Carta Trámite

22 de mayo de 2024

A: Todos los Proveedores Contratados por First Medical Health Plan, Inc. para el Plan Vital

Re: ***Política Núm. ASES-OC-2023/P003 revisada relacionada a Solicitudes de Excepción de Medicamentos.***

Estimado(a) Proveedor(a):

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

Adjunto a este comunicado encontrará la Política Núm. ASES-OC-2023/P003 de la Administración de Seguros de Salud de Puerto Rico (ASES).

La ASES informa que, esta Política fue revisada el 17 de mayo de 2024.

Para detalles específicos sobre la información provista por la ASES, le exhortamos a leer detenidamente la Política Núm. ASES-OC-2023/P003, actualizada.

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.

Cordialmente,

Departamento de Cumplimiento
First Medical Health Plan, Inc.

Clinical Operations Area Government Health Plan (GHP), Vital Health Plan			
Policy: Puerto Rico Health Insurance Administration Policy for Medication Exception Requests			
Number: **ASES-OC-2023/P003**	**Review Date:** 05/17/2024	**Effective Date:** 01/01/2023	**Number of Pages:** 21
Approved By: Roxanna K. Rosario Serrano, BHE, MS **Signature:** **Date:** 5/17/2024 **Executive Director** Milagros A. Soto Mejía, MHSA, MMHC **Signature:** **Date:** 5/17/2024 **Clinical Operations Director**			
Reference: Contract Section 7.2 Medical Necessity; 42 C.F.R. § 438.210(d)(3)			

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 Vital Health Plan, also known as the Government Health Insurance Plan, for medications that: (i) are not in the Preferred Drug List (PDL) or (ii) are covered with utilization management edits under the PDL such as Step Therapy (ST), Quantity or Dose Limits (QL) or Prior Authorization (PA) requirements and prescribers wish to bypass such restrictions.

II. POLICY:

This policy is to comply with the Medicaid Drug Rebate Program (MDRP) to provide drug coverage as a benefit that ASES has elected to provide.

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 to avoid delays that may jeopardize the enrollee's life, health, or ability to regain maximum function.

An exception request may be used for a (i) Non-Preferred Drug List (Non-PDL) medications, (ii) medications covered with utilization management edits under the PDL (such as step therapy, quantity or dose limits, or prior authorization requirements), when the prescriber wishes to bypass such restrictions, or (iii) medications that are not part of the MDRP, when alternatives in the PDL and Non PDL are not clinically viable. For those cases in which an exception request is submitted for a drug that is not part of the MDRP, the MCO must encourage the prescriber to

first consider using drugs listed on the PDL and Non PDL. If the prescriber demonstrates that none of the alternatives in the PDL or Non PDL are clinically viable for the patient, then the MCO may consider approving coverage for drugs out of the MDRP drug list.

III. SCOPE:

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

IV. DEFINITIONS:

TERM	DEFINITION
Medicaid Drug Rebate Program (MDRP)	MDRP is a program that includes Centers for Medicare & Medicaid Services (CMS), state Medicaid agencies, and participating drug manufacturers that helps to offset the Federal and state costs of most outpatient prescription drugs dispensed to Medicaid patients. Under the Medicaid Drug Rebate Program, a drug manufacturer must enter into a Medicaid national drug rebate agreement with the Secretary of the U.S. Department of Health and Human Services for states to receive federal funding for using the manufacturer's products. In exchange for the rebates, state Medicaid programs must generally cover all participating manufacturer's drugs when prescribed for a medically accepted indication, although the states may limit the use of some drugs through preferred drug lists, prior authorization, and quantity limits.
Covered outpatient drug	It is a drug that may be dispensed upon prescription and has been approved by the Food and Drug Administration for safety and effectiveness. Covered outpatient drugs do not include drugs provided and billed as part of a bundled service within certain setting such as an inpatient hospital or nursing facility stay. Physician-administered drugs may be eligible for a rebate as long as the drug meets the definition of a covered outpatient drug.
Preferred Drug List (PDL)	The PDL is the list of preferred medications that are part of the MDRP. These medications are evaluated and approved by ASES' Pharmacy and Therapeutics (P&T) Committee to be covered by Vital, though ASES may assign different levels of cost-sharing within the PDL.
Non-Preferred Drug List (Non PDL)	List of medications that are not included in the PDL that are part of the MDRP. Drugs that are not included in the Non PDL may still be covered under the Exception Request, unless excluded from coverage.

