Policy and Procedure

Policy Name: Medication Utilization Review-Considering Exceptions	**Policy#:** UM-111	**Version#:** 1
Author Department: Utilization Management	**Origination Date:** 09/01/2025	
Business Units Impacted: Pharmacy Department,	**Date Last Reviewed:** 10/31/2025	
Products/LOBs: CHP+ HMO, CHP+	**Date Approved by CPT:** 10/31/2025	
	NCQA: UM11E	

DEFINITIONS:

Compendia

Summaries of drug information that are compiled by experts who have reviewed clinical data on drugs. Compendia are used for evaluation of FDA-approved indications (labeled use) and off-label use of drugs. Compendia include, but are not limited to, Micromedex, DrugDex, and the National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium.

Compendia Support

The compendia listed above will be accepted at the following levels:

1. **NCCN Drugs and Biologics Compendium** – indication support is Category 1 or 2A.
2. **Micromedex DrugDex®** – indication support is Class I, Class IIa, or Class IIb.
3. **Wolters Kluwer Lexi-Drugs®** – indication listed as "Use: Off-Label" and rated as "Evidence Level A" with a "Strong" recommendation for inclusion.
4. Peer-reviewed medical literature including scientific, medical, and pharmaceutical publications to establish a community standard of care.

Coverage Determination

Any determination made with regard to:

1. A decision about whether to provide or pay for a medication that the enrollee believes may be covered by the plan. A decision not to pay may be made if:
    a. The provider does not provide a clinically sound rationale as to why formulary alternatives cannot be tried or would not be appropriate for the patient to try.
    b. The drug is determined not to be medically necessary.
    c. The drug is furnished by an out-of-network pharmacy.
    d. The drug is not written by a validated provider, or
    e. The drug is otherwise excluded by regulation.
2. A decision concerning a tiering exception request.
3. A decision concerning a formulary exception request.
4. A decision on the amount or cost-sharing for a drug.
5. A decision whether an enrollee has, or has not, satisfied a prior authorization or other utilization management requirement, including quantity limits and step therapy.

Specialty Pharmaceutical / Medication

A legend drug that requires a prescription, or any mixture or compound containing a minimum of

Policy Name: Medication Utilization Review-Considering Exceptions	**Policy#:** UM-111	**Version#:** 1
Author Department: Utilization Management	**Origination Date:** 09/01/2025	
Business Units Impacted: Pharmacy Department,	**Date Last Reviewed:** 10/31/2025	
Products/LOBs: CHP+ HMO, CHP+	**Date Approved by CPT:** 10/31/2025	
	NCQA: UM11E	

one prescription ingredient that meets the following:

- Is only available through one or more specialty pharmacies; OR
- Meets at least 4 of the following 10 criteria:
    1. Drug meets the CMS minimum cost threshold for the specialty tier.
    2. Drug is a complex, large molecule or a biological/biopharmaceutical/biotech product.
    3. Drug is used to treat a small population with a rare and/or chronic disease.
    4. Special patient storage and handling requirements (such as refrigeration, freezing, HAZMAT, etc.) or requires special shipping and handling to get to the patient.
    5. Drug requires unique or complex administration, such as an injectable product or administration under provider supervision.
    6. Disease state needs to be closely supervised or monitored, including frequent follow-up.
    7. Drug therapy requires strict adherence or an adherence program for efficacy.
    8. Drug therapy requires safety monitoring for potential adverse effects.
    9. Initiated by or in consultation with a specialist.
    10. Drug is a part of a Risk Evaluation and Mitigation Strategy (REMS) program.

SCOPE:
Colorado Access will ensure consistent evaluation and determination of medication authorization requests.

PURPOSE:
The organization has pharmaceutical management procedures that promote the clinically appropriate use of pharmaceuticals.

