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 Policy Number: C30376-A

Anti-Infectives

PRODUCTS AFFECTED

Avycaz (ceftazidime-avibactam), Baxdela (delafloxacin), Blujepa (gepotidacin), Contepo (fosfomycin), Cubicin (daptomycin), daptomycin, Emblaveo (aztreonam-avibactam), Fetroja (cefiderocol), Kimyrsa (oritavancin), Nuzolvence (zoliflodacin), Nuzyra (omadacycline), Orbactiv (oritavancin), Orlynvah (sulopenem etzadroxil-probenecid), Recarbrio (imipenem, cilastatin, and relebactam), Rezzayo (rezafungin), Sivextro (tedizolid), Teflaro (ceftaroline), Vabomere (meropenem-vaborbactam), Vibativ (telavancin), Xacduro (sulbactam-durlobactam), Xerava (eravacycline), Zemdri (plazomicin), Zerbaxa (ceftolozane-tazobactam), Zevtera (ceftobiprole)

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:

Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:

Infection

REQUIRED MEDICAL INFORMATION:

This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by-case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight,

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body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

A. FOR ALL INDICATIONS:

1. Documentation the member has an infection caused by or strongly suspected to be caused by a type of pathogen and site of infection within the FDA label or compendia supported
AND
2. CONTINUATION AFTER INPATIENT START: Use of first-line treatments not required if request is for continuation of therapy that was started in an inpatient setting (within the last 14 days) and member is at time of request transitioning to an outpatient site of care [DISCHARGE DOCUMENTATION REQUIRED WHICH INCLUDES INFECTIOUS DISEASE PRESCRIBER RECOMMENDED DURATION OF THERAPY, START AND END DATE]
AND
3. FOR IV REQUESTS OF A PRODUCT WITH AN ORAL ALTERNATIVE: Documentation of medically necessary use of IV formulation for the current active infection instead of oral formulation
AND
4. FOR MEDICATION TYPICALLY ADMINISTERED AS INPATIENT HOSPITAL TREATMENT REQUESTED AS OUTPATIENT: Requested medication is appropriate for member's clinical status, infection severity, and administration requirements for the requested setting of care
AND
5. ANY CONDITION SPECIFIC REQUIREMENT BELOW

B. COMMUNITY ACQUIRED PNEUMONIA (CABP):

1. Documented diagnosis of community acquired pneumonia (CABP)
AND
2. Documentation of inadequate treatment response, serious side effects, contraindication, or non-susceptibility to a first-line antibiotic treatment, such as a macrolide, preferred fluoroquinolone, beta-lactam, or tetracycline

C. ACUTE BACTERIAL SKIN AND SKIN STRUCTURE INFECTION (ABSSSI):

1. Documented diagnosis of acute bacterial skin and skin structure infection (ABSSSI)
AND
2. Documentation of inadequate treatment response, serious side effects, contraindication, or non-susceptibility to a first-line antibiotic treatment for the site of infection such as a beta-lactam, tetracycline, clindamycin, trimethoprim-sulfamethoxazole, preferred fluoroquinolone, or vancomycin

D. OSTEOMYELITIS:

1. Documented diagnosis of osteomyelitis
AND
2. Documentation of inadequate treatment response, serious side effects, non-susceptibility report for current infection, or FDA labeled contraindication to ALL of the following: i. For MSSA - nafcillin, cefazolin, oxacillin, OR ii. For MRSA - vancomycin, daptomycin
OR

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3. Prescriber provides detailed medical necessity rationale against outpatient parenteral antimicrobial therapy with i. For MSSA - nafcillin, cefazolin, oxacillin, OR ii. For MRSA - vancomycin, daptomycin

E. UNCOMPLICATED URINARY TRACT INFECTION (uUTI):

1. Documented diagnosis of uncomplicated urinary tract infection (uUTI) (infection confined to the bladder in an afebrile man or woman)
AND
2. Documentation of inadequate treatment response, serious side effects, contraindication, or non-susceptibility to a first-line antibiotic treatment, such as nitrofurantoin, trimethoprim-sulfamethoxazole, preferred fosfomycin, or preferred fluoroquinolone
AND
3. FOR ORLYNVAH: Documentation the member has limited or no alternative options for treatment of the infection per the FDA label