Exception Request	A request to obtain coverage by exception of a drug that is not included in Vital's PDL, or to bypass utilization management restrictions that apply to drugs listed on the PDL, Non PDL, and for drugs not part of MDRP. 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 states that certain medications, not otherwise covered under Vital, might be covered through an exception process by which the patient's health care provider must substantiate the clinical need for such exception.

Medications that are part of the MDRP are evaluated and approved by ASES' Pharmacy and Therapeutics (P&T) Committee to be covered by Vital, are classified as preferred drugs, and are part of the PDL, though different levels of cost-sharing may apply. The remaining drugs that are

part of the MDRP not included in the PDL are classified as non-preferred drugs and are part of the Non PDL, though different levels of cost-sharing may apply. The medications that are part of the Non PDL may be covered under special circumstances and will be subject to the MCO's evaluation upon the physician's request for exception, on a case-by-case basis, to determine whether it complies with the protocol established by ASES for Non PDL. If it is not in compliance, the medication will be denied; and if it complies, it will be approved.

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

Certain drugs are considered excluded from coverage and will not be paid for by Vital even if an Exception Request is submitted. For example, under Section 1927(d)(2) of the Social Security Act, Vital 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 (OTC) medications unless, they are specifically included in Vital 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. Furthermore, 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 medications prescribed for the purpose of treating a condition not covered under Vital. In addition, the Puerto Rico Medicaid State Plan excludes certain drugs from coverage, as these drug therapies are covered under other non-Medicaid government health programs. Required medication for the outpatient treatment of Hepatitis C, Spinal Muscular Atrophy (SMA), Cleft palate-cleft lip, Inflammatory Bowel Disease (IBD), Albinism, Rheumatoid Arthritis, Scleroderma, Multiple Sclerosis, Hemophilia, Tuberculosis, Lupus, Pulmonary Hypertension and Primary Ciliary Dyskinesia are included under Special Coverage. Any costs incurred for required medication for the outpatient treatment of Hepatitis C shall be funded through separate payment by ASES to PBM. Treatments indicated for psoriasis, acne, rosacea, or vitiligo are NOT considered cosmetics.

ASES, through its Pharmacy and Therapeutics (P&T) Committee will continue reviewing the PDL and Non PDL from time to time and evaluate additional recommendations on potential cost-saving pharmacy initiatives, including the evaluation of the utilization of high-cost specialty medications and orphan drugs and the exceptions process through which such drugs are to be approved, under the direction and approval of ASES. The Pharmacy Financial committee (PFC) will review some recommendations made by the P&T as per ASES' discretion.

VI. PROCESSING OF REQUESTS FOR EXCEPTION:

If a medication included on the Non PDL is submitted to the Pharmacy Benefit Manager (PBM) for adjudication, the pharmacy will receive the following message at the point of sale: *_Drug on Non-Preferred Drug List (Non PDL). Exception request required. Validate other alternatives in PDL before proceeding.* If a medication is part of MDRP, but not included in the PDL and Non PDL (as determined by ASES) is submitted to the PBM for adjudication, the pharmacy will receive the following message at the point of sale: *Claim reject by non-formulary. For exceptions fax prescription at XXX.XXXX.XXX or call for support at XXX.XXX.XXX* (the fax and phone number will vary by MCO). If a medication that is not part of MDRP is submitted to the PBM for adjudication, the pharmacy will receive the following message at the point of sale: *CMS Non Rebatable NDC. Please resubmit another NDC.*

To request an exception, the prescriber 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 the sections below). If the request includes the documentation described in Section A below, the pharmacy may 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 or by the pharmacy in representation of the patient. The request 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 expected duration of treatment.

3. Incomplete requests that do not include all the information listed in Section A.2 above will be returned by the MCO or pharmacy receiving the request to the prescriber 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 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 prescriber 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, the MCO must authorize at least a 72-hour supply of the requested drug if the drug is not statutorily excluded. An emergency 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 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. 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 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' authorization to grant an extension is delegated to the MCO, if the MCO complies with the intent and purpose set forth in the 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 to collect additional information, such that the extension is in the Enrollee's best interest.

