



## Clinical Operations Prior Authorizations, Exceptions and Appeals Programs

*All timeframes and processes contained in this document refer to CVS Caremark® standard protocols based on federal laws and regulations. Timeframes and processes may vary based on client requirements or state regulations.*

CVS Caremark may be delegated to perform prior authorizations (PA), exceptions or appeals on behalf of our clients. CVS Caremark and the client will enter into a mutually agreed upon written contract, which defines the requirements for processing PAs, exceptions and/or appeals on the client's behalf. The client provides CVS Caremark with a copy of its Summary Plan Description, including the Prescription Benefit section that describes the prescription benefits to plan members. Employees of CVS Caremark may not participate in a PA, exceptions or appeals review if there is a personal, professional or financial conflict of interest with the claimant.

CVS Caremark may, depending on the client's plan, conduct two types of reviews: Clinical and Non-Clinical Reviews.

- An **Initial Clinical Review** is an initial review of a request for a drug covered by the terms of the Plan when clinically appropriate, including but not limited to PA, step therapy, formulary exceptions and quantity limit exceptions. CVS Caremark will conduct an Initial Clinical Review utilizing the rules, guidelines, protocols or criteria for coverage adopted by or provided by the Plan and as set forth in the Plan Design Document (PDD).
- An **Initial Non-Clinical Review** is an initial review of a request for a drug not covered by the terms of the Plan, including the PDD, the preferred drug lists, formulary or other plan benefits selected by the client. An Initial Non-Clinical Review does not involve an assessment of whether the requested drug is medically necessary.

### **Initial Clinical Reviews**

#### **Prior Authorization Program**

PA is available as a stand-alone service to clients. It may also be provided in conjunction with quantity limits or step therapy protocols when a member fails to meet the requirements for these programs. Prescription claims are processed at the point of sale by the adjudication system to determine if the claim is subject to a PA. If the claim is subject to a PA, a reject message will display informing the dispensing pharmacy to have the prescribing practitioner contact the CVS Caremark PA Department.

A PA may be initiated by phone call, fax, electronic request or in writing to CVS Caremark by a member's prescribing physician or his/her representative. A member or pharmacist may initiate a PA by calling the PA department, who will reach out to the prescribing physician to obtain the necessary information or they will be instructed to have the member's physician or designated representative contact CVS Caremark directly. Phone calls received during regular business hours will be routed directly to the CVS Caremark PA team.

If the call is received outside of business hours, the caller will be prompted to call back during regular business hours if it is a non-urgent request. If the request is urgent, the automated system will advise the caller to hold for the answering service. The service will then contact the PA department for the on-call pharmacist to process the request within the allowable timeframe.

Once CVS Caremark has received a request, the PA department will check to determine if a new PA is still required and will review the member's PA history for duplicate or pending requests.



The PA request is evaluated using client-approved criteria. A decision will be made solely on the clinical information available at the time of the review.

PAs are processed within the following timeframes:

- **Urgent requests** from the member's physician are processed within 72 hours from receipt of the request. However, the CVS Caremark standard is to complete the review within 24 hours from receipt of all necessary information.
- **Non-urgent requests** are processed within 15 days from receipt of the request. However, the CVS Caremark standard is to complete the review within 72 hours from receipt of all necessary information.

If the information provided is incomplete, and if time permits based on state or federal regulations, the PA department will request the additional information from the physician's office. Once the physician's office provides CVS Caremark with the required information, the original PA is reviewed to make a determination. If the required information is not provided, the PA will be denied.

If the PA is approved, the technician enters the documentation and applicable overrides into the CVS Caremark authorization system. A test claim is processed to ensure the claim will pay when the member fills the prescription at the pharmacy. Approval letters are generated and faxed to the physician and mailed to the member.

If the PA does not meet the criteria requirements as required by the plan or state rules, the appropriate clinical reviewer will deny the PA request. Denial letters are generated and faxed to the physician and mailed to the member. Denial letters include directions on how to appeal the denial.

CVS Caremark PA activity reporting is available, if requested by the client.

### **Exceptions Program**

A standard exceptions program is available to support client requests to make exceptions to certain aspects of a client's plan design. Exception requests will only be considered if, and to the extent that, a plan allows exceptions.

Exceptions are available for covered and non-covered medications. For the latest list of available exceptions, refer to the Clinical Plan Management (CPM) form.

