

## Carta Trámite

9/24/2021

A: Todos los Proveedores Contratados por First Medical Health Plan, Inc. para el Plan Vital, Región Única y Población Vital-X (Virtual)

***Re: Carta Normativa 21-0921 relacionada a Criterios de Pre-Autorización para Solicitudes de Medicamentos no en Formulario Vía Excepción Plan Vital***

Estimado(a) Proveedor(a):

Reciba un cordial saludo de parte de First Medical Health Plan, Inc.

Adjunto a este comunicado encontrará la Carta Normativa 21-0921 de la Administración de Seguros de Salud de Puerto Rico (ASES).

A través de esta Carta Normativa, la ASES informa que, efectivo el 1 de noviembre de 2021, habrá disponible un archivo que incluirá los criterios de pre-autorización para medicamentos fuera del Formulario de Medicamentos en Cubierta del Plan Vital. Dichos criterios deberán ser utilizados como referencia cuando se evalúe la documentación médica requerida para aprobar o denegar un medicamento no-formulario. Este proceso está alineado con la Política de Manejo de Medicamentos por Excepción del Plan Vital. Se incluye la Política para su referencia.

Es importante mencionar que, si un medicamento no es añadido al formulario, luego de ser evaluado por el Comité de Farmacia y Terapéutica de ASES, su protocolo con los respectivos criterios de pre-autorización se incluirá en el archivo "Criterios de Pre-Autorización para solicitudes de excepción en el Plan Vital a través del siguiente enlace: <https://app.box.com/v/protocolosases>.

Le exhortamos a que lea detenidamente la Carta Normativa 21-0921 para que se familiarice con las instrucciones impartidas por la ASES.

Si usted tiene alguna pregunta relacionada a este comunicado y/o necesita información adicional, siéntase en la libertad de comunicarse con nuestro Centro de Servicio al Proveedor al número libre de cargos 1-844-347-7802 de lunes a viernes de 7:00 a.m. a 7:00 p.m. También, puede acceder a [www.firstmedicalvital.com](http://www.firstmedicalvital.com).

Cordialmente,

Departamento de Cumplimiento  
First Medical Health Plan, Inc.



GOBIERNO DE PUERTO RICO

ADMINISTRACIÓN DE SEGUROS DE SALUD

Director Ejecutivo | Jorge E. Galva, JD, MHA | [jgalva@asespr.org](mailto:jgalva@asespr.org)

## Carta Normativa 21-0921

21 de septiembre de 2021

**A: Organizaciones contratadas de Manejo Coordinado de Salud (MCO), Grupos Médicos Primarios (GMP), Administrador del Beneficio de Farmacia, Red de Farmacias y Proveedores Participantes del Plan Vital**

**RE: Criterios de Pre-autorización para solicitudes de medicamentos no en formulario vía excepción en Plan Vital**

Las organizaciones de Manejo Coordinado de Salud (MCO) contratadas bajo el Plan de Salud del Gobierno – Plan Vital, deberán mantener un procedimiento estandarizado para tomar decisiones oportunas y apropiadas sobre solicitudes de medicamentos que no están en formulario vía excepción, de acuerdo con los requisitos de ASES, y en conformidad con 42 C.F.R. § 438.210 (d) (3). Es el mayor interés de la ASES que todo MCO logre evitar retrasos que puedan poner en peligro la vida, la salud, o la capacidad del afiliado para recuperar la función máxima.

A esos fines, efectivo el **1ro de noviembre de 2021**, los MCO tendrán disponible un archivo que incluirá los criterios de pre-autorización para medicamentos *no-formulario* del Plan Vital. Dichos criterios deben ser utilizados como referencia cuando el MCO evalúe la documentación médica requerida para aprobar o denegar un medicamento *no-formulario*. Este proceso está alineado con la Política de Manejo de Medicamentos por Excepción del Plan Vital. (*Favor de hacer referencia a la Política de Manejo de Medicamentos por Excepción*).

Los protocolos clínicos para criterio de pre-autorización para los medicamentos *no-formulario* de mayor gasto (*top 20 non-formulary drug spend*) serán compartidos con los miembros del comité de farmacia y terapéutica para recoger su insumo. Protocolos clínicos para medicamento de excepción adicionales se incluirán en el archivo a medida que se vayan desarrollando y según sean evaluados y validados por el Comité de Farmacia y Terapéutica (CFT) de ASES. Si un medicamento no es añadido al formulario, luego de haberse evaluado en el CFT, su protocolo con los respectivos criterios de pre-autorización (validados por el CFT) serán incluidos en el archivo denominado **“Criterios de Pre-autorización para solicitudes de excepción en Plan Vital”** vía enlace: <https://app.box.com/v/protocolosases>.

