



SmartPA Criteria Proposal

Drug/Drug Class:	Electrolyte Depleting Agents, Potassium Lowering PDL Edit
First Implementation Date:	April 4, 2019
Revised Date:	October 14, 2021
Prepared For:	MO HealthNet
Prepared By:	MO HealthNet/Conduent
Criteria Status:	<input checked="" type="checkbox"/> Existing Criteria <input type="checkbox"/> Revision of Existing Criteria <input type="checkbox"/> New Criteria

Executive Summary

Purpose: The MO HealthNet Pharmacy Program will implement a state-specific preferred drug list.

Why Issue Selected: Participants with chronic kidney disease and heart failure are at a higher risk for hyperkalemia, especially in participants who take medications that may increase potassium levels already such as any renin-angiotensin-aldosterone system (RAAS) inhibitor. The main causes of hyperkalemia involve increased potassium release from the cells or decreased urinary potassium excretion. Potassium enters the body exogenously through diet, oral intake, or intravenous infusion, stored in the cells and then excreted in the urine. Without a controlled potassium level, an increase in potassium levels may lead to muscle paralysis and potentially fatal cardiac arrhythmias. Management of chronic hyperkalemia in these participants can include pharmacologic management with a non-absorbable cation exchanger, such as sodium polystyrene sulfonate, patiomer, and sodium zirconium cyclosilicate. Dichlorphenamide, a carbonic anhydrase inhibitor (CAI), is approved for use in participants with primary hypokalemic and hyperkalemic periodic paralysis and related variants. There are no other FDA-approved alternatives for this disease state however, acetazolamide, also a CAI, has been used for treatment of periodic paralysis off-label and should be considered.

Total program savings for the PDL classes will be regularly reviewed.

Program-Specific Information:	Preferred Agents	Non-Preferred Agents
	<ul style="list-style-type: none"> • Kionex[®] Susp • Sodium Polystyrene Sulfonate Pwd/Susp • SPS[®] Susp • SPS[®] Rectal Enema 	<ul style="list-style-type: none"> • Keveyis[®] • Lokelma[®] • Veltassa[®] Pwd Pack

Type of Criteria: Increased risk of ADE Preferred Drug List
 Appropriate Indications Clinical Edit

Data Sources: Only Administrative Databases Databases + Prescriber-Supplied

Setting & Population

- Drug class for review: Electrolyte Depleting Agents, Potassium Lowering
- Age range: All appropriate MO HealthNet participants aged 18 years or older

Approval Criteria

- Participants aged 18 years or older for non-preferred agents **AND**
- Failure to achieve desired therapeutic outcomes with trial on 1 or more preferred agents
 - Documented trial period of preferred agents **OR**
 - Documented ADE/ADR to preferred agents **AND**
- For Lokelma: documented therapeutic trial (60 days) of Veltassa in the past year **OR**
- For Keveyis: documented diagnosis of periodic paralysis as determined by at clinical consultant review

Denial Criteria

- Lack of adequate trial on required preferred agents
- Therapy will be denied if all approval criteria are not met

Required Documentation

Laboratory Results:
MedWatch Form:

Progress Notes:
Other:

Disposition of Edit

Denial: Exception Code "0160" (Preferred Drug List)
Rule Type: PDL

Default Approval Period

1 year

References

1. Mount, D., (2019). Causes and evaluation of hyperkalemia in adults. In J.P. Forman (Ed.), *UpToDate*.
2. Evidence-Based Medicine and Fiscal Analysis: "Electrolyte Depleters/Potassium Lowering Agents", Conduent Business Services, L.L.C., Richmond, VA; June 2021.
3. Evidence-Based Medicine Analysis: "Electrolyte Depleters, Potassium Lowering Agents", UMKC-DIC; March 2021.
4. Kionex [package insert]. Minneapolis, MN: Perrigo; 2019.
5. Veltassa [package insert]. Redwood City, CA: Relypsa Inc; May 2018.
6. Keveyis [package insert]. Trevose, PA: Strongbridge US Inc; November 2019.
7. Lokelma [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; October 2020.
8. USPDI, Micromedex; 2021.
9. Facts and Comparisons eAnswers (online); 2021 Clinical Drug Information, LLC.
10. Acetazolamide [package insert]. East Brunswick, NJ: Avet Pharmaceuticals Inc.; June 2020.