QUANTITY LIMIT PRIOR AUTHORIZATION CRITERIA

DRUG CLASS	**SELECT INJECTABLE, INTRAVENOUS ANTIMICROBIALS**
BRAND NAME (generic)	
	ABELCET (amphotericin B lipid complex)
	AMBISOME (amphotericin B liposome)
	(amphotericin B)
	CANCIDAS (caspofungin)
	(ceftriaxone vials)
	COLY-MYCIN M (colistimethate)
	CUBICIN (daptomycin)
	CUBICIN RF (daptomycin)
	DALVANCE (dalbavancin)
	(daptomycin)
	DAPZURA RT (daptomycin)
	INVANZ (ertapenem)
	KIMYRSA (oritavancin)
	(levofloxacin injection)
	(meropenem)
	MYCAMINE (micafungin)

ORBACTIV
(oritavancin)

(streptomycin)

(tobramycin injection)

TYGACIL
(tigecycline)

(vancomycin injection vials, bottles)

VFEND IV
(voriconazole injection)

Status: CVS Caremark® Criteria
Type: Quantity Limit; Post Limit Prior Authorization

POLICY

FDA-APPROVED INDICATIONS

Abelcet
Abelcet is indicated for the treatment of invasive fungal infections in patients who are refractory to or intolerant of conventional amphotericin B therapy. This is based on open-label treatment of patients judged by their physicians to be intolerant to or failing conventional amphotericin B therapy.

AmBisome
AmBisome is indicated for the following:
- Empirical therapy for presumed fungal infection in febrile, neutropenic patients.
- Treatment of Cryptococcal Meningitis in HIV-infected patients.
- Treatment of patients with Aspergillus species, Candida species and/or Cryptococcus species infections (see above for the treatment of Cryptococcal Meningitis) refractory to amphotericin B deoxycholate, or in patients where renal impairment or unacceptable toxicity precludes the use of amphotericin B deoxycholate.
- Treatment of visceral leishmaniasis. In immunocompromised patients with visceral leishmaniasis treated with AmBisome, relapse rates were high following initial clearance of parasites.

Amphotericin B
Amphotericin B for Injection USP should be administered primarily to patients with progressive, potentially life-threatening fungal infections. This potent drug should not be used to treat noninvasive fungal infections, such as oral thrush, vaginal candidiasis and esophageal candidiasis in patients with normal neutrophil counts.
Amphotericin B for Injection USP is specifically intended to treat potentially life threatening fungal infections: aspergillosis, cryptococcosis (torulosis), North American blastomycosis, systemic candidiasis, coccidioido-mycosis, histoplasmosis, zygomycosis including mucormycosis due to susceptible species of the genera Absidia, Mucor and Rhizopus, and infections due to related susceptible species of Conidiobolus and Basidiobolus, and sporotrichosis.
Amphotericin B may be useful in the treatment of American mucocutaneous leishmaniasis, but it is not the drug of choice as primary therapy.

Cancidas
Empirical Therapy for Presumed Fungal Infections in Febrile, Neutropenic Patients
Cancidas is indicated as empirical therapy for presumed fungal infections in febrile, neutropenic adult and pediatric patients (3 months of age and older).

Treatment of Candidemia and Other Candida Infections
Cancidas is indicated for the treatment of candidemia and the following candida infections: intraabdominal abscesses, peritonitis, and pleural space infections in adult and pediatric patients (3 months of age and older).
Limitations of Use: Cancidas has not been studied in endocarditis, osteomyelitis, and meningitis due to Candida.
Treatment of Esophageal Candidiasis
Cancidas is indicated for the treatment of esophageal candidiasis in adult and pediatric patients (3 months of age and older).
Limitations of Use: Cancidas has not been approved for the treatment of oropharyngeal candidiasis (OPC). In the study that evaluated the efficacy of caspofungin in the treatment of esophageal candidiasis, patients with concomitant OPC had higher relapse rate of the OPC.
Treatment of Invasive Aspergillosis in Patients Who Are Refractory to or Intolerant of Other Therapies
Cancidas is indicated for the treatment of invasive aspergillosis in adult and pediatric patients (3 months of age and older) who are refractory to or intolerant of other therapies.
Limitations of Use: Cancidas has not been studied as initial therapy for invasive aspergillosis.