Todos los MCOs serán responsables de orientar debidamente a su red de proveedores en cuanto a lo expresado en esta Carta Normativa. Agradecemos la colaboración de todos los MCO y la de sus proveedores en identificar la mejor terapia para nuestros beneficiarios del Plan Vital garantizarles el acceso y la continuidad de sus tratamientos.

Cordialmente,

Jorge E. Galva Rodríguez, JD, HSA  
Director Ejecutivo

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## ASES Policy for Medication Exception Requests: Frequently Asked Questions

### Applicability

**Q:** Does this policy apply to inpatient drugs covered under Medicaid or “carve-out” programs where drug therapies may be covered under other non-Medicaid government health programs?

**A:** No. This policy applies to Medicaid covered outpatient drugs only.

### Interactions with Enrollees and Prescribers

**Q:** Will prescribing physicians have access to the ASES protocols? Is it the MCO’s responsibility to provide the ASES protocols or is it the PBM’s responsibility?

**A:** Drug formularies are published and accessible through ASES’ website at [www.asespr.org](http://www.asespr.org). There is no federal Medicaid requirement to publish clinical protocols. This is required of commercial plans in some states, and ASES or the MCOs could choose to publish them to make it easier for the prescribing physicians to look-up applicable requirements. ASES recommends publishing the same.

**Q:** Does the pharmacy notify the enrollee of the exclusion of the drug from the FMC or LME? Will the prescriber also be notified of the exclusion or is the expectation that the enrollee will go back to the prescriber?

**A:** If the pharmacy is attempting to dispense the medication and receives notice of the rejection at the point-of-sale, the pharmacy should notify both the patient and the prescriber so that the prescriber knows to file an exception request.

### Submission of an Exception Request

**Q:** Who determines when all the requirements for an exception request are included for submission?

**A:** The MCO’s clinical reviewer ultimately decides if there is enough information required to evaluate the request. If the pharmacist is facilitating the submission of the request though, he or she should be encouraged to assess the request to see if all the standard requirements for submission are included, specifically: (1) the prescription, (2) a supporting statement setting forth clinical justification and medical necessity, (3) duration of treatment, and (4) evidence of compliance. However, the MCO may still determine that the request is incomplete despite the pharmacist’s initial assessment.

**Q:** Is an exceptions request considered incomplete if it is missing any of the standard information listed above?

**A:** Yes. The MCO must return the request within 24 hours and the 24-hour processing timeframe does not start until the request is complete and all the standard information is included.

**Q:** Can an exception request come from the pharmacy? Can incomplete requests be returned to the pharmacy?

**A:** An exception request can only come from the prescriber. The pharmacy can help facilitate the submission of the request, but the request itself and supporting statement must come from the prescribing physician or provider. Incomplete requests can be returned to the pharmacy only if they originate from the pharmacy. The request should be returned to whoever submitted the original request, i.e. the enrollee, the pharmacy, or the prescriber.

**Q:** Can an exception request be submitted by phone?

**A:** No. An exception request will only be accepted in writing from the patient’s health care provider and shall be received in the MCO’s Pharmacy Clinical Unit via regular mail, e-mail, or fax.

**Q:** If an exceptions request is missing a diagnosis, can the MCO simply return the request instead of requesting additional information?

## ASES Policy for Medication Exception Requests: Frequently Asked Questions

**A:** No, because diagnosis is not one of the standard requirements for submission of a request. It is considered a request for additional information, not an incomplete request.

**Q:** How will high-cost drugs and/or orphan drugs that are not currently on the FMC and LME be managed?

**A:** They will be reviewed like any other non-FMC and non-LME covered outpatient drug, unless these drugs are statutorily excluded or covered under a carve-out, non-Medicaid government health care program.

### Evaluation of an Exception Request

**Q:** Shouldn't it be mandatory that the MCO must "request that the patient's medical records show such contraindication with drugs that the patient is already taking..." versus leaving it up to the clinical reviewer's discretion?

