

MEDICATION COVERAGE POLICY

PHARMACY AND THERAPEUTICS ADVISORY COMMITTEE

POLICY	Bacterial Infections	P&T DATE	9/12/2023
THERAPEUTIC CLASS	Infectious Disease	REVIEW HISTORY (MONTH/YEAR)	12/22, 9/21, 9/20, 2/19, 9/17, 9/16, 9/15, 5/15, 2/15, 11/12, 9/12, 9/11, 5/11, 9/10, 9/08, 6/08, 5/07
LOB AFFECTED	Medi-Cal		

This policy has been developed through review of medical literature, consideration of medical necessity, generally accepted medical practice standards, and approved by the HPSJ Pharmacy and Therapeutic Advisory Committee.

Effective 1/1/2022, the Pharmacy Benefit is regulated by Medi-Cal Rx. Please visit <https://medi-calrx.dhcs.ca.gov/home/> for portal access, formulary details, pharmacy network information, and updates to the pharmacy benefit. All medical claims require that an NDC is also submitted with the claim. If a physician administered medication has a specific assigned CPT code, that code must be billed with the correlating NDC. If there is not a specific CPT code available for a physician administered medication, the use of unclassified CPT codes is appropriate when billed with the correlating NDC.

OVERVIEW

Prescription and OTC antibiotics are used to treat bacterial infections. Generally, mild, localized infections may be treated with prescription or OTC topical antibiotic products. Prescription oral and/or IV antibiotic agents are required for more severe, disseminated infections. According to the CDC, more than 2 million people in the U.S. become infected with bacteria that are resistant to antibiotics each year.¹ Appropriate use of antibiotics (correct drug, dose, and length of treatment) is essential to preventing the spread of antibiotic resistance. The purpose of this coverage policy is to review the available agents (Table 1) and distinguish where the medications may be billed to. For agents listed for coverage under the medical benefit, this coverage is specific to outpatient coverage only (excludes emergency room and inpatient coverage).

Table 1: Available Systemic Antibiotics

CPT Code	Generic Name (Brand Name)	Available Strengths	Pharmacy Benefit	Outpatient Medical Benefit (Restrictions)
Penicillins				
--	Amoxicillin (Moxatag)	Chewable Tablets		
		Amoxicillin 125 mg	Yes	No
		Amoxicillin 250 mg	Yes	No
		Oral suspension		
		Amoxicillin 125 mg/5 ml	Yes	No
		Amoxicillin 200 mg/5 ml	Yes	No
		Amoxicillin 250 mg/5 ml	Yes	No
		Amoxicillin 400 mg/5 ml	Yes	No
		Capsules		
		Amoxicillin 250 mg	Yes	No
		Amoxicillin 500 mg	Yes	No
		Tablets		
		Amoxicillin 500 mg	Yes	No
		Amoxicillin ER 775 mg	Yes	No
Amoxicillin 875 mg	Yes	No		
--	Amoxicillin/ potassium clavulanate (Augmentin, Augmentin XR)	Oral suspension		
		Amox 125 mg-clav 31.25 mg/5ml	Yes	No
		Amox 200 mg-clav 28.5 mg/5 ml	Yes	No
		Amox 250 mg-clav 62.5 mg/5 ml	Yes	No
		Amox 400 mg-clav 57 mg/5 ml	Yes	No
		Amox 600 mg-clav 42.9 mg/5 ml	Yes	No
		Tablets		
		Amox 250 mg/clav 125 mg	Yes	No
		Amox 500 mg/clav 125 mg	Yes	No
		Amox 875 mg/clav 125 mg	Yes	No

