

Injectable Antibiotics
Effective 09/01/2023

Plan	<input checked="" type="checkbox"/> MassHealth UPPL <input type="checkbox"/> Commercial/Exchange	Program Type	<input checked="" type="checkbox"/> Prior Authorization <input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Benefit	<input checked="" type="checkbox"/> Pharmacy Benefit <input type="checkbox"/> Medical Benefit (NLX)		
Specialty Limitations			
Contact Information	Specialty Medications		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
Exceptions			

Overview

No PA†	Require PA
Cubicin® (daptomycin)	Avycaz® (ceftazidime/avibactam)
daptomycin	Baxdela® (delafloxacin injection)
Teflaro® (ceftaroline)	Dalvance® (dalbavancin)
vancomycin injection	Fetroja® (cefiderocol)
	Kimyrsa® (oritavancin)
	Nuzyra® (omadacycline injection)
	Orbactiv® (oritavancin)
	Recarbrio® (imipenem/cilastatin/relebactam)
	Tygacil® (tigecycline)
	Sivextro® (tedizolid injection)
	Synercid® (dalbopristin/quinupristin)
	Vabomere® (meropenem/vaborbactam)
	Vibativ® (telavancin)
	Xenleta® (Iefamulin injection)
	Xerava® (eravacycline)
	Zemdri® (plazomicin)
	Zerbaxa® (ceftolozane/tazobactam)
	Zyvox® (linezolid injection)*

*A-rated generic available, both brand and A-rated generic require PA.

† There are many other injectable antibiotics that are available without PA

Coverage Guidelines

Authorization may be reviewed on a case by case basis for members who are new to the plan currently receiving treatment with requested medication excluding when the product is obtained as samples or via manufacturer's patient assistance programs.

OR

Authorization will be granted when all the following criteria has been met:

Avycaz, Recarbrio, Tygacil, Xerava, Zerbaxa

ALL of the following:

1. Diagnosis of Complicated intra-abdominal infection (cIAI)
2. If the request is for Tygacil® or Zerbaxa®, member is ≥18 years of age
3. Paid claims within the past 30 days or physician documentation of an inadequate response, adverse reaction to **TWO** or contraindication (e.g., culture not susceptible) to **ALL** of the following:
 - a. Combination therapy with aztreonam and metronidazole and vancomycin
 - b. Combination therapy with metronidazole and cefepime
 - c. Combination therapy with metronidazole and cefotaxime
 - d. Combination therapy with metronidazole and ceftazidime
 - e. Combination therapy with metronidazole and ceftriaxone
 - f. Combination therapy with metronidazole and ciprofloxacin
 - g. Combination therapy with metronidazole and levofloxacin
 - h. doripenem
 - i. ertapenem
 - j. imipenem/cilastatin
 - k. meropenem
 - l. moxifloxacin
 - m. piperacillin/tazobactam
4. If the request is for Avycaz® or Zerbaxa®, the requested agent will be used concurrently with metronidazole
5. Requests for brand name Tygacil® must meet the above criteria and the prescriber must submit medical records documenting an inadequate response or adverse reaction to generic tigecycline injection (as per the Brand Name guideline).

Avycaz, Fetroja, Recarbrio, Vabomere, Zemdri, Zerbaxa

ALL of the following:

1. Diagnosis of Complicated urinary tract infection (cUTI)
2. If the request is for Vabomere® (meropenem/vaborbactam), Zemdri® (plazomicin), or Zerbaxa® (ceftolozane/tazobactam), member is >18 years of age
3. Paid claims within the past 30 days or physician documentation of an inadequate response, adverse reaction to **TWO** or contraindication (e.g., culture not susceptible) to **ALL** of the following:
 - a. amikacin
 - b. ampicillin/sulbactam
 - c. aztreonam
 - d. ceftriaxone
 - e. cefepime
 - f. ceftazidime
 - g. ciprofloxacin or levofloxacin
 - h. ertapenem
 - i. gentamicin



- j. imipenem/cilastatin
 - k. meropenem
 - l. piperacillin/tazobactam
4. Requests for Vabomere® or Fetroja® for an infection other than cUTI and the request documents known or suspected infection with Klebsiella pneumoniae carbapenemase (KPC) producing bacteria or carbapenem resistance will be reviewed on a case-by-case basis.