4. 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 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)*. Required information will be requested through fax, email, or by contacting the prescriber. The prescriber will be notified 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 PDL/Non PDL which are contraindicated, patient has experienced or would experience an adverse reaction to PDL/Non PDL drugs, evidence of therapeutic failure after available alternatives on PDL were attempted, drug is not covered in the PDL for a particular diagnosis.

        5) Laboratory results, if requested on clinical protocol for drugs on the PDL or requested by MCO for drugs on Non PDL or Non-Formulary

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 prescriber.

D. Evaluation and Determination

1. The MCO shall first verify that:

a. The request is for a drug:

i. A) That is included on the PDL with certain clinical or other utilization management restrictions that the prescriber seeks to bypass through an exception, B) Included in the Non PDL, C) Not included in the PDL and Non PDL specified by ASES (Non-formulary), or D) Not included on the MDRP drug list 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.

b. If the physician is requesting a PDL alternative:

i. The MCO shall verify that the prescribed drug complies with the clinical protocol established by ASES for drugs included in the PDL and is consistent with general medically accepted guidelines.

ii. If the prescriber seeks to bypass other utilization management restrictions where a clinical protocol is not available (quantity limit, age limit etc.), a supporting statement is required setting forth the clinical reason(s) that the requested prescription drug is medical necessary.

c. If the physician is requesting a Non PDL alternative (Exhibit A):

i. The MCO shall first confirm if it is the first time the patient will be using the prescribed medication by validating the patient medical record, previous authorization, or pharmacy printout. If it is not the first time a patient is using the prescribed medication, but the patient is new to Vital Health Plan the following also applies.

1) The prescriber must provide a supporting statement setting forth the clinical reason(s) that the requested prescription drug is medically necessary to treat the patient's disease or medical condition. The supporting statement must indicate that the requested prescription drug is medically necessary because it complies with at least one (1) of the statements below:

a. All PDL 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 contraindications, or that the prescriber provide scientific literature showing the strong possibility of serious adverse health effects because of taking the PDL alternatives; or

b. Patient has experienced a serious adverse reaction to all the alternative drugs that appear in the PDL; or

c. Therapeutic failure of all available alternatives in the PDL, either because these alternatives were ineffective or would adversely affect the health or condition of the patient.

ii. If it is not the first time the patient is using the prescribed medication and the patient is not new to Vital Health Plan (including those members that changed to any of the GHIP MCOs):

1) The exception request could be granted if the patient received previous approval by the exception process and patient has use within the past 90 days. Previous approval can be confirmed by evidence of paid claims, pharmacy printouts, or previous authorization.

a. If a patient does not fulfill one of the criteria mentioned, the prescriber will need to justify the use of the medication with the requisites mentioned in section D.1.c.i.

d. If the physician is requesting an alternative not listed on the PDL or Non PDL (Non formulary) or the medication is not part of MDRP (Exhibit A):

i. The MCO shall first confirm if it is the first time the patient will be using the prescribed medication by validating by patient medical record, previous authorization, or pharmacy printout. If it is not the first time a patient is using the prescribed medication, but the patient is new to Vital the following also applies.

1) The prescriber must provide a supporting statement setting forth the clinical reason(s) that the requested prescription drug is medically necessary to treat the patient's disease or medical condition. The supporting statement must indicate that the requested prescription drug is medically necessary because it complies with at least one (1) of the statements below:

a. All PDL and Non PDL 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 contraindications, or that the prescriber provide scientific literature showing the strong possibility of serious adverse health effects because of taking the PDL and Non PDL alternatives; or

b. Patient has experienced a serious adverse reaction to the alternative drugs that appear in the PDL and Non PDL; or

Therapeutic failure of all available alternatives on the PDL and Non PDL, either because these alternatives were ineffective or would adversely affect the health or condition of the patient. ii. If it is not the first time the patient is using the prescribed medication and the patient is not new to

Vital Health Plan (including those members that changed to any of the GHIP MCOs):

1) The exception request could be granted if the patient received previous approval by the exception process and patient has use within the past 90 days. Previous approval can be confirmed by evidence of paid claims, pharmacy printouts, or previous authorization.

    a. If a patient does not fulfill one of the criteria mentioned above the prescriber will need to justify the use of the medication with the requisites mentioned in section D.1.d.i.

