

MEDICATION COVERAGE POLICY

PHARMACY AND THERAPEUTICS ADVISORY COMMITTEE

POLICY	Bacterial Infections	P&T DATE	9/14/2021
THERAPEUTIC CLASS	Infectious Disease	REVIEW HISTORY	9/20, 2/19, 9/17, 9/16,
LOB AFFECTED	Medi-Cal	(MONTH/YEAR)	9/15, 5/15, 2/15, 11/12, 9/12, 9/11, 5/11, 9/10, 9/08, 6/08, 5/07

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.

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 coverage criteria of HPSJ's formulary antibiotic agents (*Table 1*).

Table 1: Available Systemic Antibiotics

Generic Name (Brand Name)	Strength & Dosage form	Formulary Limits	Average Cost per 30 Days	Notes
Penicillins				
Amoxicillin (Moxatag)	Chewable Tablets			
	Amoxicillin 125 mg	--	\$15.54	--
	Amoxicillin 250 mg	--	\$10.23	--
	Oral suspension			
	Amoxicillin 125 mg/5 ml	--	\$2.74	--
	Amoxicillin 200 mg/5 ml	--	\$3.89	--
	Amoxicillin 250 mg/5 ml	--	\$3.27	--
	Amoxicillin 400 mg/5 ml	--	\$3.35	--
	Capsules			
	Amoxicillin 250 mg	--	\$2.76	--
	Amoxicillin 500 mg	--	\$1.89	--
	Tablets			
	Amoxicillin 500 mg	--	\$3.46	--
	Amoxicillin ER 775 mg	NF		--
Amoxicillin 875 mg	--	\$2.43	--	
Amoxicillin/ potassium clavulanate (Augmentin, Augmentin XR)	Oral suspension			
	Amox 125 mg-clav 31.25 mg/5ml	NF	--	--
	Amox 200 mg-clav 28.5 mg/5 ml	--	\$10.01	--
	Amox 250 mg-clav 62.5 mg/5 ml	NF	\$124.20	--
	Amox 400 mg-clav 57 mg/5 ml	--	\$11.97	--
	Amox 600 mg-clav 42.9 mg/5 ml	--	\$10.90	--
	Tablets			
	Amox 250 mg/clav 125 mg	--	\$50.07	--
	Amox 500 mg/clav 125 mg	--	\$6.74	--
	Amox 875 mg/clav 125 mg	--	\$5.56	--
	Amox 1000 mg/clav 62.5 mg	NF	--	--
	Chewable Tablets			
	Amox 125 mg/clav 31.25 mg	NF	--	--
	Amox 200 mg/clav 28.5 mg	NF	--	--
Amox 250 mg/clav 62.5 mg	NF	--	--	
Amox 400 mg/clav 57 mg	NF	--	--	
Ampicillin	Oral suspension			
	Ampicillin 125 mg/5 ml	--	--	--
	Ampicillin 250 mg/5 ml	--	--	--
	Capsules			
	Ampicillin 250 mg	--	--	--

