



Prior Authorization Approval Criteria
Department of Pharmacy Services

Generic Name: Dalfopristin/quinupristin

Brand Name: Synercid®

Medication Class: antibiotic (streptogramins)

FDA Approved Uses:

- Vancomycin-resistant *Enterococcus faecium* bacteremia (VREF)
- Complicated skin and skin structure infections, caused by *Staphylococcus aureus* and *Streptococcus pyogenes*

Available Dosage Forms:

- Intravenous Powder for Solution: (Dalfopristin - Quinupristin) 350 MG-150 MG

Usual Dose:

- Vancomycin-resistant *Enterococcus faecium* infection: 7.5 mg/kg IV every 8 hr
- Complicated skin and skin structure infection : 7.5 mg/kg IV every 12 hr

Duration of Therapy:

- Complicated skin and skin structure infections: minimum is 7 days
- Vancomycin-resistant *E. faecium* infection: Variable

Approximate Monthly Cost (based on AWP 2006):

- 500 mg (150 mg quinupristin; 350 mg dalfopristin)/10 mL vial = \$156.57
- 7 day course (15 vials) = \$ 2,349 (skin and skin structure infection)
- 7 day course (~22 vials) = \$ 3,445 (VREF)

Criteria for Use: (*bullet points below are all inclusive unless otherwise noted*)

- Patient has a diagnosis of vancomycin-resistant *E. faecium* infection

Or

- Complicated skin and/or skin structure infection

Criteria for Continuation of Therapy:

- Chronic therapy is not indicated

Cautions:

- Synercid is a CYP 3A4 inhibitor (potential for interactions)

Monitoring:

- fever
- CBC
- symptomatic improvement
- bilirubin levels



Contraindications:

- hypersensitivity to synergid

Not Approved if:

- Above criteria is not met

Special Considerations: Synergid was approved for VREF under the FDA's accelerated approval regulations based on demonstrated effect on a surrogate endpoint (i.e. Synergid's ability to clear VREF from the bloodstream) that is likely to predict clinical benefit. Currently there are no data from well-controlled clinical studies that confirm the validity of this surrogate marker. A study to verify the clinical benefit of therapy with Synergid on traditional clinical endpoints (i.e. cure of the underlying infection) is presently underway.

P&T Approval: _____ Date: _____