		Amox 1000 mg/clav 62.5 mg	Yes	No
		Chewable Tablets		
		Amox 125 mg/clav 31.25 mg	Yes	No
		Amox 200 mg/clav 28.5 mg	Yes	No
		Amox 250 mg/clav 62.5 mg	Yes	No
		Amox 400 mg/clav 57 mg	Yes	No
		Oral suspension		
		Ampicillin 125 mg/5 ml	Yes	No
		Ampicillin 250 mg/5 ml	Yes	No
		Capsules		
		Ampicillin 250 mg	Yes	No
		Ampicillin 500 mg	Yes	No
		Injection (IM, IV) powder		
		Ampicillin 125 MG	Yes	Yes
		Ampicillin 250 mg	Yes	Yes
		Ampicillin 500 mg	Yes	Yes
		Ampicillin 1 gram	Yes	Yes
		Ampicillin 2 gram	Yes	Yes
		Ampicillin 10 gram	Yes	Yes
		Injection (IM, IV) powder		
		1.5 gm (amp 1 gm/sulb 0.5 gm)	Yes	Yes
		3 gm (amp 2 gm/sulb 1 gm)	Yes	Yes
		Capsules		
		Dicloxacillin 250 mg	Yes	No
		Dicloxacillin 500 mg	Yes	No
		Injection (frozen) for IV infusion		
		Nafcillin 20 mg/ml in 3.6% Dextrose	Yes	Yes
		Injection (IM, IV) Powder		
		Nafcillin 1 gram	Yes	Yes
		Nafcillin 2 gram	Yes	Yes
		Nafcillin 10 gram	Yes	Yes
		IM suspension		
		Bicillin L-A 600,000 units/1 ml	Yes	Yes
		Bicillin L-A 1.2 million units/2 ml	Yes	Yes
		Bicillin L-A 2.4 million units/4 ml	Yes	Yes
		Injection (IV) solution		
		Penicillin G potassium 20,000 units/ml	Yes	Yes
		Penicillin G potassium 40,000 units/ml	Yes	Yes
		Penicillin G potassium 60,000 units/ml	Yes	Yes
		Injection (IM, IV) reconstituted solution		
		Penicillin G potassium 3 million units	Yes	Yes
		Penicillin G potassium 5 million units	Yes	Yes
		Penicillin G potassium 20 million units	Yes	Yes
		Oral solution		
		Penicillin VK 125 mg/5 ml	Yes	No
		Penicillin VK 250 mg/5 ml	Yes	No
		Tablets		
		Penicillin VK 250 mg	Yes	No
		Penicillin VK 500 mg	Yes	No
		IV solution		
		2.25 gram (pip 2 gram,-tazo 0.25 gram/50 ml)	Yes	Yes
		3.375 gram (pip 3 gram-tazo 0.375 gram /50 ml)	Yes	Yes
		4.5 gram (pip 4 gram-tazo 0.5 gram/100 ml)	Yes	Yes

		IV powder for reconstitution		
		2.25 gram (pip 2 gram-tazo 0.25 gram)	Yes	Yes
		3.375 gram (pip 3 gram-tazo 0.375 gram)	Yes	Yes
		4.5 gram (pip 4 gram-tazo 0.5 gm)	Yes	Yes
		40.5 gram (pip 36 gram-tazo 4.5 gram)	Yes	Yes

CPT Code	Generic Name (Brand Name)	Available Strengths	Pharmacy Benefit	Outpatient Medical Benefit (Restrictions)
Cephalosporins - 1st generation				
--	Cefadroxil (Duricef)	Oral Suspension		
		Cefadroxil 250 mg/5ml	Yes	No
		500 mg/5 ml	Yes	No
		Capsules		
		Cefadroxil 500 mg	Yes	No
		Tablets		
J0690	Cefazolin (Ancef)	Injection (IM, IV) reconstituted solution		
		Cefazolin 100 mg	Yes	Yes
		Cefazolin 200 mg	Yes	Yes
		Cefazolin 500 mg	Yes	Yes
		Cefazolin 1 gram	Yes	Yes
		Cefazolin 2 gram	Yes	Yes
		Cefazolin 10 gram	Yes	Yes
		Cefazolin 20 gram	Yes	Yes
		IV solution in D5W		
		Cefazolin 1 gram/50 ml	Yes	Yes
		Cefazolin 2 gram/50 ml	Yes	Yes
		Cefazolin 2 gram/100 ml	Yes	Yes
--	Cephalexin (Keflex, Daxbia)	Oral suspension		
		Cephalexin 125 mg/5 ml	Yes	No
		Cephalexin 250 mg/5 ml	Yes	No
		Capsules		
		Cephalexin 250 mg	Yes	No
		Cephalexin (Daxbia) 333 mg	Yes	No
		Cephalexin 500 mg	Yes	No
		Cephalexin 750 mg	Yes	No
		Tablets		
		Cephalexin 250 mg	Yes	No
Cephalexin 500 mg	Yes	No		
--	Cefaclor (Ceclor, Raniclolor)	Oral suspension		
		Cefaclor 125 mg/5 ml	Yes	No
		Cefaclor 250 mg/5 ml	Yes	No
		Cefaclor 375 mg/5 ml	Yes	No
		Capsules		
		Cefaclor 250 mg	Yes	No
		Cefaclor 500 mg	Yes	No
Cefaclor XR 500 mg tablet	Yes	No		
S0074	Cefotetan (Cefotan)	Injection (IM, IV)		
		Cefotetan 1 gram	Yes	Yes
		Cefotetan 2 gram	Yes	Yes
J0694	Cefoxitin (Mefoxin)	Injection (IV)		
		Cefoxitin 1 gram	Yes	Yes
		Cefoxitin 2 gram	Yes	Yes
		Cefoxitin 10 gram	Yes	Yes
--	Cefprozil (Cefzil)	Oral suspension		

		Cefprozil 125 mg/5 ml	Yes	No
		Cefprozil 250 mg/5 ml	Yes	No
		Tablets		
		Cefprozil axetil 250 mg	Yes	No
		Cefprozil axetil 500 mg	Yes	No
		Oral suspension		
		Ceftin 125 mg/5 ml	Yes	No
		Ceftin 250 mg/5 ml	Yes	No
		Tablets		
		Cefuroxime axetil 250 mg	Yes	No
		Cefuroxime axetil 500 mg	Yes	No
		Injection (IM, IV)		
		Cefuroxime axetil 750 mg	Yes	Yes (PA)
		Cefuroxime axetil 1.5 gram	Yes	Yes (PA)
		Cefuroxime axetil 7.5 gram	Yes	Yes (PA)
J0697				