	Ampicillin 500 mg	--	\$12.40	--
	Injection (IM, IV) powder			
	Ampicillin 125 MG	NF	--	--
	Ampicillin 250 mg	NF	--	--
	Ampicillin 500 mg	NF	--	--
	Ampicillin 1 gram	NF	--	--
	Ampicillin 2 gram	NF	\$159.86	--
	Ampicillin 10 gram	NF	--	--
Ampicillin-sulbactam (Unasyn)	Injection (IM, IV) powder			
	1.5 gm (amp 1 gm/sulb 0.5 gm)	NF	\$108.53	--
	3 gm (amp 2 gm/sulb 1 gm)	NF	\$67.25	--
Dicloxacillin	Capsules			
	Dicloxacillin 250 mg	--	\$21.59	--
	Dicloxacillin 500 mg	--	\$37.55	--
Nafcillin (Nallpen)	Injection (frozen) for IV infusion			
	Nafcillin 20 mg/ml in 3.6% Dextrose	NF	\$883.23	--
	Injection (IM, IV) Powder			
	Nafcillin 1 gram	NF	--	--
	Nafcillin 2 gram	NF	\$31.57	--
	Nafcillin 10 gram	NF	\$526.12	--
Penicillin G benzathine (Bicillin L-A)	IM suspension			
	Bicillin L-A 600,000 units/1 ml	NF	--	--
	Bicillin L-A 1.2 million units/2 ml	NF	\$351.20	--
	Bicillin L-A 2.4 million units/4 ml	NF	\$367.64	--
Penicillin G (Pfizerpen-G)	Injection (IV) solution			
	Penicillin G potassium 20,000 units/ml	NF	\$205.86	--
	Penicillin G potassium 40,000 units/ml	NF	--	--
	Penicillin G potassium 60,000 units/ml	NF	--	--
	Injection (IM, IV) reconstituted solution			
	Penicillin G potassium 3 million units	NF	--	--
	Penicillin G potassium 5 million units	NF	\$48.96	--
	Penicillin G potassium 20 million units	NF	--	--
Penicillin V Potassium	Oral solution			
	Penicillin VK 125 mg/5 ml	--	\$11.37	--
	Penicillin VK 250 mg/5 ml	--	\$9.39	--
	Tablets			
	Penicillin VK 250 mg	--	\$3.43	--
	Penicillin VK 500 mg	--	\$2.84	--
Piperacillin/tazobactam (Zosyn)	IV solution			
	2.25 gram (pip 2 gram,-tazo 0.25 gram/50 ml)	NF	--	--
	3.375 gram (pip 3 gram-tazo 0.375 gram /50 ml)	NF	\$377.43	--
	4.5 gram (pip 4 gram-tazo 0.5 gram/100 ml)	NF	--	--
	IV powder for reconstitution			
	2.25 gram (pip 2 gram-tazo 0.25 gram)	NF	\$64.83	--
	3.375 gram (pip 3 gram-tazo 0.375 gram)	NF	\$98.97	--
	4.5 gram (pip 4 gram-tazo 0.5 gm)	NF	\$114.40	--
40.5 gram (pip 36 gram-tazo 4.5 gram)	NF	\$153.36	--	

Generic Name (Brand Name)	Strength & Dosage form	Formulary Limits	Average Cost per 30 days	Notes
Cephalosporins – 1st generation				
Cefadroxil (Duricef)	Oral Suspension			
	Cefadroxil 250 mg/5ml	NF	--	--
	500 mg/5 ml	NF	--	--
	Capsules			
	Cefadroxil 500 mg	NF	\$12.83	--
Cefadroxil (Duricef)	Tablets			
	Cefadroxil 1 gram	NF	--	--
	Injection (IM, IV) reconstituted solution			
	Cefazolin 100 mg	NF	--	--
	Cefazolin 200 mg	NF	--	--
Cefazolin (Ancef)	Cefazolin 500 mg	NF	--	--
	Cefazolin 1 gram	NF	--	--
	Cefazolin 2 gram	NF	--	--
	Cefazolin 10 gram	NF	\$5.64	--
	Cefazolin 20 gram	NF	--	--
	IV solution in D5W			
	Cefazolin 1 gram/50 ml	--	\$101.87	Limited to 7 day supplies.
	Cefazolin 2 gram/50 ml	--	\$239.95	
	Cefazolin 2 gram/100 ml	NF	\$163.30	--
	Cephalexin (Keflex, Daxbia)	Oral suspension		
Cephalexin 125 mg/5 ml		--	\$14.99	--
Cephalexin 250 mg/5 ml		--	\$17.38	--
Capsules				
Cephalexin 250 mg		--	\$2.75	--
Cephalexin (Daxbia) 333 mg		NF	--	--
Cephalexin 500 mg		--	\$3.32	--
Cephalexin 750 mg		NF	--	--
Tablets				
Cephalexin 250 mg		NF	\$44.27	Non-Formulary Capsules are on formulary
Cephalexin 500 mg	NF	\$64.45		
Cephalosporins – 2nd generation				
Cefaclor (Ceclor, Raniclор)	Oral suspension			
	Cefaclor 125 mg/5 ml	--	--	--
	Cefaclor 250 mg/5 ml	--	--	--
	Cefaclor 375 mg/5 ml	--	--	--
	Capsules			
	Cefaclor 250 mg	--	\$15.71	--
	Cefaclor 500 mg	--	\$30.65	--
Cefaclor (Ceclor, Raniclор)	Cefaclor XR 500 mg tablet	NF	--	--
	Injection (IM, IV)			
	Cefotetan 1 gram	NF	--	--
Cefotetan (Cefotan)	Cefotetan 2 gram	NF	--	--
	Injection (IV)			
Cefoxitin (Mefoxin)	Cefoxitin 1 gram	NF	--	--
	Cefoxitin 2 gram	NF	--	--
	Cefoxitin 10 gram	NF	--	--
Cefprozil (Cefzil)	Oral suspension			
	Cefprozil 125 mg/5 ml	NF	--	--
	Cefprozil 250 mg/5 ml	NF	--	--
	Tablets			
	Cefprozil axetil 250 mg	NF	\$15.70	--
Cefprozil (Cefzil)	Cefprozil axetil 500 mg	NF	--	--
	Oral suspension			
Cefurxoime (Ceftin, Zinacef)	Ceftin 125 mg/5 ml	NF	--	--