Ceftriaxone
Before instituting treatment with Ceftriaxone appropriate specimens should be obtained for isolation of the causative organism and for determination of its susceptibility to the drug. Therapy may be instituted prior to obtaining results of susceptibility testing.
To reduce the development of drug-resistant bacteria and maintain the effectiveness of Ceftriaxone for injection, USP and other antibacterial drugs, Ceftriaxone for injection, USP should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.
Ceftriaxone for injection, USP is indicated for the treatment of the following infections when caused by susceptible organisms:
Lower Respiratory Tract Infections caused by Streptococcus pneumoniae, Staphylococcus aureus, Haemophilus influenzae, Haemophilus parainfluenzae, Klebsiella pneumoniae, Escherichia coli, Klebsiella aerogenes (formerly Enterobacter aerogenes), Proteus mirabilis or Serratia marcescens.
Acute Bacterial Otitis Media caused by Streptococcus pneumoniae, Haemophilus influenzae (including beta-lactamase producing strains) or Moraxella catarrhalis (including beta-lactamase producing strains).
Note: In one study lower clinical cure rates were observed with a single dose of Ceftriaxone compared to 10 days of oral therapy. In a second study comparable cure rates were observed between single dose Ceftriaxone and the comparator. The potentially lower clinical cure rate of Ceftriaxone should be balanced against the potential advantages of parenteral therapy.
Skin and Skin Structure Infections caused by Staphylococcus aureus, Staphylococcus epidermidis, Streptococcus pyogenes, Viridans group streptococci, Escherichia coli, Enterobacter cloacae, Klebsiella oxytoca, Klebsiella pneumoniae, Proteus mirabilis, Morganella morganii,* Pseudomonas aeruginosa, Serratia marcescens, Acinetobacter calcoaceticus, Bacteroides fragilis* or Peptostreptococcus species.
Urinary Tract Infections (complicated and uncomplicated) caused by Escherichia coli, Proteus mirabilis, Proteus vulgaris, Morganella morganii or Klebsiella pneumoniae.
Uncomplicated Gonorrhea (cervical/urethral and rectal) caused by Neisseria gonorrhoeae, including both penicillinase- and nonpenicillinase-producing strains, and pharyngeal gonorrhea caused by nonpenicillinase-producing strains of Neisseria gonorrhoeae.
Pelvic Inflammatory Disease caused by Neisseria gonorrhoeae. Ceftriaxone sodium, like other cephalosporins, has no activity against Chlamydia trachomatis. Therefore, when cephalosporins are used in the treatment of patients with pelvic inflammatory disease and Chlamydia trachomatis is one of the suspected pathogens, appropriate antichlamydial coverage should be added.
Bacterial Septicemia caused by Staphylococcus aureus, Streptococcus pneumoniae, Escherichia coli, Haemophilus influenzae or Klebsiella pneumoniae.
Bone and Joint Infections caused by Staphylococcus aureus, Streptococcus pneumoniae, Escherichia coli, Proteus mirabilis, Klebsiella pneumoniae or Enterobacter species.
Intra-Abdominal Infections caused by Escherichia coli, Klebsiella pneumoniae, Bacteroides fragilis, Clostridium species (Note: most strains of Clostridium difficile are resistant) or Peptostreptococcus species.
Meningitis caused by Haemophilus influenzae, Neisseria meningitidis or Streptococcus pneumoniae. Ceftriaxone has also been used successfully in a limited number of cases of meningitis and shunt infection caused by Staphylococcus epidermidis* and Escherichia coli.*
* Efficacy for this organism in this organ system was studied in fewer than ten infections.

Surgical Prophylaxis: The preoperative administration of a single 1g dose of Ceftriaxone may reduce the incidence of postoperative infections in patients undergoing surgical procedures classified as contaminated or potentially contaminated (e.g., vaginal or abdominal hysterectomy or cholecystectomy for chronic calculous cholecystitis in high-risk patients, such as those over 70 years of age, with acute cholecystitis not requiring therapeutic antimicrobials, obstructive jaundice or common duct bile stones) and in surgical patients for whom infection at the operative site would present serious risk (e.g., during coronary artery bypass surgery). Although Ceftriaxone has been shown to have been as effective as cefazolin in the prevention of infection following coronary artery bypass surgery, no placebo-controlled trials have been conducted to evaluate any cephalosporin antibiotic in the prevention of infection following coronary artery bypass surgery.
When administered prior to surgical procedures for which it is indicated, a single 1g dose of Ceftriaxone provides protection from most infections due to susceptible organisms throughout the course of the procedure.

Coly-Mycin M
Coly-Mycin M Parenteral is indicated for the treatment of acute or chronic infections due to sensitive strains of certain gram-negative bacilli. It is particularly indicated when the infection is caused by sensitive strains of Pseudomonas aeruginosa. This antibiotic is not indicated for infections due to Proteus or Neisseria. Coly-Mycin M Parenteral has proven clinically effective in treatment of infections due to the following gram-negative organisms: Klebsiella aerogenes (formerly Enterobacter aerogenes), Escherichia coli, Klebsiella pneumoniae and Pseudomonas aeruginosa.
Coly-Mycin M Parenteral may be used to initiate therapy in serious infections that are suspected to be due to gram-negative organisms and in the treatment of infections due to susceptible gram-negative pathogenic bacilli.
To reduce the development of drug-resistant bacteria and maintain the effectiveness of Coly-Mycin M and other antibacterial drugs, Coly-Mycin M should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.

Cubicin, Cubicin RF, Daptomycin 350mg, Daptomycin 500mg, Dapzura RT
Complicated Skin and Skin Structure Infections (cSSSI)
Cubicin, Cubicin RF, Daptomycin for Injection, and Dapzura RT are indicated for the treatment of adult[11] and pediatric patients (1 to 17 years of age) with complicated skin and skin structure infections (cSSSI) caused by susceptible isolates of the following Gram-positive bacteria: Staphylococcus aureus (including methicillin-resistant isolates), Streptococcus pyogenes, Streptococcus agalactiae, Streptococcus dysgalactiae subsp. equisimilis, and Enterococcus faecalis (vancomycin-susceptible isolates only).
Staphylococcus aureus Bloodstream Infections (Bacteremia) in Adult Patients, Including Those with Right-Sided Infective Endocarditis, Caused by Methicillin-Susceptible and Methicillin-Resistant Isolates
Cubicin, Cubicin RF, Daptomycin for Injection, and Dapzura RT are indicated for the treatment of adult patients with Staphylococcus aureus bloodstream infections (bacteremia), including adult patients with right-sided infective endocarditis, caused by methicillin-susceptible and methicillin-resistant isolates.
Staphylococcus aureus Bloodstream Infections (Bacteremia) in Pediatric Patients (1 to 17 Years of Age)
Cubicin, Cubicin RF, Daptomycin for Injection, and Dapzura RT are indicated for the treatment of pediatric patients (1 to 17 years of age) with Staphylococcus aureus bloodstream infections (bacteremia).
Limitations of Use
Cubicin, Cubicin RF, Daptomycin for Injection, and Dapzura RT are not indicated for the treatment of pneumonia.
Cubicin, Cubicin RF, Daptomycin for Injection, and Dapzura RT are not indicated for the treatment of left-sided infective endocarditis due to S. aureus. The clinical trial of Cubicin, Cubicin RF, Daptomycin for Injection, and Dapzura RT in adult patients with S. aureus bloodstream infections included limited data from patients with left-sided infective endocarditis; outcomes in these patients were poor. Cubicin, Cubicin RF, Daptomycin for Injection, and Dapzura RT have not been studied in patients with prosthetic valve endocarditis.
Cubicin, Cubicin RF, Daptomycin for Injection, and Dapzura RT are not recommended in pediatric patients younger than 1 year of age due to the risk of potential effects on muscular, neuromuscular, and/or nervous systems (either peripheral and/or central) observed in neonatal dogs.
Usage
Appropriate specimens for microbiological examination should be obtained in order to isolate and identify the causative pathogens and to determine their susceptibility to daptomycin.
To reduce the development of drug-resistant bacteria and maintain the effectiveness of Cubicin, Cubicin RF, Daptomycin for Injection, Dapzura RT and other antibacterial drugs, Cubicin, Cubicin RF, Daptomycin for Injection, and Dapzura RT should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria.