STATEMENT OF POLICY:
Colorado Access ensures that medications are used safely, effectively, and in alignment with evidence-based clinical criteria. Utilization management processes—such as prior authorization, quantity limits, step therapy, and exception reviews—are applied consistently across all medications. Coverage determinations are issued timely and in accordance with state and federal requirements, with clear notifications to members and providers. Exceptions are considered when clinical documentation demonstrates medical necessity or formulary

Policy Name: Medication Utilization Review-Considering Exceptions	**Policy#:** UM-111	**Version#:** 1
Author Department: Utilization Management	**Origination Date:** 09/01/2025	
Business Units Impacted: Pharmacy Department,	**Date Last Reviewed:** 10/31/2025	
Products/LOBs: CHP+ HMO, CHP+	**Date Approved by CPT:** 10/31/2025	
	NCQA: UM11E	

alternatives are inappropriate.

PROCEDURES:

1. General Information and Procedures

A. Colorado Access will provide timely standard and expedited coverage determinations in accordance with exceptions policies/criteria and Department of Insurance (DOI). Colorado Access does not consider the presentation of a prescription at the pharmacy counter as a request for a coverage determination. Written information will be provided to enrollees about coverage determinations, appeals, formulary, or cost-sharing status of drugs at initial enrollment, upon request, or upon notification of an adverse coverage determination/denial. Criteria used are the same whether the drug is being used for medical or behavioral treatment.

B. All medications follow an identical process for evaluating appropriateness for formulary placement and potential utilization management requirements, regardless of medication category. Colorado Access and its Pharmacy Benefit Manager (PBM) evaluate several elements, including but not limited to clinical indications, clinical effectiveness, potential side effects, age appropriateness, cost, and available rebates when presenting recommendations to the COA Pharmacy and Therapeutics Committee (P&T) for formulary placement and utilization management requirements.

C. All medications identified in the CHP+ formulary (available at www.coaccess.com) are included in the Colorado Access Pharmacy Benefit. Utilization management edits include the following:

1. Prior Authorization (PA)
   - Certain drugs require prior authorization and are flagged ‘PA’ in the formulary list.
   - The provider must submit a prior authorization request and have it approved before the prescription may be filled at a network pharmacy.
   - PA ensures that drug use is appropriate, including FDA-approved or compendia-supported indication, approved age ranges, and absence of clinical contraindications.
   - Exceptions to PA may be requested with supporting FDA or compendia documentation.

Policy Name: Medication Utilization Review-Considering Exceptions	**Policy#:** UM-111	**Version#:** 1
Author Department: Utilization Management	**Origination Date:** 09/01/2025	
Business Units Impacted: Pharmacy Department,	**Date Last Reviewed:** 10/31/2025	
Products/LOBs: CHP+ HMO, CHP+	**Date Approved by CPT:** 10/31/2025	
	NCQA: UM11E	

2. Quantity Limits (QL)
    - Some drugs have quantity limits to ensure use aligns with FDA-approved dosing guidelines and are flagged 'QL' in the formulary.
    - Prescribed amounts within the limit can be obtained without additional paperwork.
    - Quantities exceeding limits require submission for a quantity limit exception with supporting clinical documentation.

3. Step Therapy (ST)
    - Certain conditions require trying specific drugs before others will be covered, flagged 'ST' in the formulary.
    - ST applies when alternatives have more robust evidence, fewer side effects, or are more cost-effective.
    - Exceptions may be requested if:
      a. Prior therapy is ineffective or likely to be ineffective/adversely affect the patient.
      b. Prior therapy has caused or is likely to cause adverse reactions.

    Note: Antidepressants, antipsychotics, and anticonvulsants may bypass step therapy if the patient is stable on current therapy.

4. Non-Formulary Exception
    - If a prescribed medication is not on the formulary, the provider must submit clinical documentation showing that at least 2 formulary alternatives have been tried/failed or are clinically inappropriate.
    - Requested medication must be FDA-approved or compendia-supported for the requested population.
    - Coverage for medications without FDA-approved safety/efficacy data will be reviewed individually.
    - *Exceptions:* If fewer than 2 alternatives exist, all available alternatives must be tried/failed or deemed inappropriate.