Cefitin 250 mg/5 ml	NF	--	--
Tablets			
Cefuroxime axetil 250 mg	--	\$13.44	--
Cefuroxime axetil 500 mg	--	\$10.27	--
Injection (IM, IV)			
Cefuroxime axetil 750 mg	NF	--	--
Cefuroxime axetil 1.5 gram	NF	--	--
Cefuroxime axetil 7.5 gram	NF	--	--

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Generic Name (Brand Name)	Strength & Dosage form	Formulary Limits	Average Cost per 30 Days	Notes
Cephalosporins – 3rd generation				
Cefdinir (Omnicef)	Oral suspension			Step therapy to 1 course of generic first-line antibiotics within the last 90 days
	Cefdinir 125 mg/5 ml	ST	\$13.59	
	Cefdinir 250 mg/5 ml	ST	\$14.42	
	Capsules			
	Cefdinir 300 mg capsule	ST	\$10.43	
Cefditoren (Spectracef)	Tablets			
	Cefditoren 200 mg	NF	--	--
	Cefditoren 400 mg	NF	--	--
Cefixime (Suprax)	Chewable tablets			
	Suprax 100 mg	NF	--	--
	Suprax 200 mg	NF	--	--
	Oral suspension			
	Cefixime 100 mg/5 ml	NF	\$294.90	--
	Cefixime 200 mg/5 ml	NF	--	--
	Capsules			
	Suprax 400 mg	NF	\$94.01	--
	Tablets			
	Suprax 400 mg	NF	--	--
Cefotaxime (Claforan)	Injections (IM, IV)			
	Cefotaxime 500 mg	NF	--	--
	Cefotaxime 1 gram	NF	--	--
	Cefotaxime 2 gram	NF	--	--
	Cefotaxime 10 gram	NF	--	--
Cefpodoxime (Vantin)	Oral suspension			
	Cefpodoxime 50 mg/5 ml	NF	--	--
	Cefpodoxime 100 mg/5 ml	NF	--	--
	Tablets			
	Cefpodoxime 100 mg	NF	\$36.92	--
	Cefpodoxime 200 mg	NF	\$102.96	--
Ceftazidime (Fortaz, Tazicef)	In 50 ml D5W IV solution			
	Fortaz 1 gram	NF	--	--
	Fortaz 2 gram	NF	--	--
	Injection (IM, IV)			
	Ceftazidime 1 gram	NF	\$15.91	--
	Ceftazidime 2 gram	NF	\$82.07	--
	Ceftazidime 6 gram	NF	\$63.25	--
Ceftibuten (Cedax)	Oral suspension			
	Cedax 90 mg/5 ml	NF	--	--
	Ceftibuten 180 mg/5 ml	NF	--	--
	Capsules			
	Ceftibuten 400 mg	NF	--	--
Ceftriaxone (Rocephin)	Injection (IM, IV) reconstituted solution			
	Ceftriaxone 250 mg	F	\$1.28	