PA = Prior Authorization

CPT Code	Generic Name (Brand Name)	Available Strengths	Pharmacy Benefit	Outpatient Medical Benefit (Restrictions)
Cephalosporins – 3rd generation				
		Oral suspension		
		Cefdinir 125 mg/5 ml	Yes	No
		Cefdinir 250 mg/5 ml	Yes	
		Capsules		
		Cefdinir 300 mg capsule	Yes	
		Tablets		
		Cefditoren 200 mg	Yes	No
		Cefditoren 400 mg	Yes	No
		Chewable tablets		
		Suprax 100 mg	Yes	No
		Suprax 200 mg	Yes	No
		Oral suspension		
		Cefixime 100 mg/5 ml	Yes	No
		Cefixime 200 mg/5 ml	Yes	No
		Capsules		
		Suprax 400 mg	Yes	No
		Tablets		
		Suprax 400 mg	Yes	No
		Injections (IM, IV)		
		Cefotaxime 500 mg	Yes	Yes
		Cefotaxime 1 gram	Yes	Yes
		Cefotaxime 2 gram	Yes	Yes
		Cefotaxime 10 gram	Yes	Yes
		Oral suspension		
		Cefpodoxime 50 mg/5 ml	Yes	No
		Cefpodoxime 100 mg/5 ml	Yes	No
		Tablets		
		Cefpodoxime 100 mg	Yes	No
		Cefpodoxime 200 mg	Yes	No
		In 50 ml D5W IV solution		
		Fortaz 1 gram	Yes	Yes (PA)
		Fortaz 2 gram	Yes	Yes (PA)
		Injection (IM, IV)		
		Ceftazidime 1 gram	Yes	Yes (PA)
		Ceftazidime 2 gram	Yes	Yes (PA)
		Ceftazidime 6 gram	Yes	Yes (PA)
		Oral suspension		
		Ceftibuten (Cedax)		

		Cedax 90 mg/5 ml	Yes	No
		Ceftibuten 180 mg/5 ml	Yes	No
		Capsules		
		Ceftibuten 400 mg	Yes	No
J0696	Ceftriaxone (Rocephin)	Injection (IM, IV) reconstituted solution		
		Ceftriaxone 250 mg	Yes	Yes
		Ceftriaxone 500 mg	Yes	
		Ceftriaxone 1 gm	Yes	
		Ceftriaxone 2 gm	Yes	Yes (PA)
		Ceftriaxone 10 gm	Yes	Yes (PA)
		IV reconstituted solution		
		Ceftriaxone in D5W 1 gm/50mL	Yes	Yes (PA)
Ceftriaxone in D5W 2 gm/50mL	Yes			
Cephalosporins – 4th generation				
J0692	Cefepime (Maxipime)	Injection (IM, IV) reconstituted solution		
		Cefepime 1 gm	Yes	Yes (PA)
		Cefepime 2 gm	Yes	Yes (PA)
		Injection (in D5W)		
		Cefepime 1 gram	Yes	Yes (PA)
		Cefepime 2 gram	Yes	Yes (PA)
J0699	Cefiderocol (Fetroja)	IV reconstituted solution		
		Cefiderocol 1 gram	Yes	Yes (PA)
Cephalosporins – 5th generation				
J0712	Ceftaroline fosamil (Teflaro)	IV reconstituted solution		
		Teflaro 400 mg	Yes	Yes
		Teflaro 600 mg	Yes	Yes
Combination Cephalosporins				
J0714	Ceftazidime/avibactam (Avycaz)	Injection (IV)		
		Avycaz 2.5 gram (Ceftazidime 2 gram- 500 mg avibactam)	Yes	Yes (PA)
--	Ceftolozane/Tazobactam (Zerbaxa)	Injection (IV)		
		Zerbaxa 1.5 gram (Ceftolozane 1 gram-tazobactam 500 mg)	Yes	Yes (PA)

PA = Prior Authorization

CPT Code	Generic Name (Brand Name)	Available Strengths	Pharmacy Benefit	Outpatient Medical Benefit (Restrictions)
Carbapenems				
J1267	Doripenem (Doribax)	Injection (IV) Reconstituted		
		Doripenem 250 mg	Yes	Yes
		Doripenem 500 mg	Yes	Yes
J1335	Ertapenem (Invanz)	Injection (IM, IV) reconstituted solution		
		INVanz 1 gm	Yes	Yes (PA)
J0743	Imipenem/cilastatin (Primaxin I.V.)	IV powder for reconstitution		
		Imi 250 mg/cilas 250 mg	Yes	Yes (PA)
		Imi 500 mg/cilas 500 mg	Yes	Yes (PA)
J0742	Imipenem/cilastatin/relebactam (Recarbrio)	Imipenem 500 mg/cilastatin 500 mg/relebactam 250 mg	Yes	Yes (PA)
J2185	Meropenem (Merrem)	IV reconstituted solution		
		Meropenem 500 mg	Yes	Yes (PA)
		Meropenem 1 gm	Yes	Yes (PA)
Aminoglycosides				
J0278	Amikacin	Injection (IM, IV)		