F. COMPLICATED URINARY TRACT INFECTION (cUTI):

1. Documented diagnosis of complicated urinary tract infection (cUTI) (infection beyond the bladder in women or men including pyelonephritis, febrile or bacteremic UTI, catheter-associated UTI, flank pain, chills or other signs of systemic illness)
AND
2. Documentation of inadequate treatment response, serious side effects, contraindication, or non-susceptibility to a first-line antibiotic treatment, such as trimethoprim-sulfamethoxazole, preferred fluoroquinolone, third or fourth generation cephalosporin (e.g., ceftriaxone, cefepime, etc.), piperacillin-tazobactam, or carbapenem
AND
3. FOR FETROJA AND ZEMDRI: Documentation the member has limited or no alternative options for treatment of the infection per the FDA label

G. FOR GONORRHEA:

1. Documented diagnosis of gonorrhea
AND
2. Documentation of inadequate treatment response, serious side effects, contraindication, or non-susceptibility to standard treatment with ceftriaxone (with or without azithromycin)

H. FOR INTRA-ABDOMINAL INFECTION:

1. Documented diagnosis of complicated intra-abdominal infection (cIAI)
AND
2. Documentation of inadequate treatment response, serious side effects, contraindication, or non-susceptibility to beta-lactam/beta-lactamase inhibitor, ertapenem, cephalosporin plus metronidazole, or preferred fluoroquinolone plus metronidazole
AND
3. FOR EMBLAVEO AND RECARBRIO: Documentation the member has limited or no alternative treatment options for the infection per the FDA label

I. FOR CANDIDEMIA OR INVASIVE CANDIDIASIS:

1. Documented diagnosis of candidemia or invasive candidiasis
AND
2. Request is for Rezzayo (rezafungin)
AND

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3. Documentation of inadequate treatment response, serious side effects, contraindication, or non-susceptibility to a preferred antifungal treatment (oral fluconazole, IV voriconazole, or IV amphotericin if diagnostically appropriate)
AND
4. Documentation the member has limited or no alternative options for treatment of the infection per the FDA label

J. FOR HABP/VABP;

1. Documented diagnosis of healthcare-acquired bacterial pneumonia/ventilator-associated bacterial pneumonia (HABP/VABP)
AND
2. Documentation of inadequate treatment response, serious side effects, contraindication, or non-susceptibility to a first line antibiotic treatment, such as preferred fluoroquinolone, piperacillin-tazobactam, cefepime, carbapenem, vancomycin, or linezolid
AND
3. FOR XACDURO: Documentation infection is caused by a susceptible isolate of carbapenem-resistant *Acinetobacter baumannii-calcoaceticus* complex

K. FOR DAPTOMYCIN, TEFLARO, VIBATIV:

1. Documentation of FDA labeled contraindication to Vancomycin
OR
2. Documentation of inadequate treatment response, serious side effects, or non-susceptibility report for the current infection to Vancomycin
OR
3. Prescriber provides detailed medical necessity rationale against outpatient parenteral antimicrobial therapy with Vancomycin

CONTINUATION OF THERAPY:

N/A, Each new infection treatment should be a new review

DURATION OF APPROVAL:

Initial authorization: Total treatment duration must be supported by FDA label or compendia supported dosing for prescribed indication (See Appendix), Continuation of Therapy: N/A

PRESCRIBER REQUIREMENTS:

Prescribed by or in consultation with a board-certified infectious disease specialist [If prescribed in consultation, consultation notes must be submitted with initial request]

AGE RESTRICTIONS:

Must be prescribed within FDA or compendia supported labeled age maximums or minimums

QUANTITY:

Dosage, frequency, and total treatment duration must be supported by FDA label or compendia supported dosing for prescribed indication

PLACE OF ADMINISTRATION:

The recommendation is that oral medications in this policy will be for pharmacy benefit coverage and patient self-administered.

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The recommendation is that infused medications in this policy will be for pharmacy or medical benefit coverage administered in a place of service that is a non-inpatient hospital facility-based location.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:

Oral, Intravenous

DRUG CLASS:

Cephalosporins, Tetracyclines, Fluoroquinolones, Aminoglycosides, Antifungals, Anti-Infective Agents - Misc.