	Ceftriaxone 500 mg	F	\$0.97	Limited to 1 fill per 365 days.
	Ceftriaxone 1 gm	F	\$3.27	
	Ceftriaxone 2 gm	NF	\$3.91	--
	Ceftriaxone 10 gm	NF	\$19.58	--
	IV reconstituted solution			
	Ceftriaxone in D5W 1 gm/50mL	F	\$135.60	Limited to 7 day supplies.
	Ceftriaxone in D5W 2 gm/50mL	F	\$230.90	

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Generic Name (Brand Name)	Strength & Dosage form	Formulary Limits	Average Cost per 30 Days	Notes
Cephalosporins – 4th generation				
Cefepime (Maxipime)	Injection (IM, IV) reconstituted solution			
	Cefepime 1 gm	NF	\$47.55	--
	Cefepime 2 gm	NF	\$55.90	--
	Injection (in D5W)			
	Cefepime 1 gram	NF	\$758.56	
Cefiderocol (Fetroja)	IV reconstituted solution			
	Cefiderocol 1 gram	NF	--	--
Cephalosporins – 5th generation				
Ceftaroline fosamil (Teflaro)	IV reconstituted solution			
	Teflaro 400 mg	NF	--	--
	Teflaro 600 mg	NF	--	--
Combination Cephalosporins				
Ceftazidime/avibactam (Avycaz)	Injection (IV)			
	Avycaz 2.5 gram (Ceftazidime 2 gram- 500 mg avibactam)	NF	--	--
Ceftolozane/Tazobactam (Zerbaxa)	Injection (IV)			
	Zerbaxa 1.5 gram (Ceftolozane 1 gram-tazobactam 500 mg)	NF	\$1010.61	--

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Generic Name (Brand Name)	Strength & Dosage form	Formulary Limits	Average Cost per 30 Days	Notes
Carbapenems				
Doripenem (Doribax)	Injection (IV) Reconstituted			
	Doripenem 250 mg	NF	--	--
	Doripenem 500 mg	NF	--	--
Ertapenem (Invanz)	Injection (IM, IV) reconstituted solution			
	INVanz 1 gm	NF	\$429.74	--
Imipenem/cilastatin (Primaxin I.V.)	IV powder for reconstitution			
	Imi 250 mg/cilas 250 mg	NF	--	--
	Imi 500 mg/cilas 500 mg	NF	--	--
Meropenem (Merrem)	IV reconstituted solution			
	Meropenem 500 mg	NF	\$19.66	--
	Meropenem 1 gm	NF	\$158.47	--

