilization management measures for either the FMC or LME alternative drugs, such as dose restrictions to limit the number of doses available, or alternative forms of the drug, e.g. liquid versus pill, or oral versus injected or infused, could be appropriate.

6. The MCO will make a determination, with the available information, before expiration of the applicable timeframes set forth in Section B.

E. Notification of Decision:
   1. If the exception request does not fully meet the established clinical criteria or protocol for the medication, it will be denied by the MCO's authorized clinician-reviewer.
      a. The prescribing physician, pharmacy and patient will be verbally notified by the MCO's representatives within the applicable timeframes required in the preceding sections.
      b. A denial letter also will be mailed within three (3) business days of verbal notification to the patient in accordance with Section 14.4.3 of the MCO Contract, including an explanation of the reasons for the denial and a description of the appeal process.
      c. The denial determination will be documented in the PBM PA Management Application.

   2. If the request is approved, the MCO will document the determination and the date and time approved in the PBM PA Management Application. The pharmacy will then process and dispense the requested medication. The dispensing pharmacy representatives will verbally notify the beneficiary and prescribing

physician of the approval. An approval letter also will be mailed within three (3) business days of verbal notification.

3. If a requested medication is approved through an exception, that approval will be valid for the lesser of the duration indicated by the prescribing physician or the period specified in the clinical protocol but in any case, no longer than twelve (12) months. The approval is also valid as long as:
    a. The patient remains enrolled in the GHIP, and
    b. The prescribing physician continues to prescribe the drug, and
    c. The drug continues to be safe for the treatment of the patient's condition.

4. The determination (approval or denial) and supporting evidence will be documented and filed as per MCOs' internal process.

Approved by:

Mrs. Angela Avila Marrero
Executive Director

19/July/2017
Date of Approval