When culture and susceptibility information is available, it should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy. Empiric therapy may be initiated while awaiting test results.

Dalvance
Dalvance is indicated for the treatment of adult and pediatric patients with acute bacterial skin and skin structure infections (ABSSSI), caused by designated susceptible strains of the following Gram-positive microorganisms: Staphylococcus aureus (including methicillin-susceptible and methicillin-resistant isolates), Streptococcus pyogenes, Streptococcus agalactiae, Streptococcus dysgalactiae, Streptococcus anginosus group (including S. anginosus, S. intermedius, S. constellatus) and Enterococcus faecalis (vancomycin susceptible isolates).
Usage
To reduce the development of drug-resistant bacteria and maintain the effectiveness of Dalvance and other antibacterial agents, Dalvance should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.

Invanz
Complicated Intra-Abdominal Infections
Invanz is indicated for the treatment of adult patients and pediatric patients (3 months of age and older) with complicated intra-abdominal infections due to Escherichia coli, Clostridium clostridiiforme, Eubacterium lentum, Peptostreptococcus species, Bacteroides fragilis, Bacteroides distasonis, Bacteroides ovatus, Bacteroides thetaiotaomicron, or Bacteroides uniformis.
Complicated Skin and Skin Structure Infections, Including Diabetic Foot Infections without Osteomyelitis
Invanz is indicated for the treatment of adult patients and pediatric patients (3 months of age and older) with complicated skin and skin structure infections, including diabetic foot infections without osteomyelitis due to Staphylococcus aureus (methicillin susceptible isolates only), Streptococcus agalactiae, Streptococcus pyogenes, Escherichia coli, Klebsiella pneumoniae, Proteus mirabilis, Bacteroides fragilis, Peptostreptococcus species, Porphyromonas asaccharolytica, or Prevotella bivia. Invanz has not been studied in diabetic foot infections with concomitant osteomyelitis.
Community Acquired Pneumonia
Invanz is indicated for the treatment of adult patients and pediatric patients (3 months of age and older) with community acquired pneumonia due to Streptococcus pneumoniae (penicillin susceptible isolates only) including cases with concurrent bacteremia, Haemophilus influenzae (beta-lactamase negative isolates only), or Moraxella catarrhalis.
Complicated Urinary Tract Infections Including Pyelonephritis
Invanz is indicated for the treatment of adult patients and pediatric patients (3 months of age and older) with complicated urinary tract infections including pyelonephritis due to Escherichia coli, including cases with concurrent bacteremia, or Klebsiella pneumoniae.
Acute Pelvic Infections Including Postpartum Endomyometritis, Septic Abortion and Post Surgical Gynecologic Infections
Invanz is indicated for the treatment of adult patients and pediatric patients (3 months of age and older) with acute pelvic infections including postpartum endomyometritis, septic abortion and post-surgical gynecological infections due to Streptococcus agalactiae, Escherichia coli, Bacteroides fragilis, Porphyromonas asaccharolytica, Peptostreptococcus species, or Prevotella bivia.
Prophylaxis of Surgical Site Infection Following Elective Colorectal Surgery
Invanz is indicated in adults for the prevention of surgical site infection following elective colorectal surgery.
Usage
To reduce the development of drug-resistant bacteria and maintain the effectiveness of Invanz and other antibacterial drugs, Invanz should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.

Kimyrsa
Kimyrsa is indicated for the treatment of adult patients with acute bacterial skin and skin structure infections (ABSSSI) caused by susceptible isolates of the following Gram positive microorganisms:
Staphylococcus aureus (including methicillin-susceptible and methicillin-resistant isolates), Streptococcus pyogenes, Streptococcus agalactiae, Streptococcus dysgalactiae, Streptococcus anginosus group (includes S. anginosus, S. intermedius, and S. constellatus), and Enterococcus faecalis (vancomycin-susceptible isolates only).
Usage

To reduce the development of drug-resistant bacteria and maintain the effectiveness of Kimyrsa and other antibacterial drugs, Kimyrsa should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.