FDA-APPROVED USES:

Indicated for infection caused by designated susceptible bacteria or fungus

COMPENDIAL APPROVED OFF-LABELED USES:

Daptomycin: Septic arthritis (alternative agent), Osteomyelitis and/or discitis (alternative agent), vancomycin-resistant enterococci, MRSA-associated prosthetic device infections, MRSA-associated spinal implant infections, empiric treatment of febrile neutropenia, treatment of intraabdominal infections, including peritonitis, appendicitis, intraabdominal abscess, spontaneous bacterial peritonitis, and peritoneal dialysis-related peritonitis

Nuzyra (omadacycline): Bubonic or pharyngeal plague infection

Vibativ (telavancin): Bacteremia due to *S. aureus* (MRSA)

APPENDIX

APPENDIX:

Medication	Labeled Indication	Age	Dosing
Avycaz (ceftazidime-avibactam)	cIAI	No restriction	Adults: 2.5 g every 8 hours by IV infusion over 2 hours for 5 to 14 days, WITH METRONIDAZOLE Pediatrics: age based every 8 hours by IV infusion over 2 hours for 5 to 14 days, WITH METRONIDAZOLE
Avycaz (ceftazidime-avibactam)	cUTI HABP/VABP	No restriction	Adults: 2.5 g every 8 hours by IV infusion over 2 hours for 7 to 14 days Pediatrics: age based every 8 hours by IV infusion over 2 hours for 7 to 14 days
Baxdela (delafloxacin)	ABSSSI	18 and older	300mg IV every 12 hours OR 450mg orally every 12 hours for 5 to 14 days
Baxdela (delafloxacin)	CABP	18 and older	300mg IV every 12 hours OR 450mg orally every 12 hours for 5 to 10 days
Blujepa (gepotidacin)	Uncomplicated UTI	12 and older	1,500 mg twice daily for 5 days
Blujepa (gepotidacin)	Gonorrhea	12 and weight	Two 3 g doses, 10 to 12 hours apart
Contepo (fosfomicin)	Complicated UTI	18 and older	6 g every 8 hours by IV infusion over 1 hour for up to 14 days
Cubicin (daptomycin)	cSSSI	1 and older	Adult: 4 mg/kg once every 24 hours for 7 to 14 days Pediatric: age and weight based once every 24 hours for 7 to 14 days

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Cubicin (daptomycin)	Staphylococcus aureus blood stream infections (bacteremia)	1 and older	Adult: 6 mg/kg once every 24 hours for 2 to 6 weeks Pediatric: age and weight based once every 24 hours for up to 42 days
Cubicin (daptomycin)	Staphylococcus aureus blood stream infections with right sided endocarditis	18 and older	6 mg/kg once every 24 hours for 2 to 6 weeks
Emblaveo (aztreonam-avibactam)	cIAI caused by certain susceptible gram-negative bacteria	18 and older	Loading dose: 2.67 g Maintenance dose: 2 g every 6 hours by IV infusion over 3 hours for 5 to 14 days
Fetroja (cefiderocol)		18 and older	2 grams every 8 hours by IV infusion over 3 hours for 7 to 14 days
Kimyrsa (oritavancin)	ABSSSI	18 and older	1,200 mg administered as a single dose by IV infusion over 1 hour
Nuzolvece (zoliflodacin)	Gonorrhea	12 and weight	3 g once
Nuzyra (omadacycline)	ABSSSI	18 and older	200 mg IV once or 100 mg IV twice daily as loading dose on day 1, then 100 mg IV once daily for up to 14 days OR After IV loading dose, 300 mg PO once daily for up to 14 days; 450 mg PO as loading dose on days 1 and 2, then 300 mg PO once daily for up to 14 days
Nuzyra (omadacycline)	CABP	18 and older	200 mg IV once or 100 mg IV twice daily as loading dose on day 1, then 100 mg IV once daily for up to 14 days OR After IV loading dose, 300 mg PO once daily for up to 14 days; 300 mg PO twice daily as loading dose on day 1, then 300 mg PO once daily for up to 14 days
Orbactiv (oritavancin)	ABSSSI	18 and older	1,200 mg administered as a single dose by IV infusion over 3 hours
Orlynvah (sulopenem-probenecid)	Uncomplicated UTI in women	18 and older	1 tablet twice daily for 5 days
Recarbrio (imipenem, cilastatin, relebactam)	HABP/VABP Complicated UTI cIAI	18 and older	1.25 grams (imipenem 500 mg, cilastatin 500 mg, and relebactam 250 mg) IV infusion over 30 minutes every 6 hours for 4 to 14 days
Recarbrio (imipenem, cilastatin, relebactam)	HABP/VABP Complicated UTI cIAI	Birth and >2 kg	Weight based every 6 or 8 hours for 4 to 14 days. 30 kg or greater follow adult dosing.
Rezzayo (rezafungin)	Candidemia, Invasive candidiasis	18 and older	400 mg once (loading dose) followed by 200 mg once weekly thereafter. Max of 4 weekly doses including the loading dose.
Sivextro (tedizolid)	ABSSSI	12 and older	200 mg IV or orally once daily for 6 days
Teflaro (ceftaroline)	ABSSSI	No restriction	Adult: 600 mg IV every 12 hours for 5 to 14 days Pediatric: age and weight based every 8 to 12 hours for 5 to 14 days
Teflaro (ceftaroline)	CABP	2 months and older	Adult: 600 mg IV every 12 hours for 5 to 7 days Pediatric: age and weight based every