		Amikacin 500 mg/2 ml	Yes	Yes (PA for Facilities)	
		Amikacin 1 gram /4 ml	Yes	Yes (PA for Facilities)	
J1580	Gentamicin	Injection (IM, IV) solution			
		Gentamicin 40 mg/ml	Yes	Yes	
		Gentamicin 80 mg/ml	Yes	Yes	
--	Neomycin	Neomycin 500 mg tablet	Yes	No	
J0291	Plazomicin (Zemdri)	Plazomicin 500mg/10mL	Yes	Yes	
J3260	Tobramycin (Bethkis, Kitabis, Tobi)	Injection (IM, IV)			
		Tobramycin 10 mg/2 ml	Yes	Yes	
		Tobramycin 80 mg/2 ml	Yes	Yes	
		Tobramycin 1.2 gram/30 ml	Yes	Yes	
		Tobramycin 2 gram/ 50 ml	Yes	Yes	
--		Tobi Podhaler 28 mg inhalation capsule	Yes	No	
J7682, J7685		Tobramycin 300 mg/5 ml inhalation solution (Tobi)	Yes	Yes (PA)	
		Tobramycin 300mg/4ml (Bethkis)	Yes	Yes (PA)	
J3000		Streptomycin	Streptomycin 1 g/5ml	Yes	Yes
Cyclic Lipopeptide					
J0878	Daptomycin (Cubicin)	Injection (IV)			
		Cubicin 350mg, 500mg	Yes	Yes	
Fluoroquinolones					
--	Ciprofloxacin (Cipro, Cipro XR)	Tablets			
		Ciprofloxacin 100 mg	Yes	No	
		Ciprofloxacin 250 mg		No	
		Ciprofloxacin 500 mg		No	
		Ciprofloxacin 750 mg		No	
			Ciprofloxacin ER 500 mg	Yes	No
			Ciprofloxacin ER 1000 mg	Yes	No
		Oral suspension			
			Ciprofloxacin 250 mg/5 ml (Cipro 5%)	Yes	No
			Ciprofloxacin 500 mg/5 ml (Cipro 10%)	Yes	No
J0744		Injection (IV)			
		Ciprofloxacin 200 mg/100 ml	Yes	Yes (PA)	
		Ciprofloxacin 400 mg/ 200 ml	Yes	Yes (PA)	
--	Gemifloxacin (Factive)	Tablets	Yes	No	
--	Levofloxacin (Levaquin)	Oral Solution	Yes	No	
		Levofloxacin 25 mg/ml			
J1956		IV solution			
		Levofloxacin 25 mg/ml	Yes	Yes (PA)	
		Levofloxacin 750 mg/150 ml	Yes	Yes (PA)	
--		Tablets			
		Levofloxacin 250 mg	Yes	No	
		Levofloxacin 500 mg		No	
Levofloxacin 750 mg	No				
--	Moxifloxacin (Avelox)	Tablets			
		Moxifloxacin 400 mg tablet	Yes	No	
		IV solution			
J2280, J2281		Moxifloxacin 400 mg/250 mL	Yes	Yes (PA)	
--	Ofloxacin	Ofloxacin 400 mg tablet	Yes	No	