Levofloxacin injection
Levofloxacin injection is indicated for the treatment of adults (≥18 years of age) with mild, moderate, and severe infections caused by susceptible isolates of the designated microorganisms in the conditions listed in this section. Levofloxacin injection is indicated when intravenous administration offers a route of administration advantageous to the patient (e.g., patient cannot tolerate an oral dosage form).
Nosocomial Pneumonia
Levofloxacin injection is indicated for the treatment of nosocomial pneumonia due to methicillin-susceptible Staphylococcus aureus, Pseudomonas aeruginosa, Serratia marcescens, Escherichia coli, Klebsiella pneumoniae, Haemophilus influenzae, or Streptococcus pneumoniae. Adjunctive therapy should be used as clinically indicated. Where Pseudomonas aeruginosa is a documented or presumptive pathogen, combination therapy with an anti-pseudomonal β-lactam is recommended.
Community-Acquired Pneumonia: 7- to 14-day Treatment Regimen
Levofloxacin injection is indicated for the treatment of community-acquired pneumonia due to methicillin-susceptible Staphylococcus aureus, Streptococcus pneumoniae (including multi-drug-resistant Streptococcus pneumoniae [MDRSP]), Haemophilus influenzae, Haemophilus parainfluenzae, Klebsiella pneumoniae, Moraxella catarrhalis, Chlamydophila pneumoniae, Legionella pneumophila, or Mycoplasma pneumoniae.
MDRSP isolates are isolates resistant to two or more of the following antibacterials: penicillin (MIC ≥2 mcg/mL), second generation cephalosporins, e.g., cefuroxime, macrolides, tetracyclines and trimethoprim/sulfamethoxazole.
Community-Acquired Pneumonia: 5-day Treatment Regimen
Levofloxacin injection is indicated for the treatment of community-acquired pneumonia due to Streptococcus pneumoniae (excluding multi-drug-resistant isolates [MDRSP]), Haemophilus influenzae, Haemophilus parainfluenzae, Mycoplasma pneumoniae, or Chlamydophila pneumoniae.
Complicated Skin and Skin Structure Infections
Levofloxacin injection is indicated for the treatment of complicated skin and skin structure infections due to methicillin-susceptible Staphylococcus aureus, Enterococcus faecalis, Streptococcus pyogenes, or Proteus mirabilis.
Uncomplicated Skin and Skin Structure Infections
Levofloxacin injection is indicated for the treatment of uncomplicated skin and skin structure infections (mild to moderate) including abscesses, cellulitis, furuncles, impetigo, pyoderma, wound infections, due to methicillin-susceptible Staphylococcus aureus, or Streptococcus pyogenes.
Chronic Bacterial Prostatitis
Levofloxacin injection is indicated for the treatment of chronic bacterial prostatitis due to Escherichia coli, Enterococcus faecalis, or methicillin-susceptible Staphylococcus epidermidis.
Inhalational Anthrax (Post-Exposure)
Levofloxacin injection is indicated for inhalational anthrax (post-exposure) to reduce the incidence or progression of disease following exposure to aerosolized Bacillus anthracis. The effectiveness of levofloxacin is based on plasma concentrations achieved in humans, a surrogate endpoint reasonably likely to predict clinical benefit. Levofloxacin injection has not been tested in humans for the post-exposure prevention of inhalation anthrax. The safety of levofloxacin injection in adults for durations of therapy beyond 28 days or in pediatric patients for durations of therapy beyond 14 days has not been studied. Prolonged levofloxacin injection therapy should only be used when the benefit outweighs the risk.
Plague
Levofloxacin injection is indicated for treatment of plague, including pneumonic and septicemic plague, due to Yersinia pestis (Y. pestis) and prophylaxis for plague in adults and pediatric patients, 6 months of age and older. Efficacy studies of levofloxacin injection could not be conducted in humans with plague for ethical and feasibility reasons. Therefore, approval of this indication was based on an efficacy study conducted in animals.
Complicated Urinary Tract Infections: 5-day Treatment Regimen
Levofloxacin injection is indicated for the treatment of complicated urinary tract infections due to Escherichia coli, Klebsiella pneumoniae, or Proteus mirabilis.
Complicated Urinary Tract Infections: 10-day Treatment Regimen
Levofloxacin injection is indicated for the treatment of complicated urinary tract infections (mild to moderate) due to Enterococcus faecalis, Enterobacter cloacae, Escherichia coli, Klebsiella pneumoniae, Proteus mirabilis, or Pseudomonas aeruginosa.
Acute Pyelonephritis: 5- or 10-day Treatment Regimen

Levofloxacin injection is indicated for the treatment of acute pyelonephritis caused by Escherichia coli, including cases with concurrent bacteremia.

Uncomplicated Urinary Tract Infections

Levofloxacin injection is indicated for the treatment of uncomplicated urinary tract infections (mild to moderate) due to Escherichia coli, Klebsiella pneumoniae, or Staphylococcus saprophyticus.

Because fluoroquinolones, including levofloxacin injection, have been associated with serious adverse reactions and for some patients uncomplicated urinary tract infection is self-limiting, reserve levofloxacin injection for treatment of uncomplicated urinary tract infections in patients who have no alternative treatment options.

Acute Bacterial Exacerbation of Chronic Bronchitis

Levofloxacin injection is indicated for the treatment of acute bacterial exacerbation of chronic bronchitis (ABECB) due to methicillin-susceptible Staphylococcus aureus, Streptococcus pneumoniae, Haemophilus influenzae, Haemophilus parainfluenzae, or Moraxella catarrhalis.

Because fluoroquinolones, including levofloxacin injection, have been associated with serious adverse reactions [see Warnings and Precautions (5.1 to 5.15)] and for some patients ABECB is self-limiting, reserve levofloxacin for treatment of ABECB in patients who have no alternative treatment options.

Acute Bacterial Sinusitis: 5-day and 10–14 day Treatment Regimens

Levofloxacin injection is indicated for the treatment of acute bacterial sinusitis (ABS) due to Streptococcus pneumoniae, Haemophilus influenzae, or Moraxella catarrhalis.

Because fluoroquinolones, including levofloxacin injection, have been associated with serious adverse reactions and for some patients ABS is self-limiting, reserve levofloxacin for treatment of ABS in patients who have no alternative treatment options.

Usage

To reduce the development of drug-resistant bacteria and maintain the effectiveness of levofloxacin and other antibacterial drugs, levofloxacin should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.

Culture and susceptibility testing

Appropriate culture and susceptibility tests should be performed before treatment in order to isolate and identify organisms causing the infection and to determine their susceptibility to levofloxacin. Therapy with levofloxacin injection may be initiated before results of these tests are known; once results become available, appropriate therapy should be selected.