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Generic Name (Brand Name)	Strength & Dosage form	Formulary Limits	Average Cost per 30 Days	Notes	
Aminoglycosides					
Amikacin	Injection (IM, IV)				
	Amikacin 500 mg/2 ml	NF	--	--	
	Amikacin 1 gram /4 ml	NF	--	--	
Gentamicin	Injection (IM, IV) solution				
	Gentamicin 40 mg/ml	--	\$2.83	--	
	Gentamicin 80 mg/ml	NF	--	--	
Neomycin	Neomycin 500 mg tablet	--	\$14.15	--	
Tobramycin (Bethkis, Kitabis, Tobi)	Injection (IM, IV)				
	Tobramycin 10 mg/2 ml	NF	--	--	
	Tobramycin 80 mg/2 ml	NF	\$1.26	--	
	Tobramycin 1.2 gram/30 ml	NF	--	--	
	Tobramycin 2 gram/ 50 ml	NF	--	--	
	Tobi Podhaler 28 mg inhalation capsule	NF	--	--	
	Tobramycin 300 mg/5 ml inhalation solution (Tobi)	PA; SP	\$1,168.63	Approval by medical necessity criteria	
	Tobramycin 300mg/4ml (Bethkis)	PA; SP	\$5,704.92	Approval by medical necessity criteria	
Cyclic Lipopeptide					
Daptomycin (Cubicin)	Injection (IV)				
	Cubicin 350 mg	NF	\$3673.02	--	
	Cubicin 500mg	NF	\$521.11		
Fluoroquinolones					
Ciprofloxacin (Cipro, Cipro XR)	Tablets				
	Ciprofloxacin 100 mg	QL	\$176.47	Limit 28 tablets per month	
	Ciprofloxacin 250 mg	QL	\$1.20		
	Ciprofloxacin 500 mg	QL	\$1.94		
	Ciprofloxacin 750 mg	QL	\$7.84		
	Ciprofloxacin ER 500 mg	NF	--	--	
	Ciprofloxacin ER 1000 mg	NF	--	--	
	Oral suspension				
	Ciprofloxacin 250 mg/5 ml (Cipro 5%)	QL	\$332.52	Limit 300 ml per month	
	Ciprofloxacin 500 mg/5 ml (Cipro 10%)	QL	\$155.36	Limit 150 ml per month	
	Injection (IV)				
	Ciprofloxacin 200 mg/100 ml	NF	--	--	
	Ciprofloxacin 400 mg/ 200 ml	NF	--	--	
Gemifloxacin (Factive)	Tablets Factive 320 mg	NF	--	--	
Levofloxacin (Levaquin)	Oral Solution Levofloxacin 25 mg/ml	QL; AL	\$210.65	Limit 280 ml per month. Restricted to patients age 18 & older.	
	IV solution				
	Levofloxacin 25 mg/ml	NF	--	--	
	Levofloxacin 750 mg/150 ml	NF	\$16.76	--	
	Tablets				
	Levofloxacin 250 mg	QL; AL	\$1.49	Limit 14 tablets per month. Restricted to patients age 18 & older.	
	Levofloxacin 500 mg	QL; AL	\$1.61		
Levofloxacin 750 mg	QL; AL	\$3.18			
Moxifloxacin (Avelox)	Moxifloxacin 400 mg tablet	NF	\$47.46	--	

Ofloxacin	Ofloxacin 400 mg tablet	NF	--	--
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Generic Name (Brand Name)	Strength & Dosage form	Formulary Limits	Average Cost per 30 Days	Notes
Glycopeptides				
Vancomycin	Oral solution			
	First-Vancomycin 25 mg/ml	NF	--	--
	First-Vancomycin 50 mg/ml	NF	--	--
	Vancomycin+Syr Spend SF PH4 50 mg/ml oral suspension	NF	--	--
	Firvanq 25mg/ml, 50mg/ml	PA	\$176.59	Reserved for Clostridium difficile infections as evidenced by C. diff toxin assay or C. diff DNA PCR
	Capsules			
	Vancomycin 125 mg	PA	\$113.92	Reserved for Clostridium difficile infections as evidenced by C. diff toxin assay or C. diff DNA PCR
	Vancomycin 250 mg	NF	\$577.45	--
	IV solution			
	Vancomycin 500 mg/100 ml	NF	\$23.73	--
	Vancomycin 750 mg/150 ml	NF	\$110.89	--
	Vancomycin 1 gm/200 ml	NF	\$397.97	--
	IV reconstituted solution			
	Vancomycin 500 mg	NF	\$27.85	--
	Vancomycin 750 mg	NF	\$34.98	--
	Vancomycin 1 gm	NF	\$17.38	--
Vancomycin 5 gm	NF	\$64.49	--	
Vancomycin 10 gm	NF	\$81.68	--	
Glycylglycine				
Tigecycline (Tygacil)	Injection (IV) Tygacil 50 mg reconstituted solution	NF	--	--
Lincosamide				
Clindamycin (Cleocin HCl, Cleocin Palmitate, Cleocin Phosphate)	Capsules			
	Clindamycin HCL 75 mg	--	\$13.52	--
	Clindamycin HCl 150 mg	--	\$4.81	--
	Clindamycin HCl 300 mg	--	\$7.68	--
	Oral Solution			
	Clindamycin palmitate 75 mg/5 ml	--	\$67.35	--
	Vaginal Cream			
	Clindamycin 2% cream	--	\$72.44	--
	Vaginal Suppository			
	Cleocin 100mg (ovule)	--	\$222.15	--
	Phosphate Injection (IV, IM)			
Clindamycin 300 mg/2 ml	NF	--	--	
Clindamycin 600 mg/4 ml	NF	--	--	
Clindamycin 900 mg/6 ml	NF	--	--	
Lincomycin (Lincocin)	Injection (IV, IM) Lincomycin 300 mg/ml	NF	--	--