C9462	Delafloxacin (Baxdela)	Delafloxacin 300 mg	Yes	Yes (PA)		
Glycopeptides						
--	Vancomycin	Oral solution				
		First-Vancomycin 25 mg/ml	Yes	No		
		First-Vancomycin 50 mg/ml	Yes	No		
		Vancomycin+Syr Spend SF PH4 50 mg/ml oral suspension	Yes	No		
		Firvanq 25mg/ml, 50mg/ml	Yes	No		
		Capsules				
		Vancomycin 125 mg	Yes	No		
		Vancomycin 250 mg	Yes	No		
		J3370	Vancomycin	IV solution		
				Vancomycin 500 mg/100 ml	Yes	Yes
Vancomycin 750 mg/150 ml	Yes			Yes		
Vancomycin 1 gm/200 ml	Yes			Yes		
IV reconstituted solution						
Vancomycin 500 mg	Yes			Yes		
Vancomycin 750 mg	Yes			Yes		
Vancomycin 1 gm	Yes			Yes		
J0875	Dalbavancin (Dalvance)	Dalbavancin 500 mg	Yes	Yes (PA)		
	Glycylcycline					
J3243	Tigecycline (Tygacil)	Injection (IV) Tygacil 50 mg reconstituted solution	Yes	Yes		
Lincosamide						
--	Clindamycin (Cleocin HCl, Cleocin Palmitate, Cleocin Phosphate)	Capsules				
		Clindamycin HCL 75 mg	Yes	No		
		Clindamycin HCL 150 mg	Yes	No		
		Clindamycin HCL 300 mg	Yes	No		
		Oral Solution				
		Clindamycin palmitate 75 mg/5 ml	Yes	No		
		Vaginal Cream				
		Clindamycin 2% cream	Yes	No		
		Vaginal Suppository				
		Cleocin 100mg (ovule)	Yes	No		
S0077	Clindamycin (Cleocin HCl, Cleocin Palmitate, Cleocin Phosphate)	Phosphate Injection (IV, IM)				
		Clindamycin 300 mg/2 ml	Yes	Yes (PA)		
		Clindamycin 600 mg/4 ml	Yes	Yes (PA)		
		Clindamycin 900 mg/6 ml	Yes	Yes (PA)		
J2010	Lincomycin (Lincocin)	Injection (IV, IM) Lincomycin 300 mg/ml	Yes	Yes		
Macrolides						
Q0144	Azithromycin (Zithromax)	Oral suspension				
		Azithromycin 100 mg/5 ml	Yes	No		
		Azithromycin 200 mg/5 ml	Yes	No		
		Zimax 2 gram/ 60 ml ER	Yes	No		
		Tablets				
		Azithromycin 250 mg	Yes	No		
		Azithromycin 500 mg	Yes	No		
		Azithromycin 600 mg	Yes	No		
J0456	Azithromycin (Zithromax)	Injection				
		Azithromycin 500 mg	Yes	Yes		
--	Clarithromycin (Biaxin)	Oral suspension				
		Clarithromycin 125 mg/5 ml	Yes	No		

		Clarithromycin 250 mg/5 ml	Yes	No
		Tablets		
		Clarithromycin 250 mg	Yes	No
		Clarithromycin 500 mg	Yes	No
		Clarithromycin XL 500 mg tablet	Yes	No
		Oral suspension		
		E.E.S. granules 200 mg/5 ml	Yes	No
		EryPed 200 mg/5 ml	Yes	No
		EryPed 400 mg/5 ml	Yes	No
		Erythromycin granules 200 mg/5ml	Yes	No
		Capsules	--	
		Erythromycin base 250 mg DR	Yes	No
		Erythromycin 250 mg EC	Yes	No
		Tablets		
		Erythromycin base 250 mg	Yes	No
		Erythromycin base 500 mg	Yes	No
		Erythromycin ethylsucc 400 mg	Yes	No
		Erythromycin stearate 500 mg	Yes	No
		Delayed-release tablets		
		Ery-Tab 250 mg	Yes	No
		Ery-Tab 333 mg	Yes	No
		Ery-Tab 500 mg	Yes	No
		Injection		
J1364		Erythromycin Lactobionate 500 mg	Yes	Yes (PA for Facility)
		Fidaxomicin (Dificid)		
--		Dificid 200 mg tablet	Yes	No

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Nitrofurantoin Derivative					
		Capsules			
	Nitrofurantoin (Furadantin, Macrobid, Macrochantin)	Nitrofurantoin 25 mg	Yes	No	
		Nitrofurantoin 50 mg	Yes	No	
		Nitrofurantoin 100 mg	Yes	No	
		Nitrofurantoin monohydrate 100 mg	Yes	No	
		Suspension			
		Nitrofurantoin 25 mg/5 ml	Yes	No	
Nitroimidazole					
		Tablets			
	Metronidazole (Flagyl, Flagyl ER, Metro)	Metronidazole 250 mg	Yes	No	
		Metronidazole 500 mg	Yes	No	
		Flagyl ER 750 mg	Yes	No	
		Capsules			
		Metronidazole 375 mg	Yes	No	
		Vaginal Gel			
		Metronidazole 0.75%	Yes	No	
		Injection (IV)			
S0030			Metronidazole 500 mg/100 ml	Yes	Yes (PA)
			Oral Suspension		
		Metronidazole 50 mg/ml	Yes	No	
		Metronidazole 100 mg/ml	Yes	No	

--	Secnidazole (Solosec)	Oral Packet Secnidazole 2 g	Yes	No
--	Tinidazole (Tindamax)	Tablets		
		Tinidazole 250 mg	Yes	No
		Tinidazole 500 mg	Yes	No
Oxazolidinone				
--	Linezolid (Zyvox)	Oral Suspension		
		Linezolid 100 mg/5 ml	Yes	No
		Tablets		
		Linezolid 600 mg tablet	Yes	No
J2020		Injection (IV)		
		Linezolid 600 mg/ 300 ml	Yes	Yes (PA)
--	Tedizolid (Sivextro)	Tablets		
		Sivextro 200 mg	Yes	No
J3090		Injection (IV)		
		Sivextro 200 mg	Yes	Yes (PA)