As with other drugs in this class, some isolates of Pseudomonas aeruginosa may develop resistance fairly rapidly during treatment with levofloxacin injection. Culture and susceptibility testing performed periodically during therapy will provide information about the continued susceptibility of the pathogens to the antimicrobial agent and also the possible emergence of bacterial resistance.

Meropenem for Injection 2g

Meropenem for Injection is indicated for the treatment of bacterial meningitis caused by Haemophilus influenzae, Neisseria meningitidis and penicillin-susceptible isolates of Streptococcus pneumoniae, in pediatric patients 3 months of age and older. Meropenem for injection has been found to be effective in eliminating concurrent bacteremia in association with bacterial meningitis.

Usage

To reduce the development of drug-resistant bacteria and maintain the effectiveness of Meropenem for Injection and other antibacterial drugs, Meropenem for Injection should only be used to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.

Meropenem for Injection 500mg and 1g

Complicated Skin and Skin Structure Infections (Adult Patients and Pediatric Patients 3 Months of Age and Older Only)

Merrem IV is indicated for the treatment of complicated skin and skin structure infections (cSSSI) due to Staphylococcus aureus (methicillin-susceptible isolates only), Streptococcus pyogenes, Streptococcus agalactiae, viridans group streptococci, Enterococcus faecalis (vancomycin-susceptible isolates only), Pseudomonas aeruginosa, Escherichia coli, Proteus mirabilis, Bacteroides fragilis, and Peptostreptococcus species.

Complicated Intra-abdominal Infections (Adult and Pediatric Patients)

Merrem IV is indicated for the treatment of complicated appendicitis and peritonitis caused by viridans group streptococci, Escherichia coli, Klebsiella pneumoniae, Pseudomonas aeruginosa, Bacteroides fragilis, B. thetaiotaomicron, and Peptostreptococcus species.

Bacterial Meningitis (Pediatric Patients 3 Months of Age and Older Only)

Merrem IV is indicated for the treatment of bacterial meningitis caused by Haemophilus influenzae, Neisseria meningitidis and penicillin-susceptible isolates of Streptococcus pneumoniae.

Merrem IV has been found to be effective in eliminating concurrent bacteremia in association with bacterial meningitis.

Usage

To reduce the development of drug-resistant bacteria and maintain the effectiveness of Merrem IV and other antibacterial drugs, Merrem IV should only be used to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.

Mycamine

Mycamine is indicated for:

- Treatment of Candidemia, Acute Disseminated Candidiasis, Candida Peritonitis and Abscesses in adult and pediatric patients 4 months of age and older.
- Treatment of Candidemia, Acute Disseminated Candidiasis, Candida Peritonitis and Abscesses without meningoencephalitis and/or ocular dissemination in pediatric patients younger than 4 months of age.
- Treatment of Esophageal Candidiasis in adult and pediatric patients 4 months of age and older.
- Prophylaxis of Candida Infections in adult and pediatric patients 4 months of age and older undergoing hematopoietic stem cell transplantation.

Limitations of Use

- The safety and effectiveness of Mycamine have not been established for the treatment of candidemia with meningoencephalitis and/or ocular dissemination in pediatric patients younger than 4 months of age as a higher dose may be needed.
- Mycamine has not been adequately studied in patients with endocarditis, osteomyelitis, and meningoencephalitis due to Candida.
- The efficacy of Mycamine against infections caused by fungi other than Candida has not been established.

Orbactiv

Orbactiv (oritavancin) is indicated for the treatment of adult patients with acute bacterial skin and skin structure infections (ABSSSI) caused by susceptible isolates of the following Gram-positive microorganisms:

Staphylococcus aureus (including methicillin-susceptible and methicillin–resistant isolates), Streptococcus pyogenes, Streptococcus agalactiae, Streptococcus dysgalactiae, Streptococcus anginosus group (includes S. anginosus, S. intermedius, and S. constellatus), and Enterococcus faecalis (vancomycin susceptible isolates only).

Usage

To reduce the development of drug-resistant bacteria and maintain the effectiveness of Orbactiv and other antibacterial drugs, Orbactiv should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.

Streptomycin

Streptomycin is indicated for the treatment of individuals with moderate to severe infections caused by susceptible strains of microorganisms in the specific conditions listed below:

1. Mycobacterium tuberculosis: The Advisory Council for the Elimination of Tuberculosis, the American Thoracic Society, and the Center for Disease Control recommend that either streptomycin or ethambutol be added as a fourth drug in a regimen containing isoniazid (INH), rifampin and pyrazinamide for initial treatment of tuberculosis unless the likelihood of INH or rifampin resistance is very low. The need for a fourth drug should be reassessed when the results of susceptibility testing are known. In the past when the national rate of primary drug resistance to isoniazid was known to be less than 4% and was either stable or declining, therapy with two and three drug regimens was considered adequate. If community rates of INH resistance are currently less than 4%, an initial treatment regimen with less than four drugs may be considered. Streptomycin is also indicated for therapy of tuberculosis when one or more of the above drugs is contraindicated because of toxicity or intolerance. The management of tuberculosis has become more complex as a consequence of increasing rates of drug resistance and concomitant HIV infection. Additional consultation from experts in the treatment of tuberculosis may be desirable in those settings.

2. Non-tuberculosis infections: The use of streptomycin should be limited to the treatment of infections caused by bacteria which have been shown to be susceptible to the antibacterial effects of streptomycin and which are not amenable to therapy with less potentially toxic agents.
    a. Pasteurella pestis (plague),
    b. Francisella tularensis (tularemia),
    c. Brucella,
    d. Calymmatobacterium granulomatis (donovanosis, granuloma inguinale),
    e. H. ducreyi (chancroid),
    f. H. influenzae (in respiratory, endocardial, and meningeal infections-concomitantly with another antibacterial agent),
    g. K. pneumoniae pneumonia (concomitantly with another antibacterial agent),
    h. E.coli, Proteus, Klebsiella aerogenes (formerly Enterobacter aerogenes or A. aerogenes), K. pneumoniae, and Enterococcus faecalis in urinary tract infections,
    i. Streptococcus viridans, Enterococcus faecalis (in endocardial infections -concomitantly with penicillin),
    j. Gram-negative bacillary bacteremia (concomitantly with another antibacterial agent).