Examples of **exceptions for covered drugs** include but are not limited to the following:

- **Brand Penalty:** Request to allow a member to waive the dispense as written (DAW) penalty for a brand-name medication
- **Tiering:** Request to allow a member to have a non-preferred medication at the preferred copay (e.g., third-tier medication at the second-tier copay)
- **Mandatory Mail:** Request to allow a member of a plan that mandates the use of mail service or Maintenance Choice® at CVS Pharmacy® the ability to fill maintenance medications at a retail pharmacy on a long-term basis
- **Cost Exceeds:** Request for coverage of a medication that exceeds the plan's maximum dollar amount per claim
- **Contraceptive Zero Copay (Health Care Reform):** Request to allow a member to receive a contraceptive product for a zero dollar member cost share
- **Preventive Services Zero Copay (Health Care Reform):** Request to allow a member to receive a preventive service product (excluding contraceptives) for a zero dollar member cost share
- **Preventive Breast Cancer Zero Copay (Health Care Reform):** Request to allow a member to receive tamoxifen or raloxifene for a zero dollar member cost share



Examples of **exceptions for non-covered drugs** include but are not limited to the following:

- **Formulary Exceptions:** Request to allow a member to have formulary coverage for a drug currently not covered by the CVS Caremark formulary
- **Compound:** Request to allow coverage of a compounded drug product that contains ingredients excluded from the pharmacy benefit
- **Management of Selected Unapproved Products:** Request to allow a member to have coverage for select products excluded from the pharmacy benefit
- **Miscellaneous Formulations:** Request to allow a member to have coverage of select products excluded from the pharmacy benefit

Exception requests may be initiated by contacting Customer Care or submitting a request in writing to the Exceptions department. If the request is initiated by phone, an exceptions fax form or electronic PA (ePA) request will be sent to the physician's office.

The exception fax form or ePA is completed by the member's physician and returned to the Exceptions department. A letter of medical necessity from the physician is also acceptable for exceptions reviews. The exceptions request is reviewed against the supporting criteria.

If the exception is approved, the technician enters the documentation and applicable overrides into the CVS Caremark authorization system. A test claim is processed to ensure the claim will pay when the member fills the prescription at the pharmacy. Approval letters are generated and faxed to the physician and mailed to the member.

If the exception does not meet the criteria requirements as required by the plan or state rules, the appropriate clinical reviewer will deny the exceptions request. Denial letters are generated and faxed to the physician and mailed to the member. Denial letters include directions on how to appeal the denial.

Exceptions are processed within the following timeframes:

- **Urgent requests** from the member's physician are processed within 72 hours from receipt of the request. However, the CVS Caremark standard is to complete the review within 24 hours from receipt of all necessary information.
- **Non-urgent requests** are processed within 15 days from receipt of the request. However, the CVS Caremark standard is to complete the review within 72 hours from receipt of all necessary information.

## **Initial Non-Clinical Reviews**

An Initial Non-Clinical Review is a request for coverage of medications or benefits that are not subject to a PA or an exception but are not covered by the Plan. Examples include, but are not limited to, non-covered medications, diabetes supplies and medical devices. A decision is based solely on the terms of the Plan, including the PDD, the preferred drug lists, formulary or other plan benefits selected by the client. An Initial Non-Clinical Review does not involve a clinical review or an assessment of whether the requested drug is medically necessary.

## **Appeals Program**

Once a member or member's representative is notified that a claim is wholly or partially denied (an adverse determination), he or she has the right to appeal. Appeals may be based on an adverse benefit determination from an initial clinical review or an adverse non-clinical determination from an initial non-clinical review. Appeal requests must be submitted to the Appeals department by fax, mail or phone within 180 days after receiving an adverse determination notification. Urgent appeals may be submitted by phone or in writing. Non-urgent appeals may be submitted in writing by fax or mail.



Once an appeal is received, the appeal and all supporting documenting are reviewed and completed, including a notification to the member and physician, within the following timelines:

- Urgent Pre-Service Appeal: 72 hours
- Non-Urgent Pre-Service Appeal:
  - For plans with one level of appeal: 30 days
  - For plans with two levels of appeal: 15 days
- Post-Service Appeal: 30 days

## **Review of Adverse Benefit Determinations**

### **First-Level Clinical Appeal**

First-level appeals are reviewed against predetermined medical criteria relevant to the drug or benefit being requested. This includes the consideration of relevant and supporting documentation submitted by the member or the member's authorized representative. Supporting documentation may include a letter written by the practitioner in support of the appeal, a copy of the denial letter sent by CVS Caremark, a copy of the member's payment receipt, medical records, etc. The appeal will be reviewed by an appropriately qualified reviewer. If the denial is upheld by the appeal, a denial notification will be sent to the member with instructions on how to request a second-level Medical Necessity review.