**A:** No, the decision to request the patient's medical records to support a showing of contraindication should be left up to the discretion of the clinical reviewer.

**Q:** Shouldn't any scientific literature that may be provided to support an off-label use or to show the possibility of adverse health effects as a result of taking a formulary alternative be peer reviewed?

**A:** This is not a specific requirement. The only type of scientific literature that may be used to determine a medically accepted indication for an off-label use of a drug are the American Hospital Formulary Service Drug Information, the United States Pharmacopeia – Drug Information (or its successor publications), or the DRUGDEX Information System. This is required by law under Section 1927(k)(6) of the Social Security Act. For the evaluation of adverse health effects, the weight of the scientific literature provided to support the exception request will be determined by the MCO clinical reviewer.

**Q:** If the MCO contacts the prescribing physician to request additional information or clarification to the information already submitted in a written supporting statement, does the prescriber have to provide this information in writing or submit a second written statement?

**A:** No. The prescribing physician may respond verbally to follow-up questions from the MCO as long as the physician has already submitted an initial, written supporting statement setting forth clinical justification and medical necessity. The MCO should ensure that it is documenting any discussion in call notes.

### Timeframes

**Q:** The policy states that "the outcome of the MCO's determination to approve or deny the Exception Request shall be communicated... to the enrollee, pharmacy and prescribing physician within 24 hours after the request is received and the MCO receives the standard information necessary... to make the determination." Does this mean that exception requests must be handled within 24 hours?

**A:** Yes, unless: (1) the standard information to submit an exception request has not been submitted, (2) additional information is needed to make a decision, and/or (3) an extension has been granted.

**Q:** What is the basis for the 24-hour timeframe for making a determination?

**A:** This is required in Section 1927(d)(5) of the Social Security Act as well as 42 C.F.R. § 438.210(d)(3).

**Q:** Shouldn't the timeframe be 72 hours (standard) and 24 hours (expedited) to make a determination?

**A:** No, the 72 and 24-hour timeframe only applies in Medicare Part D.

**Q:** Shouldn't the timeframe be 14 days (standard) and 72 hours (expedited) to make a determination?

## ASES Policy for Medication Exception Requests: Frequently Asked Questions

**A:** No, the 14-day and 72-hour timeframe only applies in Managed Medicaid for all other types of authorization requests except for covered outpatient drugs.

**Q:** What happens if the request is submitted over the weekend or if a request is received on Friday?

**A:** The 24-hour processing timeframe still applies.

**Q:** The policy states that “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.” Is this mandatory?

**A:** Yes, this is required under Section 1927(d)(5)(B) of the Social Security Act.

**Q:** The policy states that “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.” Is this at the discretion of the insurer? Are there any defined therapeutic categories or classes?

**A:** No. This is a legal requirement, and applies for all covered outpatient drugs in an emergency situation while an exception request is pending unless the drug is statutorily excluded.

**Q:** Should any request that says “rush” be automatically treated as an emergency situation without an independent evaluation? We are concerned because words like “rush” are sometimes used to ensure the application is processed in a timely fashion.

**A:** The policy states only that these terms “may” indicate that such a request should be treated as an emergency. The MCO clinical reviewer should determine if an emergency situation exists based on whether 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.

**Q:** When additional information is required for a request, is the 24-hour processing timeframe paused?

**A:** Yes, the 24-hour timeframe will be paused and continued once the additional information necessary to complete the evaluation is received.

**Q:** How many times can the MCO grant a request for a 72 hour extension request?

**A:** Each request for an extension can only be for a 72 hour period, but it is possible for an MCO to grant more than one extension request if the extension is in the patient’s best interest. Multiple extension requests on a single case should be used infrequently and only when justified on a case-by-case basis. ASES will require MCOs to submit monthly reports that will be used to evaluate compliance with all timeframe requirements.

**Q:** What if the prescribing physician submits additional information needed to complete an evaluation after the request has already been rendered inactive?

**A:** The MCO may reopen or reactivate the request for review using the new information provided. If a “new” case needs to be created operationally to proceed with the review, we suggest including case notes or other documentation for audit and tracking purposes to show that the current case is linked to an earlier request that had been rendered inactive.

## Decision and Notification

**Q:** What is the timeframe for sending enrollees a written denial letter for the exception request?

**A:** A written approval or denial letter should be sent within three (3) business days after providing notice of the decision by phone.