Avycaz, Fetroja, Recarbrio, Zerbaxa

ALL of the following:

1. Diagnosis of Hospital-acquired (nosocomial) bacterial pneumonia (HABP) or ventilator-associated bacterial pneumonia (VABP) caused by susceptible Gram-negative microorganisms
2. Member is >18 years of age
3. Paid claims within the past 30 days or physician documentation of an inadequate response, adverse reaction to **TWO** or contraindication (e.g., culture not susceptible) to **ALL** of the following:
 - a. Aminoglycosides (amikacin, gentamicin, tobramycin)
 - b. aztreonam
 - c. cefepime
 - d. ceftazidime
 - e. ciprofloxacin or levofloxacin
 - f. imipenem/cilastatin
 - g. meropenem
 - h. piperacillin/tazobactam

Vibativ, Zyvox

ALL of the following:

1. Diagnosis of Hospital-acquired (nosocomial) bacterial pneumonia (HABP) due to MRSA or suspected MRSA infection
2. **ONE** of the following:
 - a. Paid claims within the past 30 days or physician documentation of an inadequate response, adverse reaction or contraindication to vancomycin*
 - b. Culture is resistant to vancomycin (If cultures can be obtained)
 - c. Member has a history of MRSA infections that have not responded to vancomycin in the past
3. If the request is for Vibativ® (telavancin), then **BOTH** of the following:
 - a. Member is ≥ 18 years of age
 - b. **ONE** of the following:
 - i. Paid claims within the past 30 days or physician documentation of an inadequate response, adverse reaction or contraindication to linezolid
 - ii. Culture is resistant to linezolid (If cultures can be obtained)
 - iii. Member has a history of MRSA infections that have not responded to linezolid in the past
4. Requests for brand name Zyvox® must meet the above criteria and the prescriber must submit medical records documenting an inadequate response or adverse reaction to generic linezolid injection (as per the Brand Name guideline).

** Adverse Events caused by vancomycin such as red-man syndrome or renal adverse events are also associated with Vibativ®, and renal events in particular are higher with Vibativ®. Thus, these specific AEs are not appropriate rationale for selecting Vibativ® over vancomycin.*

Baxdela, Dalvance, Kimyrsa, Nuzyra, Orbactiv, Sivextro, Synercid, Tygacil, Vibativ, Zyvox



ALL of the following:

1. Diagnosis of Skin and soft tissue infection due to Methicillin-Resistant Staphylococcus Aureus (MRSA) or suspected MRSA infection
2. If the request is for Baxdela® (delafloxacin injection), Kimyrsa® (oritavancin), Nuzyra® (omadacycline injection), Orbactiv® (oritavancin), Sivextro® (tedizolid injection), Synercid® (dalfopristin/quinupristin), or Vibativ® (telavancin), member is ≥ 18 years of age
3. Inadequate response, adverse reaction, or contraindication (e.g., culture not susceptible) to **ALL** of the following:
 - a. ceftaroline
 - b. daptomycin
 - c. vancomycin
4. If the request is for Synercid® (dalfopristin/quinupristin) or Tygacil® (tigecycline), then **ONE** of the following is also required:
 - a. Paid claims within the past 30 days or physician documentation of an inadequate response, adverse reaction or contraindication to ALL other available agents that treat MRSA SSTIs
 - b. Culture is resistant to **ALL** other available agents that treat MRSA SSTIs (*If cultures can be obtained*)
5. If the request is for Kimyrsa® (oritavancin), medical necessity for use instead of Orbactiv® (oritavancin)
6. Requests for brand name Tygacil® or Zyvox® must meet the above criteria and the prescriber must submit medical records documenting an inadequate response or adverse reaction to generic equivalent (as per the Brand Name guideline).
7. Requests documenting an inadequate response or development of an adverse drug reaction to clindamycin for the current infection will be considered for the requested duration.