2. The supporting statement to set forth the medical necessity of the drug can be submitted as an oral or written statement within 72 hours.

3. During the evaluation process, the MCO's clinical reviewer will conduct a 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 prescriber.

    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 prescriber 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 PDL and Non PDL 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 decide, 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 process in section D, it will be denied by the MCO's authorized clinician reviewer.

   a. The prescriber, 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 prescriber 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 prescriber of the approval. An approval letter will also be mailed within three (3) business days after the patient's verbal notification. This same letter will be sent via fax or email to the prescriber and pharmacy.

3. If a requested medication is approved through an exception, that approval will be valid for the duration indicated by the prescriber 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 PDL or Non PDL 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 Vital, and

   b. The prescriber 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.

F. Case Evaluation for a Medication on Shortage

1. A drug shortage is confirmed at the following FDA or ASHP websites:

a. https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm

b. https://www.ashp.org/drug-shortages/current-shortages

2. The shortage process:

a. The following process will be applicable for the requested Non PDL or Non formulary medication when the drug information received states that the drug is being requested because the alternative PDL medication is currently in shortage. The shortage process does not apply to drugs excluded from the Social Security Act.

b. The MCO confirms the Non PDL or Non-Formulary requested drug is listed as a drug shortage at the FDA or ASHP websites. This is considered a nationwide drug shortage.

i. If the requested drug is not listed at the FDA or ASHP websites, it would be considered a local drug shortage due to the PDL medication not being available at the drugstore that supplies the pharmacy.

c. If the drug shortage is nationwide, the MCO will validate the diagnosis and the request medication will be evaluated through the medication exception request process.

i. If there are other alternatives in the PDL for the diagnosis prescribed, the MCO will offer other PDL alternatives to the prescriber.

ii. The MCO determines if there are no other available alternatives in the PDL for the diagnosis prescribed, the most cost-effective alternative can be approved for three

(3) months. When necessary, the PBM will perform an analysis and provide recommendations to ASES. If there is any change to formulary, the same utilization management edits will apply to the new medication as the product impacted, and it will be notified by Normative Letter.

d. If it is a local drug shortage, the MCO will validate the diagnosis and the request will be evaluated through the medication exception request process:

   i. The MCO will request the pharmacy to provide written evidence of the drug shortage of at least two (2) drugstores that supply the pharmacy. The MCO will attach any information provided by the pharmacy to the patient's case.

   ii. If there are other alternatives in the PDL for the diagnosis prescribed, the MCO will offer PDL alternatives to the prescriber.

   iii. If there are no other available alternatives in the PDL for the diagnosis prescribed and the pharmacy provides evidence of local drug shortage, the most cost-effective alternative can be approved for three (3) months. If evidence of local drug shortage is not received, the case will be denied. When necessary, the PBM will perform an analysis and provide recommendations to ASES. If there is any change to formulary, the same utilization management edits will apply to the new medication as the product impacted, and it will be notified by Normative Letter.

e. This drug shortage process will be integrated in the RxPath Exception Process Protocol.

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 prescribers 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. 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 prescribers to look up applicable requirements. ASES recommends publishing the same.

Q: Does the pharmacy notify the enrollee of the exclusion of the drug from PDL and Non PDL? 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 prescriber 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?

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 PDL and Non PDL managed?

A: They will be reviewed like any other 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 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 prescriber 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 prescriber 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 prescriber 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 decide, 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?

A: No, the 14-day and 72-hour timeframe only applies in Managed Medicaid for all other types of authorization requests <u>except</u> 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 prescriber 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.

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 prescriber and the pharmacy.

Effectuation of an Approved Exception Request

Q: Does an approved exception request ever expire? Please clarify the timeframe during which 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 specialties?

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.

