Policy and Procedure

Policy Name: Procedures for Pharmaceutical Management of Medically Administered Pharmaceuticals	**Policy#:** UM-110	**Version#:** 2
Author Department: Utilization Management	**Origination Date:** 08/01/2025	
Business Units Impacted: Utilization Management	**Date Last Reviewed:** 05/31/2026	
Products/LOBs: CHP+	**Date Approved by CPT:** 06/11/2026	

DEFINITIONS:
CHP+: Child Health Plan Plus

Class I recall: Removal of a distributed product due to reasonable probability that use of or exposure to the product will cause serious, adverse health consequences or death.

Class II recall: Removal of a distributed product where use of or exposure to the product may cause temporary or medically reversible adverse health consequences or where the probability of serious, adverse health consequences is remote.

Market withdrawal: Removal or correction of a distributed product which involves a minor violation that would not be subject to legal action by
the FDA.

SCOPE:
Applies to all medically administered pharmaceuticals (J-codes and Q-codes) covered under the plan's medical benefit. All other pharmaceuticals covered under the pharmacy benefit are managed by Colorado Access's pharmacy benefit manager.

STATEMENT OF POLICY:
Develop, implement, and maintain comprehensive procedures for the clinical, operational, and financial management of medically administered pharmaceuticals covered under the medical benefit, including prior authorization, medical necessity review, benefit determination, coding validation, provider communication, appeals support, regulatory compliance, quality oversight, and ongoing monitoring to ensure safe, appropriate, cost-effective, and consistent administration of covered pharmaceutical therapies.

PURPOSE:
To ensure clinically appropriate, evidence-based management of medically administered pharmaceuticals and compliance with regulatory notification, safety, and utilization management requirements.

Roles & Responsibilities
- **Chief Medical Officer**: Oversees development and review of pharmaceutical management procedures.
- **Pharmacy Team**: Audits pharmacy benefit manager (PBM) for compliance, manages medically administered pharmaceuticals medical necessity reviews and appeals, completes

Policy Name: Procedures for Pharmaceutical Management of Medically Administered Pharmaceuticals	**Policy#:** UM-110	**Version#:** 2
Author Department: Utilization Management	**Origination Date:** 08/01/2025	
Business Units Impacted: Utilization Management	**Date Last Reviewed:** 05/31/2026	
Products/LOBs: CHP+	**Date Approved by CPT:** 06/11/2026	

appeals related to denials issued by PBM, develops clinical criteria and pharmaceutical management procedures.
- **Quality Management Committee**: Reviews and approves clinical criteria and updates (medically administered drugs)
- **Pharmacy and Therapeutics Committee:** An independent group of clinical experts that objectively reviews and evaluates drugs to be considered for the Colorado Access Drug Lists (pharmacy benefit)

PROCEDURES:

A. Pharmaceutical Management Procedures

1. Colorado Access maintains policies and procedures for pharmaceutical management for pharmaceuticals that fall under the medical benefit (J-codes and Q-codes), as outlined below. Colorado Access's pharmacy benefit manager maintains policies and procedures for pharmaceutical management for pharmaceuticals covered under the pharmacy benefit. Colorado Access is responsible for distributing all procedures to network practitioners.

2. Criteria for Procedures
    a. The following criteria are used when adopting pharmaceutical management procedures:
        - Pharmaceutical classes.
        - Classes preferred or covered at any level.
        - Lists of preferred pharmaceuticals or formularies.
        - Considerations for limiting access to drugs in certain classes.
        - Prior authorization criteria.
        - Generic substitution, therapeutic interchange, step therapy or other management methods to which the practitioner's prescribing decisions are subject.
        - Within each class of pharmaceuticals:
            - Pharmaceuticals preferred or covered at any level.
            - An exceptions process available to members.
            - Substitutions made automatically or with permission of the prescribing practitioner.
            - Evidence that preferred-status pharmaceuticals can produce similar or better results for a majority of the population than other pharmaceuticals in the same class.

- Other requirements, restrictions, limitations or incentives that apply to the use of certain pharmaceuticals.

3. Use of Clinical Evidence
    a. Pharmaceutical decisions are made using clinical evidence from the following sources, as appropriate:
        - National guidelines/government agencies (i.e., FDA label, etc.).
        - Peer reviewed literature and specialty society recommendations.
        - Authoritative compendia.
        - Medical associations.
        - National commissions

4. Involvement of Pharmacists and Appropriate Practitioners
    a. Pharmaceutical management policies and procedures are reviewed and updated, as needed, on a quarterly basis via the Quality Management Committee.
    b. The Quality Management Committee is comprised of local appropriate physicians and clinical pharmacists with appropriate clinical expertise.

5. Distribution of Procedures
    a. Pharmaceutical management procedures are made available to practitioners online via Colorado Access' website. Practitioners are notified that the information is online via the provider newsletter. Practitioner notification includes a link or clear instructions on how to access the information on the website.
    b. If a practitioner does not have access to fax, email, or internet, pharmaceutical management procedures will be mailed to the practitioner's mailing address upon request.

B. Pharmaceutical Restrictions/Preferences

1. Colorado Access communicates the following, annually and within 30 calendar days in advance of updates, to members and prescribing practitioners:
    a. List of medically administered pharmaceuticals covered, including restrictions and preferences
    b. How to use the pharmaceutical management procedures.
    c. Explanation of limits or quotas.
    d. How prescribing practitioners must provide information to support exception request requirements/process.