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			8 to 12 hours for 5 to 14 days
Vabomere (meropenem-vaborbactam)	Complicated UTI	18 and older	4 g (meropenem 2 g and vaborbactam 2 g) every 8 hours by IV infusion over 3 hours for up to 14 days
Vibativ (telavancin)	cSSSI	18 and older	10 mg/kg IV infusion over 60 minutes every 24 hours for 7 to 14 days
Vibativ (telavancin)	HABP/VABP	18 and older	10 mg/kg IV infusion over 60 minutes every 24 hours for 7 to 21 days
Xacduro (sulbactam-durlobactam)	HABP/VABP	18 and older	1g/1g every 6 hours for 7-14 days. If CrCl is >140 mL/min (based on Cockcroft-Gault equation), give every 4 hours.
Xerava (eravacycline)	cIAI	18 and older	1 mg/kg every 12 hours over 1 hour for 4 to 14 days
Zemdri (plazomicin)	Complicated UTI	18 and older	15 mg/kg administered every 24 hours for 4 to 7 days
Zerbaxa (ceftolozane-tazobactam)	cIAI with metronidazole	No restriction	Adult: 1.5 g every 8 hours for 4 to 14 days Pediatric: 30 mg/kg (max 1/5 g) every 8 hours for 5 to 14 days
Zerbaxa (ceftolozane-tazobactam)	Complicated UTI	No restriction	Adult: 1.5 g every 8 hours for 7 days Pediatric: 30 mg/kg (max 1/5 g) every 8 hours for 7 to 14 days
Zerbaxa (ceftolozane-tazobactam)	HABP/VABP	18 and older	3 g every 8 hours for 8 to 14 days
Zevtera (ceftobiprole)	SAB including right-sided infective endocarditis	18 and older	667 mg every 6 hours on days 1 to 8, then 667 mg every 8 hours from day 9 for up to 42 days 2 hour infusion
Zevtera (ceftobiprole)	ABSSSI	18 and older	667 mg every 8 hours over 2 hours for 5 to 14 days
Zevtera (ceftobiprole)	CABP	3 months and older	Adult: 667 mg every 8 hours for 5 to 14 days Peds 12 to <18: 13.3 mg/kg (max 667 mg) every 8 hours for 7 to 14 days Peds 3 months to <12: 20 mg/kg (max 667 mg) every 8 hours for 7 to 14 days

ABSSSI: Acute bacterial skin and skin structure infection; CABP: Community-acquired bacterial pneumonia; cIAI: complicated intra-abdominal infections; cSSSI: Complicated skin and skin structure infections; HABP/VABP: Hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia; MRSA: methicillin-resistant *Staphylococcus aureus*; MSSA: methicillin-susceptible *Staphylococcus aureus*; SAB: *Staphylococcus aureus* bloodstream infections (bacteremia); UTI: urinary tract infection; cUTI: complicated urinary tract infection; uUTI: uncomplicated urinary tract infection; VISA: vancomycin-intermediate *Staphylococcus aureus*; VRE: vancomycin-resistant enterococci; VRSA: vancomycin-resistant *Staphylococcus aureus*;

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:

The anti-infectives class encompasses a broad spectrum of agents essential for the management of serious bacterial and fungal infections, including novel and reformulated antibiotics. These therapies are indicated for resistant Gram-positive and Gram-negative pathogens where first-line agents are ineffective or contraindicated, and their use should be informed by current susceptibility data and established clinical guidelines. Treatment guidelines from the Infectious Diseases Society of America (IDSA), as well as recommendations from the Centers for Disease Control and Prevention (CDC) and regulatory approvals by the U.S. Food and Drug Administration (FDA), provide some of the evidence base for appropriate agent selection and duration of therapy. These

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requirements support antimicrobial stewardship principles to mitigate the emergence of resistance. Clinician documentation should reflect adherence to guideline-supported indications and relevant microbiological data where applicable.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:

All other uses of antibiotics, antifungals, and anti-infectives are considered experimental/investigational and therefore, will follow Molina's Off- Label policy. All FDA labeled contraindications are exclusions to any therapy.