## ASES Policy for Medication Exception Requests: Frequently Asked Questions

**Q:** Must the approval or denial of exception requests be communicated in verbal or written form?

**A:** Yes, they should be communicated verbally to the prescriber, pharmacy and patient within the applicable timeframes. An approval or denial letter must also be mailed to the patient within three (3) business days of verbal notification.

**Q:** Will a pharmacy also be notified of a denial of exception request, or just the patient and physician?

**A:** A denial letter will be mailed to the patient only. This same letter will be sent by fax or email to the prescribing physician and the pharmacy.

### Effectuation of an Approved Exception Request

**Q:** Does an approved exception request ever expire? Please clarify the timeframe during which an approval of an exception request is effective. It is generally 6 months?

**A:** We decline to include a specific, overall timeframe for the effectiveness of an approved exception request. The MCO must defer to the duration of the course of treatment as it is prescribed, or the time period specified in the clinical protocol. We do not have a standardized time period that applies across all circumstances or types of drug classes.

**Q:** In assessing to what extent an exception request approval is valid for, what happens if the physician that continues to prescribe the drug is not the same physician but nevertheless one of the same specialty?

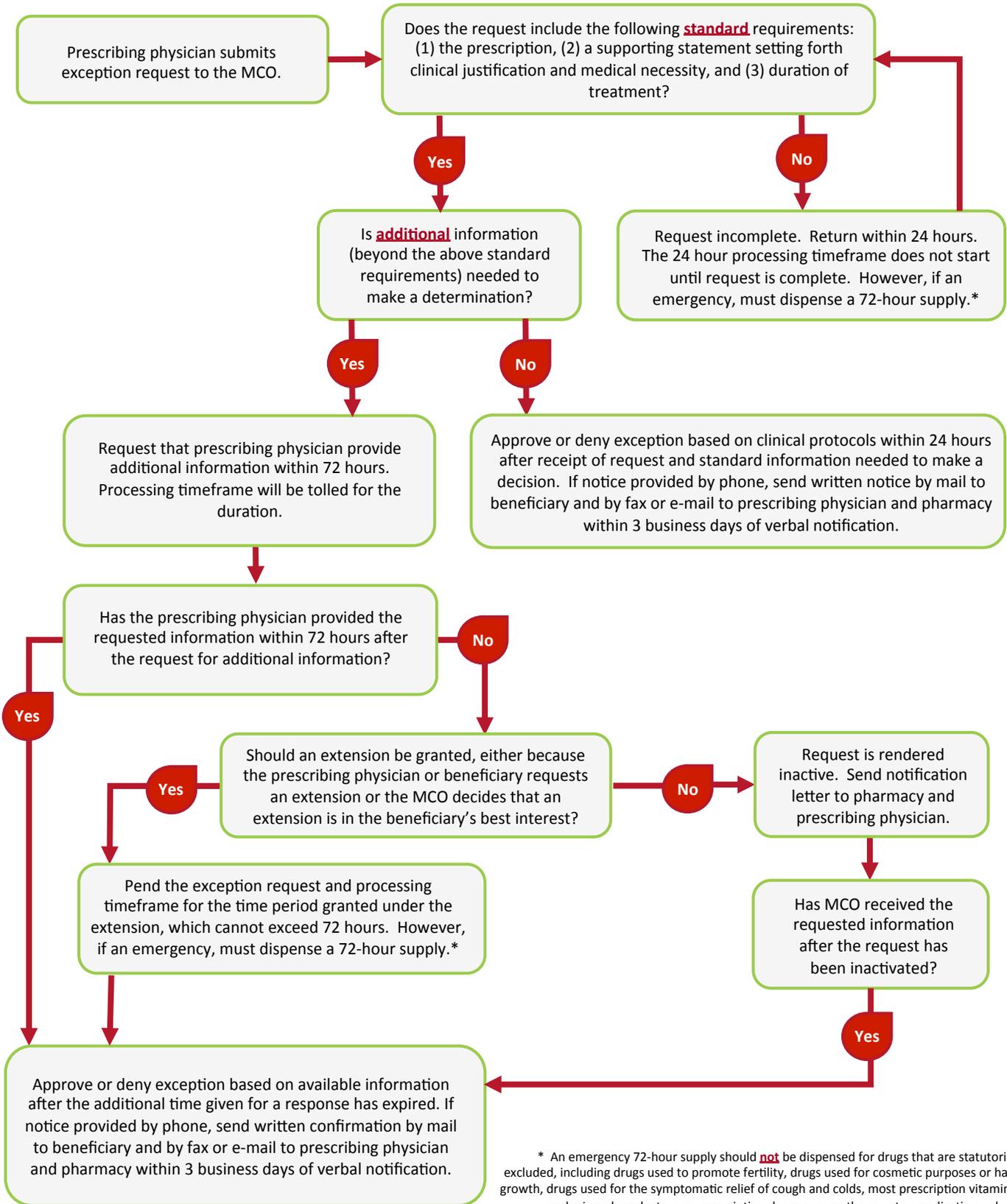
**A:** There is no impact if the physician changes during the period of time the exception request is valid, unless the new prescriber decides and informs the MCO that the drug should no longer be prescribed.

