Bobby Jindal
GOVERNOR

Kathy H. Kliebert
SECRETARY

State of Louisiana

Department of Health and Hospitals
Bureau of Health Services Financing

March 19, 2014

Re: Clinical Pre-Authorization for Zyvox® (linezolid) injection, tablets, and oral suspension for Louisiana Legacy Medicaid and Shared Health Plans.

Dear Medicaid Provider:

The Louisiana Medicaid Pharmacy Program in collaboration with the Louisiana Medicaid Drug Utilization Review (DUR) Board has established clinical pre-authorization criteria to be utilized on Zyvox® (linezolid) injection, tablets, and oral suspension. This policy becomes effective on March 25, 2014.

Claims for Zyvox will be reimbursed at Point of Sale (POS) when the prescriber has obtained an approved clinical pre-authorization. Prescribers must complete the Pharmacy Clinical Pre-Authorization Form in full and fax to 1-866-797-2329. See complete instructions enclosed on page two of this document or refer to www.lamedicaid.com.

Pharmacy claims for these medications will deny with:

NCPDP rejection code 88 DUR Reject Error mapped to
EOB 066 Clinical Pre-Authorization Required

Override provisions should be addressed through the Clinical Pre-Authorization process.

If you have concerns or comments, you may contact our pharmacy help desk at (800) 437-9101 or send a fax to (225) 342-1980. Your continued cooperation and support of the Louisiana Medicaid Program efforts are greatly appreciated.

Sincerely,

J.Ruth Kennedy
Medicaid Director

JRK/esf

Effective Date March 25, 2014

Louisiana Legacy Medicaid and Shared Health Plans

Clinical Pre-Authorization Request for Zyvox® (linezolid) Injection, Tablets, and Oral Suspension

Instructions:

1. Zyvox® should only be used to treat or prevent infections that are proven or strongly suspected to be caused by susceptible pathogens. Clinical pre-authorization is required for therapy with Zyvox® (linezolid) injection, tablets, and oral suspension for fee-for-service (Louisiana Legacy Medicaid and shared health plans) recipients.
2. Prescribers must complete the Pharmacy Clinical Pre-Authorization Form in full and fax to 1-866-797-2329. A copy of the form is included with these instructions. Additionally, requests may be mailed to the address on the form; however, phone requests cannot be processed.
3. Prescribers must include the diagnosis (or indication) and pathogen on Zyvox® requests. Covered indications, recommended dosages by route /age, and recommended durations of therapy are itemized in the table below.
4. Prescribers must indicate whether this request is for new therapy or continuation of therapy. For a particular episode of care, prescribers should consider previous inpatient Zyvox® therapy. Prescribers must document inpatient use of Zyvox® (including doses and date ranges) on requests to continue outpatient use.
5. To reduce the development of drug-resistant pathogens and to maintain Zyvox® effectiveness, special considerations related to antibiotic resistance must be addressed in requests for Zyvox®:
   a. Antibiotic resistance to all other appropriate therapies must be demonstrated by culture and sensitivity (provide C & S report) OR
   b. Antibiotic resistance must be demonstrated by a history of antibiotic use (provide documentation of previous antibiotic treatment trials and dates of trials) OR
   c. Antibiotic resistance must be suspected due to local sensitivity patterns (provide supporting clinical rationale)

   As outlined above, prescribers must include a C & S report, OR documentation of previous antibiotic treatment trials and dates of therapy, OR supporting clinical rationale with requests for Zyvox®.

Table. Covered Indications and Dosage, Route, and Frequency of Administration by Indication

Covered Infections Due to Susceptible Gram-Positive Bacteria	Pediatric Patients[1] (Birth through 11 Years of Age)	Adults and Adolescents (12 Years of Age and Older)	Duration (days)[2]
Nosocomial pneumonia caused by *Staphylococcus aureus* (methicillin-susceptible and -resistant isolates) or *Streptococcus pneumoniae*	10 mg/kg intravenous (IV) or oral every 8 hours	600 mg IV or oral every 12 hours	10 to 14
Community-acquired pneumonia caused by *S. pneumoniae*, including concurrent bacteremia, or *S. aureus* (methicillin-susceptible isolates only)			
Complicated skin and skin structure infections, including diabetic foot infections, without concurrent osteomyelitis, caused by *S. aureus* (methicillin-susceptible and -resistant isolates), *Streptococcus pyogenes* or *Streptococcus agalactiae*[3]			
Vancomycin-resistant *Enterococcus faecium* infections, including concurrent bacteremia	10 mg/kg IV or oral every 8 hours	600 mg IV or oral every 12 hours	14 to 28
Uncomplicated skin and skin structure infections caused by *S. aureus* (methicillin-susceptible isolates only) or *S. pyogenes*	**< 5 yrs:** 10 mg/kg oral every 8 hours **5-11 yrs:** 10 mg/kg oral every 12 hours	**Adults:** 400 mg oral every 12 hours **Adolescents:** 600 mg oral every 12 hours	10 to 14

(from Zyvox® [package insert], NY, NY: Pfizer & Upjohn; January 2014)

1. See prescribing information for dosing in neonates < 7 days of age.
2. Duration of therapy is the total of any inpatient days and outpatient days on Zyvox.
3. Zyvox® has not been studied in the treatment of decubitus ulcers.

LA Legacy Medicaid and Shared Health Plans
Pharmacy Clinical Pre-Authorization Form

Fax or Mail this form to:
1-866-797-2329
La Medicaid RxPA Operations
ULM College of Pharmacy
1800 Bienville Drive
Monroe, LA 71201-3765

MEMBER INFORMATION

Patient Name: Last Name	First Name	MI	
Date of Birth:	**Sex:** ☐ Male ☐ Female	**Height:**	**Weight:**
Address:	**City**	**State**	**Zip Code**
Phone #:	**Medicaid Recipient ID#: (required)**	**Plan Policy ID#: (optional)**	

PRESCRIBING PRACTITIONER INFORMATION

Practice Name:	**Specialty:**	**NPI # (2):**	
Prescribing Practitioner Name:	**Medicaid Provider ID #: (required)**	**NPI # (1):**	**DEA/License #:**
Address:	**City**	**State**	**Zip Code**
Phone #:	**Fax #:**	**Office Contact:**	

MEDICATION INFORMATION

Drug Name:	**Dosage Form:**	**Quantity:**	**Projected Duration of Treatment:**
Strength:	**Directions:**		
Dispense as Written: ☐ Yes ☐ No	**Substitutes Permitted:** ☐ Yes ☐ No		**Number of Refills:**
Currently on This Medication: ☐ Yes ☐ No	**Other Medications Tried toTreat This Condition:**		**Dates:**
List Other Current Medications: ☐ *See attached list*			
Reasons for Discontinuation of Tried Therapies:			
Diagnosis/Indication:			**ICD Diagnosis Code:***
Rationale and/or Other Information Relevant (☐ *included* lab results) to the Review of This Authorization Request: **Drug Allergies:**			

PHARMACY INFORMATION (Optional)

Pharmacy Name:	**Phone #:**	**Fax #:**

Prescribing Practitioner Signature: _____ **Date:** _____

For more information, refer to www.lamedicaid.com and follow the "Pharmacy and Prescribing Providers" link.
*Beginning October 1, 2014, only ICD-10 codes should be submitted.