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. 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?

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?

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.

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.