**Q:** While the approval for the exception is valid, who decides if a drug continues to be safe for the treatment of the patient's condition?

**A:** Safety should be determined by the prescriber's discretion to continue the patient's course of treatment on the drug. The MCO may also take into account any FDA warnings on drug safety, and work with the prescriber if necessary to escalate such warnings.

**Q:** What happens once the exception request is approved but the effectiveness of the approval expires? Must another request be made again?

**A:** Yes, a new exception request must be submitted.



\* An emergency 72-hour supply should **not** be dispensed for drugs that are statutorily excluded, including 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 MI Salud 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.



## **Puerto Rico Health Insurance Administration Policy for Medication Exception Requests**

### **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 MI Salud, also known as the Government Health Insurance Plan, 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 are 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 MI Salud providers including, but not limited to, physicians, hospitals, behavioral facilities, ambulatory facilities, and pharmacies prescribing and/or dispensing outpatient drugs.

**IV. DEFINITIONS:**

TERM	DEFINITION
Formulary of Medications Covered Dugs (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 MI Salud, though ASES may assign different levels of cost-sharing within the FMC.
List of Medications by Exception (LME)	List of medications that are <u>not</u> 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 MI Salud’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	<p><b>As defined by Section 7.2 of the Contract with MCOs</b></p> <p>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:</p> <ul style="list-style-type: none"> <li>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;</li> <li>7.2.1.2 Compatible with the standards of acceptable medical practice in the community;</li> <li>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;</li> <li>7.2.1.4 Not provided solely for the convenience of the enrollee or the convenience of the provider or hospital; and</li> <li>7.2.1.5 Not primarily custodial care (for example, foster care).</li> </ul> <p>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.</p>

## V. BACKGROUND:

ASES' contract with the MCOs stipulates that certain medications, not otherwise covered under MI Salud, 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 MI Salud are included in the FMC, though different levels of cost-sharing may apply. In addition, MI Salud 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 MI Salud 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 MI Salud even if an Exception Request is submitted. For example, under Section 1927(d)(2) of the Social Security Act, MI Salud 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 MI Salud 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 MI Salud. 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: LME Drug; Exception request required. Validate other alternatives in FMC before proceeding. 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-FMC/LME Drug. Exception request required. Validate other alternatives in FMC/LME before proceeding.

To request an exception, the prescribing physician must complete a request using the standardized Medication Request Form or, if necessary, an equivalent form 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 in writing from the patient's health care provider and shall be received in the MCO's Pharmacy Clinical Unit via regular mail, e-mail, 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 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." However, MCOs must evaluate the request to determine based on the information presented whether the patient is in an emergency situation.

Such evaluations must be conducted using appropriate clinical judgment, and shall not be used to deny a 72-hour emergency supply of the requested drug if an emergency situation does in fact exist. 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 PAHub. 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 paused and continued 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 considered inactive unless the MCO, prior to the expiration of the seventy two (72) hours, confirms that the available information is sufficient for an approval. If considered inactive for lack of requested information, a notification letter will be sent to the pharmacy and the prescribing physician.

#### 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. This same denial letter will be sent via fax or email to the prescribing physician and pharmacy.
  - 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 to the patient. This same letter will be sent via fax or email to the prescribing physician and pharmacy.
3. If a requested medication is approved through an exception, that approval will be valid for 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 MCOs may use information on record to re-approve a non-FMC or LME medication as long as the information remains accurate and complies with current clinical protocols. The approval is also valid as long as:
  - a. The patient remains enrolled in MI Salud, 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.