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CPT Code	Generic Name (Brand Name)	Available Strengths	Pharmacy Benefit	Outpatient Medical Benefit (Restrictions)
Pleuromutilin				
J0691	Lefamulin (Xenleta)	Injection (IV) Lefamulin 150 mg	Yes	Yes
--		Tablets Lefamulin 600 mg	Yes	No
Polymyxin and derivatives				
J0770	Colistimethate (Coly-Mycin M)	Injection (IV, IM) Colistimethate 150 mg	Yes	Yes (PA)
--	Polymyxin B	Injection (IV, IM) Polymyxin B 50,000 Units	Yes	Yes (PA)
Streptogramin				
J2770	Quinupristin/dalfopristin (Synercid)	Injection (IV) Synercid 500 (Quinupristin 150 mg-dalfopristin 350mg)	Yes	Yes (PA)
Sulfonamides				
--	Sulfadiazine	Tablets Sulfadiazine 500 mg	Yes	No
--	Sulfameth/trimethoprim (Septra, Bactrim, Bactrim DS, Sulfatrim Pediatric)	Oral Suspension Sulfa 200mg/Trimeth 40 mg/5 ml	Yes	No
		Tablets		
		Sulfa 400 mg/Trimeth 80 mg	Yes	No
		Sulfa 800 mg/Trimeth 160 mg	Yes	No
S0039		Injection Sulfa 80 mg/Ttrimeth 6 mg/ ml	Yes	Yes (PA)

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CPT Code	Generic Name (Brand Name)	Available Strengths	Pharmacy Benefit	Outpatient Medical Benefit (Restrictions)
Tetracyclines				
--	Doxycycline (Morgidox, Vibramycin)	Capsules (Hyclate)		No
		Doxycycline 50 mg	Yes	
		Doxycycline 100 mg	Yes	
--	Doxycycline (Adoxa, Mondoxyne, Monodox)	Capsules (Monohydrate)		
		Doxycycline 50mg	Yes	No
		Doxycycline 75 mg	Yes	No
		Doxycycline 100 mg	Yes	No

		Doxycycline 150 mg	Yes	No		
--	Doxycycline (Oracea)	Doxycycline 40 mg DR	Yes	No		
--	Doxycycline (Vibramycin)	Oral Suspension Doxycycline 25 mg/5 ml	Yes	No		
--	Doxycycline (TargaDOX, Acticlate)	Tablets (Hyclate)				
		Doxycycline 20 mg	Yes	No		
		Doxycycline 75 mg	Yes	No		
		Doxycycline 100 mg	Yes	No		
		Doxycycline 150 mg	Yes	No		
--	Doxycycline (Adoxa)	Tablets (Monohydrate)				
		Doxycycline 50 mg	Yes	No		
		Doxycycline 75 mg	Yes	No		
		Doxycycline 100 mg	Yes	No		
		Doxycycline 150 mg	Yes	No		
--	Doxycycline (Doryx)	Delayed Release Tablets (Hyclate)				
		Doxycycline 50 mg DR	Yes	No		
		Doxycycline 75 mg DR	Yes	No		
		Doxycycline 100 mg DR	Yes	No		
		Doxycycline 150 mg DR	Yes	No		
		Doxycycline 200 mg DR	Yes	No		
--		Injection (IV) Doxycycline Hyclate 100 mg	Yes	Yes (PA)		
--	Doxycycline (Atridox 10%)	Subgingival Liquid Doxycycline hyclate 50 mg	Yes	No		
--	Demeclocycline	Tablets				
		Demeclocycline 150 mg	Yes	No		
		Demeclocycline 300 mg	Yes	No		
J0122	Eravacycline (Xerava)	Injection (IV) Eravacycline 50mg	Yes	Yes (PA)		
--	Minocycline (Minocin, Solodyn, Arestin)	Arestin 1 mg subgingival cartridge	Yes	No		
		Extended-release tablets				
		Minocycline XR 45 mg	Yes	No		
		Minocycline XR 90 mg	Yes	No		
		Minocycline XR 135 mg	Yes	No		
		Solodyn 55 mg	Yes	No		
		Solodyn 65 mg	Yes	No		
		Solodyn 80 mg	Yes	No		
		Solodyn 105 mg	Yes	No		
		Solodyn 115 mg	Yes	No		
		Capsules				
		Minocycline 50 mg	Yes	No		
		Minocycline 75 mg	Yes	No		
		Minocycline 100 mg	Yes	No		
		Tablets				
		Minocycline 50 mg	Yes	No		
		Minocycline 75 mg	Yes	No		
		Minocycline 100 mg	Yes	No		
		J2265		Injection (IV) Minocycline 100 mg	Yes	Yes
		J0121	Omadacycline (Nuzyra)	Injection (IV) Omadacycline 100 mg	Yes	Yes (PA)