Zyvox

ALL of the following:

1. **ONE** of the following diagnoses:
 - a. Bone/joint infections due to MRSA or suspected MRSA
 - b. CNS infection due to MRSA or suspected MRSA
2. **ONE** of the following:
 - a. Paid claims within the past 30 days or physician documentation of an inadequate response, adverse reaction or contraindication to vancomycin
 - b. Culture is resistant to vancomycin (*If cultures can be obtained*)
 - c. Member has a history of MRSA infections that have not responded to vancomycin in the past
3. Requests for brand name Zyvox® must meet the above criteria and the prescriber must submit medical records documenting an inadequate response or adverse reaction to generic equivalent (as per the Brand Name guideline).

Baxdela, Nuzyra, Xenleta

ALL of the following:

1. Diagnosis of non-MRSA community-acquired pneumonia (CABP)
2. Member is ≥ 18 years of age
3. Paid claims within the past 30 days or physician documentation of an inadequate response or adverse reaction to a regimen containing **ONE** or contraindication to **ALL** of the following:
 - a. amoxicillin
 - b. amoxicillin/clavulanate
 - c. ampicillin-sulbactam
 - d. azithromycin



- e. cefotaxime
 - f. cefpodoxime
 - g. ceftriaxone
 - h. cefuroxime
 - i. clarithromycin
 - j. doxycycline
 - k. levofloxacin
 - l. moxifloxacin
4. If the request is for Baxdela® (delafloxacin injection) or Nuzyra® (omadacycline injection), paid claims within the past 30 days or physician documentation of an inadequate response, adverse reaction, or contraindication to Teflaro® (ceftaroline)

Baxdela, Nuzyra

ALL of the following:

1. Diagnosis of non-MRSA Skin and soft tissue infection
2. If the request is Baxdela® (delafloxacin injection) or Nuzyra® (omadacycline injection), member is ≥ 18 years of age
3. Organism susceptibility to the requested agent is provided OR if cellulitis and cultures cannot be obtained due to the nature of the infection
4. **ONE** of the following:
 - a. Paid claims within the past 30 days or physician documentation of an inadequate response to at least ONE LCA regimen that does not require a PA (e.g., fluoroquinolone, cephalosporin, aztreonam, vancomycin (gram positive coverage only), nafcillin (gram positive coverage only), etc.)
 - b. Culture is resistant to ALL potential LCA options (*If cultures can be obtained*)
 - c. Adverse reaction or contraindication to **ALL** potential LCAs
5. If the request is for Baxdela® (delafloxacin injection) or Nuzyra® (omadacycline injection), paid claims within the past 30 days or physician documentation of an inadequate response, adverse reaction, or contraindication to Teflaro® (ceftaroline)

Dalvance, Sivextro, Synercid, Tygacil, Vibativ, Zyvox for the treatment of non-MRSA/non-VRE infections

ALL of the following:

1. Organism susceptibility to the requested agent OR if certain types of infections cannot be cultured (i.e. cellulitis, many instances of osteomyelitis, pneumonia)
2. If the request is for Sivextro® (tedizolid), Synercid® (dalfopristin/quinupristin), or Vibativ® (telavancin), member is ≥ 18 years of age
3. **ONE** of the following:
 - a. Paid claims within the past 30 days or physician documentation of an inadequate response, adverse reaction or contraindication to vancomycin OR request is for Tygacil for an infection with documented (or suspected) gram negative bacteria
 - b. Culture is resistant to vancomycin (*If cultures can be obtained*)
4. Requests for brand name Tygacil®, or Zyvox® must meet the above criteria and the prescriber must submit medical records documenting an inadequate response or adverse reaction to generic equivalent (as per the Brand Name guideline).

