

SmartPA Criteria Proposal

Drug/Drug Class:	Electrolyte Depleting Agents, Phosphate Lowering PDL Edit
First Implementation Date:	January 14, 2009
Proposed Date:	June 17, 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: Chronic kidney disease occurs in approximately 20 million Americans. One of the complications of this disease is hyperphosphatemia. As the kidney loses function, its ability to eliminate phosphorus declines, which results in hyperphosphatemia. Phosphorus is responsible for growth, maintenance, and repair of body tissues, and along with calcium, prevents bone-related disorders. Phosphorus is commonly found in foods such as milk, red meat, fish, poultry, eggs, and peanuts. Due to continuous dietary intake, unfortunately, dialysis alone does not maintain normal phosphorus levels in the blood for end stage renal disease participants. Phosphate-binding agents decrease phosphorus absorption from the gastrointestinal tract by binding dietary phosphorus. Calcium containing salts not only maintain positive calcium balance but also bind phosphorus. In the event of hypocalcemia, calcium supplementation or vitamin D may be necessary to slow or prevent bone disease. Non-calcium based phosphate binders are now available and are an alternative to calcium when hypercalcemia is present.

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"> • Calcium Acetate Caps • Sevelamer Carbonate Tabs (gen Renvela®) 	<ul style="list-style-type: none"> • Auryxia® • Calcium Acetate Tabs • Calphron® • Fosrenol® • Lanthanum Carbonate • Phoslyra® • Renage!® • Renvela® • Sevelamer Hydrochloride (gen Renage!®) • Sevelamer Pwd Pack • Velporo®

Type of Criteria: Increased risk of ADE
 Appropriate Indications

Preferred Drug List
 Clinical Edit

Data Sources: Only Administrative Databases

Databases + Prescriber-Supplied

Setting & Population

- Drug class for review: Electrolyte Depleters, Phosphate Lowering Agents
- Age range: All appropriate MO HealthNet participants

Approval Criteria

- Failure to achieve desired therapeutic outcomes with trial on 2 or more preferred agents
 - Documented trial period for preferred agents **OR**
 - Documented ADE/ADR to preferred agents

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. Evidence-Based Medicine and Fiscal Analysis: "Phosphate Lowering Agents – Therapeutic Class Review", Conduent Business Services, L.L.C., Richmond, VA; June 2021.
2. Evidence-Based Medicine Analysis: "Electrolyte Depleters, Phosphate Lowering Agents", UMKC-DIC; March 2021.
3. USPDI, Micromedex; 2021.
4. Facts and Comparisons eAnswers (online); 2021 Clinical Drug Information, LLC.
5. Renvela [package insert]. Cambridge, MA: Genzyme Corporation; March 2021.
6. Velphoro [package insert]. Waltham, MA: Fresenius Medical Care North America; February 2020.