If a member's appeal is urgent, CVS Caremark will perform both the first-level and second-level review as a combined appeal review within the designated timeframes. If the first-level request is approved, no further review is required and a notice of approval will be sent to the member. If the first-level review cannot be approved, a second-level Medical Necessity review will be initiated automatically. The member will receive notice of the determination at the conclusion of the Medical Necessity review. The two levels are combined in order to meet the designated urgent appeal timeframe.

### **Second-Level Medical Necessity Appeals**

If the first-level appeal denial is upheld, the member or the member's authorized representative may choose to pursue a second-level appeal. The second-level appeal consists of a review to determine if the requested drug or benefit is medically necessary. These requests are reviewed either by an appropriately qualified reviewer or a sub-delegated medical necessity review organization (MNRO). If a member's appeal is urgent, CVS Caremark will perform the second-level review within the designated urgent appeal timeframe.

For appeals reviewed by the MNRO, the following will occur:

- CVS Caremark will forward applicable medical records, PA and appeals documentation, plan language and specific criteria to the MNRO.
- The independent physician reviewer selected by the MNRO to conduct the review will evaluate the provided documentation received with the case. If the physician reviewer determines additional information is necessary or potentially useful in the review, the physician reviewer may contact the member's physician to request such information.
- The independent physician reviewer will review current medical literature and available medical records and any additional information obtained from the prescribing physician. The independent physician reviewer will write an independent rationale in support of his or her final decision.
- The letter containing the rationale will be forwarded to CVS Caremark for communication to the member or the member's representative.



## Review of Adverse Non-Clinical Determinations

CVS Caremark provides a single-level appeal for non-clinical appeals. Upon receipt of a non-clinical appeal, CVS Caremark will review the member's request for a particular drug or benefit against the terms of the Plan, including the preferred drug lists, formularies or other defined plan benefits selected by the Plan Sponsor or in the PDD. A non-clinical appeal will not involve an assessment of whether the requested drug or benefit is medically necessary.

## Appeal Determination Process

Appeals and associated documentation are stamped with the date and time of receipt. Reviews are conducted within the applicable timeframes previously mentioned in this document. The appeal determination is rendered, and pertinent information is entered into the database. The determination is then communicated in writing to the member or the member's representative.

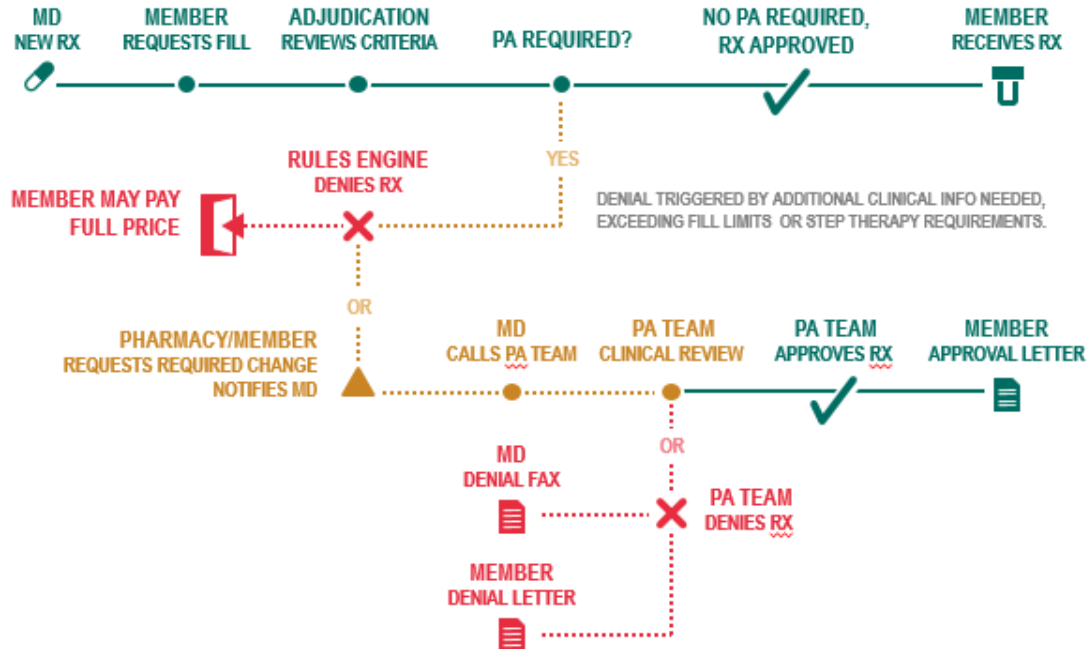
Communications are written in a manner to be understood by the member or the member's representative. Communications include:

- The specific reason(s) for the determination
- A reference to pertinent Plan provision on which the determination was based
- A notice that the member can submit a written request for the following at no cost: copies of all documents, records and other information relevant to the claim
- A copy of the specific rule, guideline, protocol or other similar criterion that was relied upon in making the determination, if applicable; or a statement that such rule, guideline, protocol or other similar criterion will be provided free of charge upon written request
- An explanation of the scientific or clinical judgment for the determination, applying the terms of the Plan to the member's medical circumstances, if the Adverse Benefit Determination or Appeal of Adverse Benefit Determination is based on a Medical Necessity; or a statement that such explanation will be provided free of charge upon written request
- A statement of the member's right to bring action under (Employee Retirement Income Security Act) ERISA Section 502(a), if applicable
- A description of the available internal appeals process and external review process, if available
- Information regarding the applicable office of health insurance consumer assistance or ombudsman established under the Section 2793 of the Public Health Services Act to assist individuals with internal claims and appeals and external review

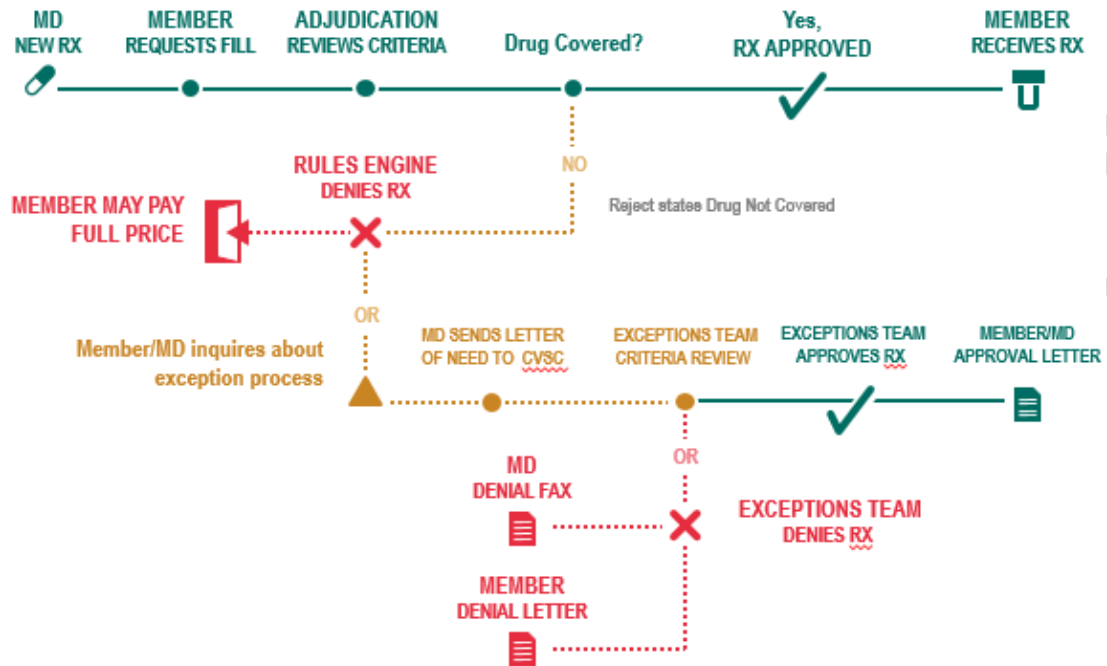
## Confidentiality

All member and client appeal documentation is handled in a confidential manner and in accordance with applicable statutes and regulations to protect the member's identity and his or her prescription history. To maintain confidentiality of member information, all appeal information becomes a part of a permanent case file.

## Prior Authorization Process



## Exceptions Example – Drug Not Covered



## Commercial Appeals High-Level Process Map