Vibativ

ALL of the following:

1. VABP due to MRSA or suspected MRSA infection



2. Member is ≥ 18 years of age
3. **ONE** of the following:
 - a. Paid claims within the past 30 days or physician documentation of an inadequate response, adverse reaction or contraindication to vancomycin
 - b. Culture is resistant to vancomycin (if cultures can be obtained)
 - c. Member has a history of MRSA infection that have not responded to vancomycin in the past
4. **ONE** of the following:
 - a. Paid claims within the past 30 days or physician documentation of an inadequate response, adverse reaction or contraindication to linezolid
 - b. Culture is resistant to linezolid (if cultures can be obtained)
 - c. Member has a history of MRSA infection that have not responded to linezolid in the past

Sivextro, Synercid, Tygacil, Zyvox

ALL of the following:

1. Documentation of VRE infection or suspected VRE infection (*culture and sensitivity report not required*)
2. If the request is for Sivextro® (tedizolid) or Synercid® (dalfopristin/quinupristin), member is ≥ 18 years of age
3. If the request is for a drug other than linezolid, then **ONE** of the following is also required:
 - a. Paid claims within the past 30 days or physician documentation of an inadequate response, adverse reaction or contraindication to linezolid
 - b. Culture is resistant to linezolid (*if cultures can be obtained*)
4. Requests for brand name Tygacil®, or Zyvox® must meet the above criteria and the prescriber must submit medical records documenting an inadequate response or adverse reaction to generic equivalent (as per the Brand Name guideline).

Continuation of Therapy

Prescriber provides documentation of the following:

1. Member has responded to the antibiotic but more treatment time is required for infection resolution
2. Length of recertification: As requested by prescriber

Limitations

1. Initial approvals will be granted for the following:
 - a. Up to 14 days if prescriber does not indicate a duration of therapy for treatment of:
 - i. UTIs
 - ii. Intra-abdominal infections
 - iii. Pneumonia
 - iv. SSTIs
 - v. Bacteremia
 - vi. Non-MRSA/Non-VRE infections
 - vii. CNS infections (e.g., meningitis, brain abscess, spinal epidural abscess)
 - viii. VRE infections
 - b. Up to 2 months if prescriber does not indicate a duration of therapy for treatment of:
 - i. Bone/joint infections (e.g., osteomyelitis, septic arthritis, etc.)
 - ii. Endocarditis
 - c. Dalvance: maximum is 8 days
 - d. Kimyrsa, Orbactiv: maximum is 1 dose
 - e. Sivextro: maximum is 6 days
 - f. All other agents: duration as requested by prescriber



2. Reauthorizations will be granted for: duration as requested by prescriber.

Appendix

Vancomycin PICC line considerations

If prescriber documents any of the following contraindications for PICC placement, request may be approved

- burns, trauma, skin infections, or history of venous thrombosis at insertion sites
- actively bacteremic patients
- coagulopathy (e.g., claims for warfarin)
- renal failure or ESRD (need to preserve veins for dialysis catheters)
- inability to monitor vancomycin levels as an outpatient

Placement of PICC would require hospital admission or re-admission should be considered for requests for IV antibiotics.

Use of Telavancin and Dalbavancin for Treatment of Vancomycin Resistant Enterococci

PA requests that document VRE infection with cultures showing resistance to vancomycin and linezolid in addition to sensitivity to the requested agent (Vibativ® [telavancin] or Dalvance® [dalbavancin]) may be approved.

Requests may also be approved if the prescriber documents inadequate response, adverse reaction or contraindication to linezolid and cultures show resistance to vancomycin and sensitivity to the requested agent (Vibativ® [telavancin] or Dalvance® [dalbavancin]).

Agents for the Treatment of Carbapenem-Resistant Enterobacterales (CRE)

Regardless of previous trials, if a request documents that the causative microbe is resistant to ertapenem and meropenem, or it is suspected that the microbe is resistant to both and susceptibility testing is not able to be performed, request may be APPROVED.

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Review History

02/08/2023 - Reviewed and created for Feb P&T; matched MH UPPL. Effective 4/1/23.



08/09/23 – Reviewed and updated for P&T. Admin update: benefit change to PB only. Formatting updates to diagnosis and removal of requiring ‘documentation’. Effective 9/1/23