--		Tablet Omadaycline 150 mg	Yes	No
--	Sarecycline (Seysara)	Tablet Sarecycline 60mg, 100mg, 150mg	Yes	No
--	Tetracycline	Capsules		
		Tetracycline 250 mg	Yes	No
		Tetracycline 500 mg	Yes	No

PA = Prior Authorization

CPT Code	Generic Name (Brand Name)	Available Strengths	Pharmacy Benefit	Outpatient Medical Benefit (Restrictions)
Monobactam				
S0073	Aztreonam (Azactam, Cayston)	IV solution (IV, IM)		
		Aztreonam 1 gram	Yes	Yes (PA)
		Aztreonam 2 gram	Yes	Yes (PA)
--		Inhalation Solution		
		Cayston 75 mg/ml	Yes	No
Miscellaneous				
--	Clofazimine	Clofazimine 50 mg capsule	Yes	No
--	Dapsone	Tablets		
		Dapsone 25 mg	Yes	No
		Dapsone 100 mg	Yes	No
--	Fosfomycin (Monurol)	Monurol 3 gm oral packets	Yes	No
--	Methenamine (Hiprex)	Tablets		
		Methenamine hippurate 1 gram	Yes	No
		Methenamine mandelate 0.5 gram	Yes	No
		Methenamine mandelate 1 gram	Yes	No
--	Trimethoprim (Primsol)	Oral solution		
		Primsol 50 mg/5 ml	Yes	No
		Tablets		
		Trimethoprim 100 mg	Yes	No
Monoclonal Antibody				
J0565	Bezlotoxumab (Zinplava)	IV solution 1000mg/40 ml (40ml)	Yes	Yes (PA)
Antitubercular Agents				
--	Isoniazid	Solution		
		Isoniazid 50 mg/5mL	Yes	No
		Tablet		
		Isoniazid 100 mg	Yes	No
		Isoniazid 300 mg	Yes	No
--	Ethambutol	Tablet		
		Ethambutol 100 mg	Yes	No
		Ethambutol 400 mg	Yes	No
--	Pyrazinamide	Tablet Pyrazinamide 500 mg	Yes	No
--	Rifampin	Capsule		
		Rifampin 150 mg	Yes	No
		Rifampin 300 mg	Yes	No
--	Rifapentine (Priftin)	Tablet Rifapentin 150 mg	Yes	No
--	Rifabutin (Mycobutin)	Capsule		

		Rifabutin 150 mg	Yes	No
--	Bedaquiline (Sirturo)	Tablet		
		Sirturo 20 mg tablet	Yes	No
		Sirturo 100 mg tablet	Yes	No

PA = Prior Authorization

⊞ EVALUATION CRITERIA FOR APPROVAL/EXCEPTION CONSIDERATION

Below are the coverage criteria and required information for agents with medical benefit restrictions. This coverage criteria has been reviewed and approved by the HPSJ Pharmacy & Therapeutics (P&T) Advisory Committee. For agents that do not have established prior authorization criteria, HPSJ will make the determination based on Medical Necessity criteria as described in HPSJ Medical Review Guidelines (UM06).

The following general Medical Necessity criteria are used when there are no diagnosis-or procedure-specific criteria applicable to the situation. All criteria below must be met for the service to be considered medically necessary.

1. The services are prescribed by a licensed health care practitioner practicing within the scope of his/her license in the context of his/her treatment of the individual.
2. The services are safe, effective, and consistent with nationally accepted standards of medical practice.
3. The services are not experimental or investigational.
4. The services are individualized, specific, and consistent with the individual's signs, symptoms, history, and diagnosis.
5. The services follow peer reviewed evidence based literature that support medical necessity. These services are reasonably expected, in a clinically meaningful way, to:
 - i. Help restore or maintain the individual's health, or
 - ii. Improve or prevent deterioration of the individual's disorder or condition, or
 - iii. Delay progression of a disorder or condition characterized by a progressively deteriorating course when that disorder or condition is the focus of treatment for this episode of care.
6. The individual complies with the essential elements of treatment.
7. The services are not primarily for the convenience of the individual, practitioner, caregiver, family, or another party.
8. Services are not being sought as a way to potentially avoid legal proceedings, incarceration, or other legal consequences.
9. The services are not predominantly domiciliary or custodial.
10. No exclusionary criteria are met.

IV Medications—Submitting UM (Medical) Authorization vs. Pharmacy Authorization:

Most IV medications can be covered under both medical and pharmacy benefits—depending on the setting of administration. **For an IV medication that is to be dispensed through a LTC pharmacy or outpatient pharmacy that requires claims adjudication through a Pharmacy Benefit Manager, please submit a pharmacy authorization to Medi-Cal Rx.** For all other administration settings (including buy-and-bill), please submit a UM authorization if PA is required.