D. All PA, quantity limit, step therapy, and non-formulary requests are stored in the PBM-maintained database.

Policy Name: Medication Utilization Review-Considering Exceptions	**Policy#:** UM-111	**Version#:** 1
Author Department: Utilization Management	**Origination Date:** 09/01/2025	
Business Units Impacted: Pharmacy Department,	**Date Last Reviewed:** 10/31/2025	
Products/LOBs: CHP+ HMO, CHP+	**Date Approved by CPT:** 10/31/2025	
	NCQA: UM11E	

E. Colorado Access covers some OTC medications for CHP+. See the formulary for the most current list: CHP HMO Formulary.
F. Injectables administered by healthcare professionals and IV infusions are reviewed under the medical benefit. Standard requests are completed within 10 calendar days: expedited requests within 72 hours. Extensions may be granted for insufficient information.
G. Brand vs. Generic: Members may pay the cost difference if requesting a brand-name medication on formulary unless a clinical exception applies.
H. Emergency Dispensing: Contracted pharmacies may dispense up to 72 hours' supply for after-hours/weekends. Retroactive emergency authorization may be requested the next business day.

2. Utilization Management and Review

A. Standard Procedures
1. Maintain written procedures for processing initial and continuing authorizations.
2. Accept requests from providers and pharmacies, requesting additional information as needed.
3. Providers submit requests orally or in writing; standard requests are completed in a reasonable time. Pharmacy notifications are sent within 24 hours for prior authorization requests per SSA Section 1927(d)(5).
4. Decision notifications sent via fax to providers and dispensing pharmacies; members notified by mail if applicable.
5. Reasonable attempts will be made to contact providers for supporting documentation.
6. Re-authorization timeframes:
   a. One year
   b. Lifetime (includes mental health and SUD medications)
   c. Other pre-determined timeframes based on drug or condition changes

B. Expedited Review
- Decisions sent to providers and pharmacies; members notified by mail if applicable.

C. UM Process Editing
1. Automatic electronic edits via PBM point-of-sale system.
2. Manual healthcare professional review for direct requests.

D. Non-Formulary Exceptions

Policy Name: Medication Utilization Review-Considering Exceptions	**Policy#:** UM-111	**Version#:** 1
Author Department: Utilization Management	**Origination Date:** 09/01/2025	
Business Units Impacted: Pharmacy Department,	**Date Last Reviewed:** 10/31/2025	
Products/LOBs: CHP+ HMO, CHP+	**Date Approved by CPT:** 10/31/2025	
	NCQA: UM11E	

- Requests submitted via fax/email, clinical pharmacist reviews formulary and documentation.
- Approvals/denials follow defined criteria; urgent requests processed within 72 hours, non-urgent within 7 days.
- Duration of approval follows standard timeframes (1 year, lifetime, or other pre-determined period).
- Complex cases escalated to licensed physician reviewer.

E. Step Therapy Exceptions
- Clinical pharmacist reviews claims, chart notes, and formulary.
- Approvals and denials follow defined criteria, duration per standard timeframe.

F. Quantity Limit Exceptions
- Reviewed for compliance with FDA/compendia dosing.
- Approvals or denials documented, duration per standard timeframe.

G. Tiering Exceptions
- Reviewed for lower-tier alternatives; approvals follow 12-month duration or tiering rules.
- Specialty medications are not eligible for tiering exceptions.
- Support teams are notified of decisions to generate letters and ensure override in system.

3. Requests for Lost, Stolen, or Vacation Overrides
- See RxDP12 and RxDP13 for detailed procedures.

Attachments:
N/A

Compliance and Quality Review
- Results reported quarterly to the QI Committee.
- Annual review of this Policy and Procedure is required to align with updated NCQA standards.

REFERENCES:
RX DP12
RX DP13

Policy and Procedure

Policy Name: Medication Utilization Review-Considering Exceptions	**Policy#:** UM-111	**Version#:** 1
Author Department: Utilization Management	**Origination Date:** 09/01/2025	
Business Units Impacted: Pharmacy Department,	**Date Last Reviewed:** 10/31/2025	
Products/LOBs: CHP+ HMO, CHP+	**Date Approved by CPT:** 10/31/2025	
	NCQA: UM11E	

ATTACHMENTS:
None

POLICY HISTORY:
SUMMARY OF REVIEW/REVISION/APPROVAL DATES:
Version 1: 10/31/2025, New policy

APPROVAL BODY: COA Core Policy Team **APPROVAL DATE:** 10/31/2025

****Confidential & Proprietary****