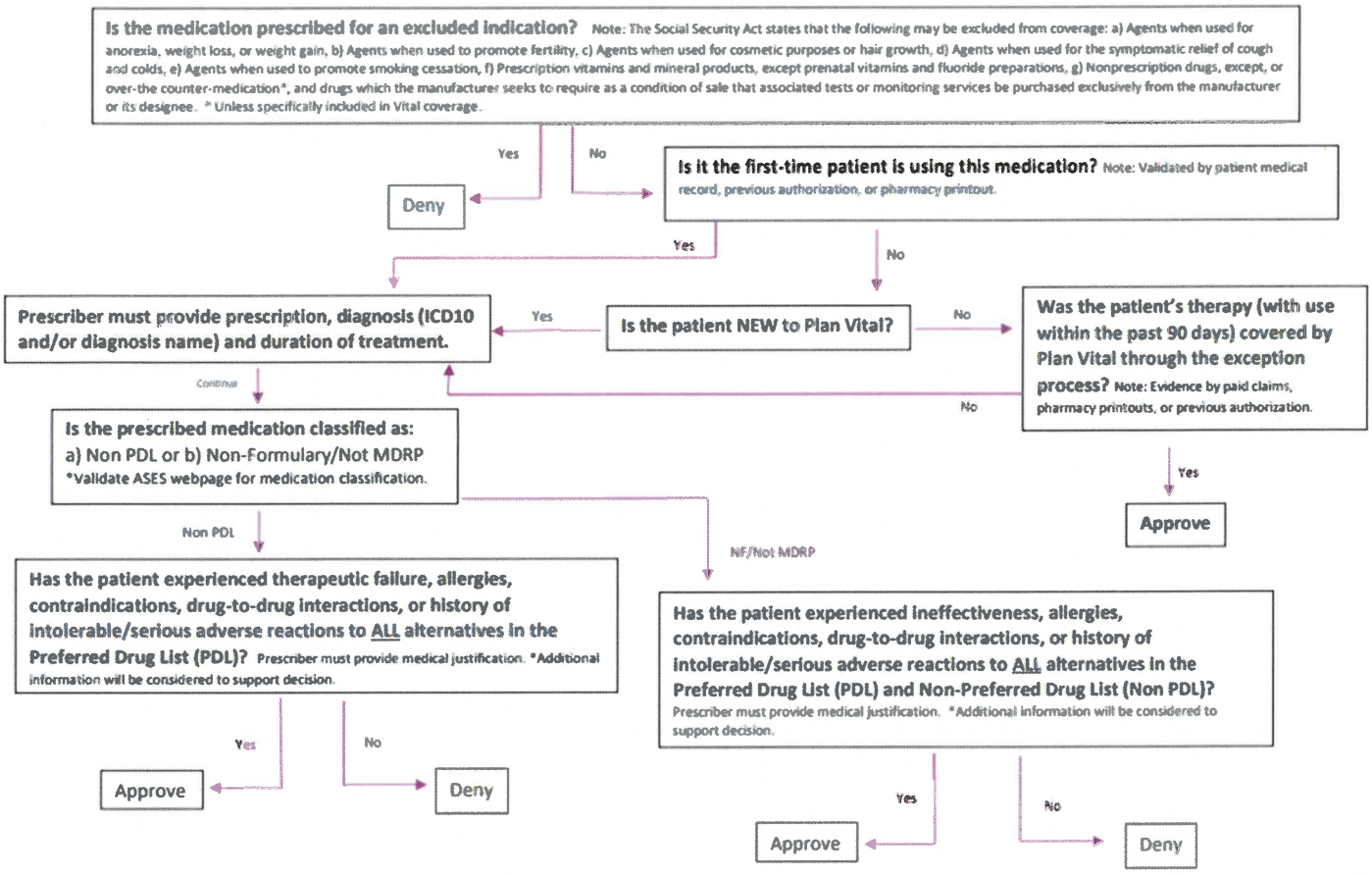
Q: While the approval for the exception is valid, who decides if a drug continues to be safe for the treatment of the patient's condition?

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 consider 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.

Exhibit A: Flowchart of Non PDL and Non-Formulary Drugs Evaluation Process



Reviews and Approvals

Update	Section Review	Modification and Reason
5/17/2024	-Background Section, Page 4 -Case Evaluation for a Medication on Shortage, Page 13	**Language related to Not cosmetic medications was incorporated.** **Shortage process was incorporated.**
1/18/2023	-Entire document	**MDRP language was incorporated to the entire document.**