Aminoglycosides
<i>Amikacin, Gentamicin, Neomycin, Tobramycin</i>

Neomycin, Tobramycin 300 mg/5 ml Inhalation solution:

- Coverage Criteria:** Tobramycin 300 mg/5 ml Inhalation solution must meet criteria
- Limits:** None
- Required Information for Approval:** Clinical documentations of Pseudomonas aeruginosa with cystic fibrosis treatment

Monoclonal Antibody

Bezlotoxumab (Zinplava)

Bezlotoxumab (Zinplava) 1000mg/40 ml IV solution

Coverage Criteria: Bezlotoxumab (Zinplava) is reserved for patients who meet ALL of the following criteria:

- a. Positive (detected) C. diff toxin on assay or DNA PCR
- b. Currently receiving standard of care antibiotic therapy for C.diff.
- c. High risk of C.diff infection recurrence meeting any of the following:
 - i. Individuals 65 years of age or older, with a history of C.diff infection (CDI) in the past 6 months
 - ii. Immunocompromised state (eg. active hematologic malignancy, prior solid organ transplant, AIDS/immunodeficient conditions, etc.
 - iii. Clinically severe CDI (as defined by a Zar score of ≥ 2); or
 - iv. Clostridium difficile ribotypes 027, 078, 244

Limits: IV: 10mg/kg as a single dose infused over 60 minutes

Required Information for Approval:

- o Positive (detected) C.diff toxin on assay or DNA PCR
- o On standard antibiotics for C. diff (e.g vancomycin, fidaxomicin, etc)
- o Clinical documentation of high risk patients for CDI recurrence.

Other Notes: The safety and efficacy of repeat administration of bezlotoxumab have not been studied.

⊕ **CLINICAL JUSTIFICATION**

HPSJ's bacterial infection management policy is based on recommendations by *the Infectious Diseases Society of America (IDSA)* and *the Centers for Disease Control and Prevention (CDC)*.

Doxycycline monohydrate is less acidic than doxycycline hyclate, which can improve patient GI tolerability.⁴ However, this theoretical difference in tolerability has not been proven clinically. There are no head-to-head studies to date suggesting one formulation is more safe or effective than the other. One potential clinical consideration in deciding which salt formulation to prescribe is if the patient is on long-term acid suppressive therapy, gastrectomy, or gastric bypass surgery (resulting in high pH)—in which case bioavailability of doxycycline monohydrate may be reduced.⁵

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<https://doi.org/10.1093/cid/ciab549>

⊞ REVIEW & EDIT HISTORY

Document Changes	Reference	Date	P&T Chairman
Creation of Policy	Clindesse .doc	05/2007	Allen Shek, PharmD
Update to Policy	Tindamax revised 6-08.doc	06/2008	Allen Shek, PharmD
Update to Policy	Prevpac Utilization review.doc	09/2008	Allen Shek, PharmD
Update to Policy	Drug Review_FQ-Levaquin_Sept08.doc	09/2008	Allen Shek, PharmD
Update to Policy	Emergency Department Prescriber Guide.docx	09/2010	Allen Shek, PharmD
Update to Policy	Factive Review 5-17-11.docx	05/2011	Allen Shek, PharmD
Update to Policy	Rifaximin 5-17-11.doc	05/2011	Allen Shek, PharmD
Update to Policy	FQ Realignment 9-20-11.docx	09/2011	Allen Shek, PharmD
Update to Policy	Nitrofurantoin Suspension 6-7-12.docx	09/2012	Allen Shek, PharmD
Update to Policy	Acute Bacterial Sinusitis Update 11-20-2012.docx	11/2012	Allen Shek, PharmD
Update to Policy	Gonorrhea Update 20121120.docx	11/2012	Allen Shek, PharmD
Update to Policy	Formulary Realignment for PT 11-20-12.docx	11/2012	Allen Shek, PharmD
Update to Policy	IBD Class Review 2-17-15.docx	02/2015	Allen Shek, PharmD
Update to Policy	Acne Class Review 5-2015.docx	05/2015	Jonathan Szkotak, PharmD, BCACP
Update to Policy	Drug Class Review – Infectious Diseases – TB 2015-09.docx	09/2015	Jonathan Szkotak, PharmD, BCACP
Update to Policy	HPSJ Coverage Policy – Infectious Disease – Bacterial Infections – 2016-09.docx	09/2016	Johnathan Yeh, PharmD
Update to Policy	HPSJ Coverage Policy – Infectious Disease – Bacterial Infections – 2017-09.docx	09/2017	Johnathan Yeh, PharmD
Update to Policy	HPSJ Coverage Policy – Infectious Disease – Bacterial Infections – 2019-02.docx	02/2019	Matthew Garrett, PharmD
Update to Policy	Bacterial Infections	09/2020	Matthew Garrett, PharmD
Update to Policy	Bacterial Infections	09/2021	Matthew Garrett, PharmD
Review of Policy	Bacterial Infections	12/2022	Matthew Garrett, PharmD
Review of Policy	Bacterial Infections	09/2023	Matthew Garrett, PharmD

Note: All changes are approved by the HPSJ P&T Committee before incorporation into the utilization policy