Clinical Policy: Step Therapy

Reference Number: AZ.CP.PST.01
Effective Date: 11.01.19
Last Review Date: 02.22
Line of Business: Arizona Medicaid (AzCH-CCP and Care1st) Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

This policy provides a list of drugs that require step therapy for drugs on the AHCCCS Preferred Drug List (PDL).

AHCCCS preferred drugs in this policy include:

a. Ramelteon (Rozerem)

AHCCCS non-preferred drugs* in this policy include:
*Any non-listed drugs that belong to the same therapeutic class as the AHCCCS preferred drugs list above are non-preferred

FDA Approved Indication(s)

Various.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of Arizona Complete Health-Complete Care Plan and Care1st that the drugs identified within this policy are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Step Therapy:

Drugs listed in the table below may be approved for a maximum of 12 months for members who have had a previous trial of or who have contraindications to required step-through agents, when the request does not exceed the FDA-approved maximum dose indicated.

Drug Name	Required Step-Through Agents
Ramelteon (Rozerem)	Both of the following (a AND b) a) Member is <6 years old b) Prior use of at least 2 preferred sleep agents: eszopiclone, temazepam 15mg, temazepam 30mg, zolpidem 5mg, zolpidem 10mg

Drug names are listed as Brand name® when only the brand name is preferred and generic (Brand name®) when the generic drug preferred even though available by both brand and generic.

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Approval duration: 12 months

II. Continued Therapy

A. Step Therapy (must meet all)**:**

1. Member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. Dose does not exceeded the FDA-approved maximum recommended dose for the relevant drug.

Approval duration: 12 months

III. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

AHCCCS: Arizona Health Care Cost Containment System
FDA: Food and Drug Administration
IR: immediate release
PDL: preferred drug list

Appendix B: Therapeutic Alternatives

Refer to required step-through drug(s) above.

Appendix C: Contraindications/Boxed Warnings

Refer to the package inserts for each of the drugs requiring step therapy.

IV. Dosage and Administration

Refer to the package inserts for each of the drugs requiring step therapy.

V. Product Availability

Refer to the package inserts for each of the drugs requiring step therapy.

VI. References

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	10.28.19	10.19
Q1 2020 review; Added AHCCCS PDL.	01.15.2020	01.20
Updated AHCCCS PDL (Advair Diskus moved from NF to F Pulmicort Respules moved from F to NF, generic Pulmicort Respules are F, Flovent Diskus moved from NF to F, added rosuvastatin, fluvastatin, Advair AG, ArmonAir to NF, removed Aerospan from NF); Changed verbiage from "Currently receiving the medication from previous payor" to "Documentation supports that member is currently receiving the medication for a covered indication"; Added rosuvastatin and fluvastatin to this policy; Removed the generic name of the inhalers in Section I for better	10.22.2020	10.20

Reviews, Revisions, and Approvals	Date	P&T Approval Date
readability; Moved the NF inhalers criteria from Section II Continued Therapy to Section I Initial Approval Criteria as no inhalers were granted for grandfathering per AHCCCS; Updated References.		
Inhaled ICS/LABA products removed from this policy and added to AZ.CP.PMN.259. Removed all other drugs. Added Ramelteon per AZ Medicaid PDL.	02.12.2021	02.21
Added Care1st logo. Added verbiage to specify that criteria also applies to Care1st.	5.10.21	04.21
Annual review; no changes.	01.31.22	02.22

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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