Policy Name: Procedures for Pharmaceutical Management of Medically Administered Pharmaceuticals	**Policy#:** UM-110	**Version#:** 2
Author Department: Utilization Management	**Origination Date:** 08/01/2025	
Business Units Impacted: Utilization Management	**Date Last Reviewed:** 05/31/2026	
Products/LOBs: CHP+	**Date Approved by CPT:** 06/11/2026	

e. Generic substitution, therapeutic interchange, and step-therapy protocols and processes.

2. On an annual basis, Colorado Access distributes pharmaceutical procedures and updates to members through the Annual Notice of Changes and Member Handbook, as well as the Member Newsletter. Colorado Access distributes pharmaceutical procedures and updates to practitioners through the Provider Newsletter. Practitioner notification includes a link or clear instructions on how to access the information on the website.

3. Within 30 days in advance of updates, Colorado Access's pharmacy benefit manager distributes letters to members and practitioners indicating the changes for pharmaceuticals covered under the pharmacy benefit. Within 30 days in advance of updates, Colorado Access distributes letters to members and prescribing practitioners for pharmaceuticals covered under the medical benefit. For pharmaceuticals covered under the pharmacy benefit, the communication of changes is limited to "negative" formulary changes to affected members and their practitioners.

C. Pharmaceutical Patient Safety Issues

1. Colorado Access is responsible for identifying and notifying members and prescribing practitioners affected by recalls related to pharmaceuticals covered under the medical benefit, as outlined below. Colorado Access's pharmacy benefit manager is responsible for identifying and notifying members and prescribing practitioners affected by recalls for pharmaceuticals covered under the pharmacy benefit.

D. <u>Class II Recalls, Class I Recalls, and Market Withdrawal</u>

1. Processing Speed
   a. For medically administered pharmaceuticals affected by a Class II recall or voluntary drug withdrawals from the market for safety reasons, Colorado Access notifies affected members and prescribing practitioners within 30 calendar days of the FDA notification.
   b. For medically administered pharmaceuticals within the medical benefit affected by a Class I recall, COA notifies members and prescribing practitioners in an expedited manner, as soon as reasonably possible after the notice is received from the FDA.

2. COA Procedure for Member and Provider Notification
   a. Upon identification of a recall/market withdrawal notification (FDA, manufacturer, or regulatory source), the Pharmacy team confirms classification (Class I/II) and scope.

Policy Name: Procedures for Pharmaceutical Management of Medically Administered Pharmaceuticals	**Policy#:** UM-110	**Version#:** 2
Author Department: Utilization Management	**Origination Date:** 08/01/2025	
Business Units Impacted: Utilization Management	**Date Last Reviewed:** 05/31/2026	
Products/LOBs: CHP+	**Date Approved by CPT:** 06/11/2026	

b. COA notifies affected members that it can identify. Affected members and prescribing practitioners are identified using batch or lot numbers or NDC codes of the withdrawn or recalled pharmaceuticals.
c. Communication to affected members will follow the letter template and includes:
    - The name of the drug/pharmaceutical.
    - The date of the withdrawal/recall.
    - The reason for the withdrawal/recall.
    - Relevant instructions for returning the pharmaceutical to the pharmacy and/or seeing the prescribing provider for directions or a new prescription.
d. Communication to affected practitioners will follow the letter template and includes:
    - The name of the pharmaceutical.
    - The date of the withdrawal/recall.
    - Patients affected (if known).

E. Review and Update of Procedures and Drug Lists

1. Annual Review Schedule
    a. The medically administered pharmaceuticals management policies and procedures, along with the list of covered medical administered pharmaceuticals, are reviewed and updated on an intermittent basis over the course of each calendar year, with all components completed at least annually.
    b. Procedural Review: Clinical management procedures related to medically administered pharmaceuticals utilization (e.g., prior authorization criteria, step therapy, exception handling) are reviewed annually by the Quality Management Committee and updated as appropriate.
    c. Drug List Review: The injectable formulary and associated restrictions or preferences are reviewed and updated at least annually, or sooner as required by regulatory, safety, or clinical developments.
    d. Pharmaceutical management policies and procedures, along with the list of covered medically administered pharmaceuticals, are managed by the Quality Management Committee.
    e. The Quality Management Committee is comprised of local physicians and pharmacists with appropriate clinical expertise.
    f. PBM recommendations for UM criteria and pharmaceutical management policies that apply to pharmaceuticals covered under the pharmacy benefit, along with the list of covered pharmaceuticals, are brought to COA Pharmacy and Therapeutics Committee for final approval.

Policy and Procedure

Policy Name: Procedures for Pharmaceutical Management of Medically Administered Pharmaceuticals	**Policy#:** UM-110	**Version#:** 2
Author Department: Utilization Management	**Origination Date:** 08/01/2025	
Business Units Impacted: Utilization Management	**Date Last Reviewed:** 05/31/2026	
Products/LOBs: CHP+	**Date Approved by CPT:** 06/11/2026	

REFERENCES:
None

ATTACHMENTS:
None

POLICY HISTORY:
SUMMARY OF REVIEW/REVISION/APPROVAL DATES: Version 1: 08/01/25, New policy, Version 2: 06/11/26 Clarification on pharmaceutical oversight, notification requirements, and recall procedures.

APPROVAL BODY: COA Core Policy Team **APPROVAL DATE**: 06/11/2026

****Confidential & Proprietary****