

SmartPA Criteria Proposal

Drug/Drug Class:	Oxazolidinone Fiscal Edit
First Implementation Date:	TBD
Proposed Date:	June 17, 2021
Prepared for:	MO HealthNet
Prepared by:	MO HealthNet/Conduent
Criteria Status:	<input type="checkbox"/> Existing Criteria <input type="checkbox"/> Revision of Existing Criteria <input checked="" type="checkbox"/> New Criteria

Executive Summary

Purpose: Ensure appropriate utilization and control of oral oxazolidinone agents

Why Issue Selected: Oxazolidinones are a class of antibiotics with strong activity against Gram-positive bacteria, including methicillin-resistant *Staphylococcus aureus* and vancomycin-resistant enterococci. Oxazolidinones exhibit their antibacterial effects by inhibiting protein synthesis through binding to the 50S subunit of the bacterial ribosome. At this time, there are two FDA approved oxazolidinone agents: Zyvox® (linezolid), approved in 2000, and Sivextro® (tedizolid phosphate), approved in 2014. Generic versions of Zyvox are now available. It is fiscally advantageous for MO HealthNet to establish guidelines for therapy with oral oxazolidinone agents.

Program-Specific Information:	Date Range FFS 4-1-2020 to 3-31-2021			
	Drug	Claims	Spend	Avg Spend per Claim
	LINEZOLID 100 MG/5 ML SUSP	32	\$37,783.98	\$1,180.74
	LINEZOLID 600 MG TABLET	481	\$29,788.54	\$61.93
	SIVEXTRO 200 MG TABLET	35	\$286,385.56	\$8,182.44

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: Oral Oxazolidinone agents
- Age range: All appropriate MO HealthNet participants

Approval Criteria

- Claim is for linezolid **OR**
- Clinical consultant review required for therapy with Sivextro (tedizolid phosphate)

Denial Criteria

- Therapy will be denied if all approval criteria are not met

Required Documentation

Laboratory Results:
MedWatch Form:

Progress Notes:
Other:

X

Disposition of Edit

Denial: Exception code "0683" (Clinical Edit)
Rule Type: CE

Default Approval Period

1 month

References

- Zyvox® (linezolid) [package insert]. New York, NY: Pharmacia & Upjohn Co, Division of Pfizer Inc; April 2021.
- Sivextro® (tedizolid phosphate) [package insert]. Whitehouse Station, NJ: Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc.; October 2020.
- Roger C, Roberts JA, Muller L. Clinical Pharmacokinetics and Pharmacodynamics of Oxazolidinones. Clin Pharmacokinet 2018; 57:559.