Tobramycin injection
Tobramycin is indicated for the treatment of serious bacterial infections caused by susceptible strains of the designated microorganisms in the diseases listed below:
Septicemia in the pediatric patient and adult caused by P. aeruginosa, E. coli, and Klebsiella sp.
Lower respiratory tract infections caused by P. aeruginosa, Klebsiella sp, Enterobacter sp, Serratia sp, E. coli, and S. aureus (penicillinase- and non-penicillinase-producing strains).
Serious central-nervous-system infections (meningitis) caused by susceptible organisms.
Intra-abdominal infections, including peritonitis, caused by E. coli, Klebsiella sp, and Enterobacter sp.
Skin, bone, and skin-structure infections caused by P. aeruginosa, Proteus sp, E. coli, Klebsiella sp, Enterobacter sp, and S. aureus.
Complicated and recurrent urinary tract infections caused by P. aeruginosa, Proteus sp (indole-positive and indole-negative), E. coli, Klebsiella sp, Enterobacter sp, Serratia sp, S. aureus, Providencia sp, and Citrobacter sp.
Aminoglycosides, including tobramycin sulfate, are not indicated in uncomplicated initial episodes of urinary tract infections unless the causative organisms are not susceptible to antibiotics having less potential toxicity. Tobramycin may be considered in serious staphylococcal infections when penicillin or other potentially less toxic drugs are contraindicated and when bacterial susceptibility testing and clinical judgment indicate its use.
Bacterial cultures should be obtained prior to and during treatment to isolate and identify etiologic organisms and to test their susceptibility to tobramycin. If susceptibility tests show that the causative organisms are resistant to tobramycin, other appropriate therapy should be instituted. In patients in whom a serious life-threatening gram-negative infection is suspected, including those in whom concurrent therapy with a penicillin or cephalosporin and an aminoglycoside may be indicated, treatment with tobramycin sulfate may be initiated before the results of susceptibility studies are obtained. The decision to continue therapy with tobramycin should be based on the results of susceptibility studies, the severity of the infection, and the important additional concepts discussed in the warnings box.
To reduce the development of drug-resistant bacteria and maintain the effectiveness of tobramycin and other antibacterial drugs, tobramycin should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antimicrobial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.

Tygacil
<u>Complicated Skin and Skin Structure Infections</u>
Tygacil is indicated in patients 18 years of age and older for the treatment of complicated skin and skin structure infections caused by susceptible isolates of Escherichia coli, Enterococcus faecalis (vancomycin-susceptible isolates), Staphylococcus aureus (methicillin-susceptible and -resistant isolates), Streptococcus agalactiae, Streptococcus anginosus grp. (includes S. anginosus, S. intermedius, and S. constellatus), Streptococcus pyogenes, Enterobacter cloacae, Klebsiella pneumoniae, and Bacteroides fragilis.
<u>Complicated Intra-abdominal Infections</u>
Tygacil is indicated in patients 18 years of age and older for the treatment of complicated intra-abdominal infections caused by susceptible isolates of Citrobacter freundii, Enterobacter cloacae, Escherichia coli, Klebsiella oxytoca, Klebsiella pneumoniae, Enterococcus faecalis (vancomycin-susceptible isolates), Staphylococcus aureus (methicillin-susceptible and -resistant isolates), Streptococcus anginosus grp. (includes S. anginosus, S. intermedius, and S.

constellatus), Bacteroides fragilis, Bacteroides thetaiotaomicron, Bacteroides uniformis, Bacteroides vulgatus, Clostridium perfringens, and Peptostreptococcus micros.

Community-Acquired Bacterial Pneumonia

Tygacil is indicated in patients 18 years of age and older for the treatment of community-acquired bacterial pneumonia caused by susceptible isolates of Streptococcus pneumoniae (penicillin-susceptible isolates), including cases with concurrent bacteremia, Haemophilus influenzae, and Legionella pneumophila.

Limitations of Use

Tygacil is not indicated for the treatment of diabetic foot infections. A clinical trial failed to demonstrate non-inferiority of Tygacil for treatment of diabetic foot infections.

Tygacil is not indicated for the treatment of hospital-acquired or ventilator-associated pneumonia. In a comparative clinical trial, greater mortality and decreased efficacy were reported in Tygacil treated patients.

Usage

To reduce the development of drug-resistant bacteria and maintain the effectiveness of Tygacil and other antibacterial drugs, Tygacil should be used only to treat infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.

Appropriate specimens for bacteriological examination should be obtained in order to isolate and identify the causative organisms and to determine their susceptibility to tigecycline. Tygacil may be initiated as empiric monotherapy before results of these tests are known.

Vancomycin injection

Septicemia

Vancomycin Hydrochloride for Injection is indicated in adults and pediatric patients (neonates and older) for the treatment of septicemia due to:

- Susceptible isolates of methicillin-resistant Staphylococcus aureus (MRSA) and coagulase negative staphylococci.
- Methicillin-susceptible staphylococci in penicillin-allergic patients, or those patients who cannot receive or who have failed to respond to other drugs, including penicillins or cephalosporins

Infective Endocarditis

Vancomycin Hydrochloride for Injection is indicated in adults and pediatric patients (neonates and older) for the treatment of infective endocarditis due to:

- Susceptible isolates of MRSA.
- Viridans group streptococci Streptococcus gallolyticus (previously known as Streptococcus bovis), Enterococcus species and Corynebacterium species. For enterococcal endocarditis, use Vancomycin Hydrochloride for Injection in combination with an aminoglycoside.
- Methicillin-susceptible staphylococci in penicillin-allergic patients, or those patients who cannot receive or who have failed to respond to other drugs, including penicillins or cephalosporins.

