

SmartPA Criteria Proposal

Drug/Drug Class:	Oxazolidinone Fiscal Edit
First Implementation Date:	October 28, 2021
Proposed Date:	December 15, 2022
Prepared for:	MO HealthNet
Prepared by:	MO HealthNet/Conduent
Criteria Status:	☒ Existing Criteria ☐ Revision of Existing Criteria ☐ 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 10-1-2021 to 9-31-2022				
Drug	Claims	Spend	Avg Spend per Claim	
LINEZOLID 100 MG/5 ML SUSP	13	\$11,831.15	\$910.09	
LINEZOLID 600 MG TABLET	682	\$34,081.02	\$49.97	
SIVEXTRO 200 MG TABLET	9	\$73,339.94	\$8,148.88	

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: 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" (Fiscal 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.