Exclusions/Discontinuation:

For linezolid or Sivextro (tedizolid), member is not concurrently taking any of the following: monoamine oxidase (MAO) inhibitor (e.g., phenelzine, isocarboxazid), selective serotonin reuptake inhibitor (SSRI), selective norepinephrine-reuptake inhibitor (SNRI), OR the member will discontinue the concurrent interacting medication and be monitored.

Discontinue delafloxacin immediately if tendonitis, tendon rupture, peripheral neuropathy, central nervous system effects, or exacerbation of myasthenia gravis is experienced.

Daptomycin is inactivated by pulmonary surfactant and must not be used for pneumonia.

Patients requiring concomitant therapy with other monoamine oxidase inhibitors or serotonergic agents (SSRIs) were excluded from Tedizolid clinical trials.

OTHER SPECIAL CONSIDERATIONS:

To reduce the development of bacterial resistance and maintain effectiveness of antibiotics, antibiotics should only be used to treat infections 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 culture and susceptibility information, local epidemiology and susceptibility patterns may contribute to empiric selection of therapy.

Clostridioides difficile-associated diarrhea (CDAD) has been reported for nearly all systemic antibacterial agents, with severity ranging from mild diarrhea to fatal colitis. Treatment with antibacterial agents can alter the normal flora of the colon and may permit overgrowth of *C. difficile*. *C. difficile* produces toxins A and B which contribute to the development of CDAD. Hypertoxin producing strains of *C. difficile* cause increased morbidity and mortality, as these infections can be refractory to antibacterial therapy and may require colectomy. CDAD must be considered in all patients who present with diarrhea following antibacterial drug use. Careful medical history is necessary because CDAD has been reported to occur more than two months after the administration of antibacterial agents. If CDAD is suspected or confirmed, antibacterial use not directed against *C. difficile* should be discontinued, if possible. Appropriate measures such as fluid and electrolyte management, protein supplementation, antibacterial treatment of *C. difficile*, and surgical evaluation should be instituted as clinically indicated.

Some products have renal dose adjustments per the FDA label. Xacduro requires dose adjustment for CL_{cr} greater than or equal to 130 mL/min.

Baxdela (delafloxacin) has a black box warning for serious adverse reactions including tendonitis, tendon rupture, peripheral neuropathy, central nervous system effects, and exacerbation of myasthenia gravis. Fluoroquinolones are associated with disabling and potentially irreversible serious adverse reactions that have occurred together, including tendinitis and tendon rupture, peripheral neuropathy, and CNS effects. Discontinue delafloxacin immediately and avoid the use of fluoroquinolones in patients who experience any of these serious adverse reactions. Exacerbation

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of myasthenia gravis: Fluoroquinolones may exacerbate muscle weakness in patients with myasthenia gravis. Avoid delafloxacin in patients with known history of myasthenia gravis.

Vibativ (telavancin) has a Black Box Warning for increased mortality in HABP/VABP patients with pre-existing moderate or severe renal impairment, nephrotoxicity, and embryofetal toxicity.

Zemdri (plazomicin) has a Black Box Warning for nephrotoxicity, ototoxicity, neuromuscular blockade and fetal harm.

CODING/BILLING INFORMATION

CODING DISCLAIMER. Codes listed in this policy are for reference purposes only and may not be all-inclusive or applicable for every state or line of business. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry-standard coding practices for all submissions. Molina has the right to reject/deny the claim and recover claim payment(s) if it is determined it is not billed appropriately or not a covered benefit. Molina reserves the right to revise this policy as needed.