Vancomycin Hydrochloride for Injection is indicated in adults and pediatric patients (neonates and older) for the treatment of early-onset prosthetic valve endocarditis caused by Staphylococcus epidermidis in combination with rifampin and an aminoglycoside.

Skin and Skin Structure Infections

Vancomycin Hydrochloride for Injection is indicated in adults and pediatric patients (neonates and older) for the treatment of skin and skin structure infections due to:

- Susceptible isolates of MRSA and coagulase negative staphylococci.
- Methicillin-susceptible staphylococci in penicillin-allergic patients, or those patients who cannot receive or who have failed to respond to other drugs, including penicillins or cephalosporins.

Bone Infections

Vancomycin Hydrochloride for Injection is indicated in adults and pediatric patients (neonates and older) for the treatment of bone infections due to:

- Susceptible isolates of MRSA and coagulase negative staphylococci.
- Methicillin-susceptible staphylococci in penicillin-allergic patients, or those patients who cannot receive or who have failed to respond to other drugs, including penicillins or cephalosporins.

Lower Respiratory Tract Infections

Vancomycin Hydrochloride for Injection is indicated in adults and pediatric patients (neonates and older) for the treatment of lower respiratory tract infections due to:

- Susceptible isolates of MRSA

- Methicillin-susceptible staphylococci in penicillin-allergic patients, or those patients who cannot receive or who have failed to respond to other drugs, including penicillins or cephalosporins.

Usage

To reduce the development of drug-resistant bacteria and maintain the effectiveness of Vancomycin Hydrochloride for Injection and other antibacterial drugs, Vancomycin Hydrochloride for Injection should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.
The parenteral form of vancomycin hydrochloride for injection, USP may be administered orally for treatment of antibiotic-associated pseudomembranous colitis produced by C. difficile and for staphylococcal enterocolitis. Parenteral administration of vancomycin hydrochloride alone is of unproven benefit for these indications. Vancomycin is not effective by the oral route for other types of infections.

Vfend IV

Invasive Aspergillosis

Vfend is indicated in adults and pediatric patients (2 years of age and older) for the treatment of invasive aspergillosis (IA). In clinical trials, the majority of isolates recovered were Aspergillus fumigatus. There was a small number of cases of culture-proven disease due to species of Aspergillus other than A. fumigatus.

Candidemia in Non-neutropenic Patients and Other Deep Tissue Candida Infections

Vfend is indicated in adults and pediatric patients (2 years of age and older) for the treatment of candidemia in non-neutropenic patients and the following Candida infections: disseminated infections in skin and infections in abdomen, kidney, bladder wall, and wounds.

Esophageal Candidiasis

Vfend is indicated in adults and pediatric patients (2 years of age and older) for the treatment of esophageal candidiasis (EC) in adults and pediatric patients 2 years of age and older.

Scedosporiosis and Fusariosis

Vfend is indicated for the treatment of serious fungal infections caused by Scedosporium apiospermum (asexual form of Pseudallescheria boydii) and Fusarium spp. including Fusarium solani, in adults and pediatric patients (2 years of age and older) intolerant of, or refractory to, other therapy.

Usage

Specimens for fungal culture and other relevant laboratory studies (including histopathology) should be obtained prior to therapy to isolate and identify causative organism(s). Therapy may be instituted before the results of the cultures and other laboratory studies are known. However, once these results become available, antifungal therapy should be adjusted accordingly.

INITIAL QUANTITY LIMIT*

Duration limits (Column A) and Daily dose limits (Column B) apply for each drug.

LIMIT CRITERIA

Limits do not accumulate together; patient is allowed the maximum limit for each drug and strength

PLEASE NOTE: Since manufacturer package sizes may vary, it is the discretion of the dispensing pharmacy to fill quantities per package size up to these quantity limits. In such cases the filling limit and day supply may be less than what is indicated.

		Column A	**Column B**	
Medication	usual/maximum recommended dose (139.9kg allows for 95th percentile dosing)[32]	**Duration per 365 days**	**Daily dose**	**package size**
Abelcet (amphotericin B lipid complex)	5mg/kg/day *5mgx139.9kg = 699.5mg/day* *699.5mg/day/100mg/vial = 7vials/day* *7vialsx20mL/vial = 140mL*	14 days	140mL	5mg/mL 20mL per vial (100mg per vial)
AmBisome (amphotericin B liposome)	6mg/kg/day, *6mgx139.9kg = 839.4mg/day* *839.4mg/day/50mg/vial = 16.8vials/day*	14 days	17 vials	50mg per vial
amphotericin B	1 mg/kg/day *1mgx139.9kg/day = 139.9mg/day* *139.9mg/day/50mg/vial = 2.8vials/day*	14 days	3 vials	50mg per vial
Cancidas	50mg/day or 70mg/day	14 days	1 vial	50mg per vial

(caspofungin)	*= 1vial/day*			70mg per vial
ceftriaxone vials, bottles	1 to 2 gm once a day (or divided doses twice a day) The total daily dose should not exceed 4gm *1vial/dosex2doses/day = 2vials/day*	14 days	2 vials	250mg per vial 500mg per vial 1gm per vial 2gm per vial
			0.5 bottle	10gm per bottle
Coly-Mycin M (colistimethate)	5mg/kg/day in 2 to 4 divided doses *5mgx139.9kg = 699.5mg/day,* *699.5mg/4doses/day = 174.9mg/dose* *174.9mg/dose/150mg/vial = 1.2vials/dose* *2vials/dosex4doses/day = 8vials/day*	14 days	8 vials	150mg per vial
Cubicin, Cubicin RF (daptomycin)	6mg/kg once every 24 hours *6mgx139.9kg = 839.4/day* *839.4mg/day/500mg/vial = 1.7vials/day*	14 days	2 vials	500mg per vial
Dapzura RT (daptomycin)				
daptomycin 500mg				
daptomycin 350mg	6mg/kg once every 24 hours *6mgx139.9kg = 839.4mg/day* *839.4mg/day/350mg/vial = 2.4vials/day*	14 days	3 vials	350mg per vial
Dalvance (dalbavancin)	1500mg as single dose or divided *1500mg/dose/500mg/vialx1dose = 3 vials*	1 day	3 vials	500mg per vial
Invanz (ertapenem)	Adult and pediatric patients 13 years of age and older: 1g given once a day *1vial/dosex1dose/day = 1vial/day* Pediatric 3 months to 12 years of age: 15mg/kg twice daily (not to exceed 1g/day), *1vial/dosex2doses/day = 2vials/day*	14 days	2 vials	1gm per vial
Kimyrsa (oritavancin)	1200mg (one dose) *1200mg/dose/1200mg/vialx1dose = 1 vial*	1 day	1 vial	1200mg per vial
levofloxacin inj	Adult: 750mg every 24 hours *750mg/day/25mg/mL = 30mL/day* *30mL/day/30mL/vial = 1 vial/day* Pediatric: 250mg every 12 hours *250mg/dose/25mg/mL = 10mL/dose* *10mL/dose/20mL/vial = 0.5vials/dose* *1vial/dosex2doses/day = 2vials/day* *2vials/dayx20mL/vial = 40mL/day*	14 days	40mL	25mg/mL 20mL per vial =500mg / 20mL vial
				25mg/mL 30mL per vial =750mg / 30mL vial
meropenem 2gm	2gm every 8 hours 2gm/dose/2gm/vial = 1vial/dose 1vial/dosex3doses/day = 3vials/day	14 days	3 vials	2gm per vial
meropenem 500mg, 1gm	2gm every 8 hours 2gm/dose/500mg/vial = 4vials/dose 4vials/dosex3doses/day = 12vials/day 2gm/dose/1gm/vial = 2vials/dose 2vials/dosex3doses/day = 6vials/day	14 days	12 vials	500mg per vial
			6 vials	1gm per vial
Mycamine (micafungin)	150mg once daily *150mg/day/50mg/vial = 3vials/day* *150mg/day/100mg/vial = 2vials/day*	14 days	3 vials	50mg per vial
			2 vials	100mg per vial
Orbactiv (oritavancin)	1200mg (one dose) *1200mg/dose/400mg/vialx1dose = 3 vials*	1 day	3 vials	400mg per vial
streptomycin	1 to 2 gm in divided doses *1gm/vialx2doses/day = 2 vials/day*	14 days	2 vials	1gm per vial
tobramycin inj	10mg/kg/day in 3 equal doses or in 4 equal doses. *10mgx139.9kg = 1399kg/day* *1399mg/day/4doses/day = 349.8mg/dose* *349.8mg/dose/40mg/mL = 8.7mL/dose* *9mL/dosex4doses/day = 36mL/day*	10 days	36mL	10mg/mL 2mL per vial (20mg / 2mL vial)
				80mg/2mL 2mL per vial (40mg / mL vial)
				40mg/mL

				30mL per vial (1200mg / 30mL vial)
				40mg/mL 50mL per vial (2000mg / 50mL vial)
			2 vials	1.2gm powd per vial
Tygacil (tigecycline)	Initial dose of 100mg *100mg/dose/50mg/vialx1dose = 2 vials* Followed by 50mg every 12 hours *50mg/dose/50mg/vial = 1vial/dose* *1vial/dosex2doses/day = 2vials/day* **2vials initial dose + followed by 1vial = 3vials 1st day*	14 days	3 vials* **Daily limit allows for maximum quantity needed for first day of treatment*	50mg per vial
vancomycin inj vials, bottles	2 grams divided either as 500mg every 6 hours *4doses/dayx1vial/dose = 4vials/day* or 1 g every 12 hours *2doses/dayx1vial/dose = 2vials/day* [oral: 125mg to 2gm in four divided doses for ten days]	14 days	4 vials	250mg per vial 500mg per vial 750mg per vial
			2 vials	1gm per vial 1.25gm per vial 1.5gm per vial 1.75gm per vial
			1 vial	2gm per vial
			0.3 bottles	5gm per bottle 10gm per bottle
Vfend IV (voriconazole inj)	Loading dose 6mg/kg every 12 hours for the first 24 hours *6mgx139.9kg/dose = 839.4mg/dose* *839.4mg/dose/200mg/vial = 4.2vials/dose* *5vials/dosex2doses = 10 vials 1st day* Maintenance dose 4mg/kg every 12 hours *4mgx139.9kg/dose = 559.6mg/dose* *559.6mg/dose/200mg/vial = 2.8vials/dose* *3vials/dosex2doses/day = 6vials/day*	14 days	10 vials* **Daily limit allows for maximum quantity needed for first day of treatment*	200mg per vial

**If the patient is requesting more than the initial quantity limit, the claim will reject with a message indicating that a prior authorization is required. The prior authorization criteria would then be applied to requests submitted for evaluation to the PA unit.

COVERAGE CRITERIA

Authorization may be granted for the requested drug when ALL of the following criteria are met:

- The requested drug will NOT be used intranasally or in a footbath
- The requested drug is being prescribed for an FDA-approved indication or an indication supported in the compendia of current literature (examples: AHFS, Micromedex, current accepted guidelines)
- The infection is proven or strongly suspected to be caused by susceptible microorganisms
- The patient meets ONE of the following:
  - The patient cannot be treated with oral therapy
  - The request is for vancomycin to be taken orally for the treatment of C. difficile associated diarrhea or for staphylococcal enterocolitis

DURATION OF APPROVAL (DOA)

- 4390-HJ:
  - serious, chronic, recurring infection: DOA: 12 months
  - other indications: DOA: 3 months

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