HCPCS CODE	DESCRIPTION
J0121	Injection, omadacycline, 1mg
J0122	Injection, eravacycline, 1 mg
J0291	Injection, plazomicin, 5 mg
J0349	Injection, rezafungin, 1 mg
J0458	Injection, aztreonam/avibactam, 7.5 mg/2.5 mg (10 mg) (Emblaveo)
J0681	Injection, ceftobiprole medocaril sodium, 3 mg (Zevtara)
J0695	Injection, ceftolozane 50 mg and tazobactam 25 mg
J0699	Injection, cefiderocol, 10 mg
J0712	Injection, ceftaroline fosamil, 10 mg
J0714	Injection, ceftazidime and avibactam, 0.5 g/0.125 g
J0742	Injection, imipenem 4 mg, cilastatin 4 mg and relebactam 2 mg
J0872	Injection, daptomycin (xellia), unrefrigerated, not therapeutically equivalent to J0878 or J0873, 1 mg
J0873	Injection, daptomycin (xellia) not therapeutically equivalent to J0878 or J0872, 1 mg
J0874	Injection, daptomycin (baxter), not therapeutically equivalent to J0878, 1 mg
J0877	Injection, daptomycin (hospira), not therapeutically equivalent to J0878, 1 mg
J0878	Injection, daptomycin, 1mg
J2186	Injection, meropenem and vaborbactam, 10mg/10mg (20mg)
J2406	Injection, oritavancin (kimyrsa), 10 mg
J2407	Injection, oritavancin (orbactiv), 10 mg
J3090	Injection, tedizolid phosphate, 1mg
J3095	Injection, telavancin, 10mg

AVAILABLE DOSAGE FORMS:

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Avycaz SOLR 2.5 (2-0.5)GM
Baxdela SOLR 300MG
Baxdela TABS 450MG
Blujepa TABS 750MG
Cubicin RF SOLR 500MG
Cubicin SOLR 500MG
DAPTOMycin SOLR 350MG, 500MG
DAPTOMycin-Sodium Chloride SOLN 1000-0.9MG/100ML-%, 350-0.9MG/50ML-%, 500-0.9MG/50ML-%, 700-0.9MG/100ML-%
Emblaveo SOLR 1.5-0.5GM
Fetroja SOLR 1GM
Kimyrsa SOLR 1200MG
Nuzyra SOLR 100MG
Nuzyra TABS 150MG
Orbactiv SOLR 400MG
Orlynvah TABS 500-500MG
Recarbrio SOLR 1.25GM
Rezzayo SOLR 200MG
Sivextro SOLR 200MG
Sivextro TABS 200MG
Teflaro SOLR 400MG, 600MG
Vabomere SOLR 2 (1-1)GM
Vibativ SOLR 750MG
Xacduro SOLR 1-1GM
Xerava SOLR 50MG, 100MG
Zemdri SOLN 500MG/10ML
Zerbaxa SOLR 1.5 (1-0.5)GM
Zevtera SOLR 500MG

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1. Avycaz (ceftazidime and avibactam) for injection, for intravenous use [prescribing information]. Verona 37135, Italy: ACS Dobfar SpA; April 2025.
2. Baxdela (delafloxacin) tablets, for oral use; for injection, for intravenous use [prescribing information]. Lincolnshire, IL: Melinta Therapeutics LLC; June 2021.
3. Blujepa (gepotidacin) tablets, for oral use use [prescribing information]. Durham, NC: GlaxoSmithKline; December 2025.
4. Contepo (fosfomycin) for injection, for intravenous use [prescribing information]. Chicago, IL: Meitheal Pharmaceuticals; October 2025.
5. Cubicin RF (daptomycin for injection), for Intravenous Use [prescribing information]. Whitehouse Station, NJ: Merck Sharp & Dohme Corp; March 2025.
6. Emblaveo (aztreonam and avibactam) for injection, for intravenous use [prescribing information]. North Chicago, IL: AbbVie Inc.; February 2025.
7. Fetroja (cefiderocol) for injection, for intravenous use [prescribing information]. Osaka, Japan: Shionogi & Co., Ltd.; July 2025.
8. Kimyrsa® (oritavancin) for injection, for intravenous use [prescribing information]. Parsippany, NJ: Melinta Therapeutics, LLC; April 2025.
9. Nuzolvence® (zolidnadacin) for oral suspension [prescribing information]. Waltham, MA: La Jolla Pharmaceutical Company; December 2025.
10. Nuzyra (omadacycline) for injection, for intravenous use; tablets, for oral use [prescribing information].

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 12. Orlynvah (sulopenem etzadroxil and probenecid) tablets, for oral use [prescribing information]. Chicago, IL: Iterum Therapeutics U.S. Limited; March 2025.
 13. Recarbrio (imipenem, cilastatin, and relebactam) for injection, for intravenous use [prescribing information]. Rahway, NJ: Merck Sharp & Dohme LLC; December 2025.
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SUMMARY OF REVIEW/REVISIONS	DATE
NEW CRITERIA CREATION	Q1 2026