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Generic Name (Brand Name)	Strength & Dosage form	Formulary Limits	Average Cost per 30 Days	Notes
Macrolides				
Azithromycin (Zithromax)	Oral suspension			
	Azithromycin 100 mg/5 ml	--	\$15.44	--
	Azithromycin 200 mg/5 ml	--	\$8.65	--
	Zimax 2 gram/ 60 ml ER	--	--	--
	Tablets			
	Azithromycin 250 mg	--	\$3.45	--
	Azithromycin 500 mg	--	\$3.72	--
	Azithromycin 600 mg	--	\$11.37	--
Azithromycin 1 gm powder packet	--	\$26.38	--	
Clarithromycin (Biaxin)	Oral suspension			
	Clarithromycin 125 mg/5 ml	NF	\$108.86	--
	Clarithromycin 250 mg/5 ml	--	\$205.81	--
	Tablets			
	Clarithromycin 250 mg	--	\$15.66	--
	Clarithromycin 500 mg	--	\$13.32	--
	Clarithromycin XL 500 mg tablet	NF	--	--
Erythromycin (EryPed, Ery-Tab, Erythrocin, E.E.S., PCE)	Oral suspension			
	E.E.S. granules 200 mg/5 ml	FL	\$742.97	Limit 1 fill per 365 days
	EryPed 200 mg/5 ml	FL	\$374.59	
	EryPed 400 mg/5 ml	NF	\$606.69	
	Erythromycin granules 200 mg/5ml	FL	--	
	Capsules			
	Erythromycin base 250 mg DR	FL	\$127.40	Limit 1 fill per 365 days
	Erythromycin 250 mg EC	FL	\$225.05	
	Tablets			
	Erythromycin base 250 mg	FL	\$457.29	Limit 1 fill per 365 days
	Erythromycin base 500 mg	FL	\$288.17	
	Erythromycin ethylsucc 400 mg	FL	--	
	Erythromycin stearate 500 mg	FL	--	
	Delayed-release tablets			
	Ery-Tab 250 mg	FL	--	Limit 1 fill per 365 days
Ery-Tab 333 mg	FL	\$188.44		
Ery-Tab 500 mg	FL	--		
Fidaxomicin (Dificid)	Dificid 200 mg tablet	PA, QL	\$2,815.47	Reserved for Clostridium difficile infections as evidenced by C. diff toxin assay or C. diff DNA PCR

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Generic Name (Brand Name)	Strength & Dosage form	Formulary Limits	Average Cost per 30 Days	Notes
Nitrofuran Derivative				
Nitrofurantoin (Furadantin, Macrobid, Macrochantin)	Capsules			
	Nitrofurantoin 25 mg	NF	\$120.25	--
	Nitrofurantoin 50 mg	--	\$15.56	--
	Nitrofurantoin 100 mg	--	\$15.27	--
	Nitrofurantoin monohydrate 100 mg	--	\$8.48	--
	Suspension			
Nitrofurantoin 25 mg/5 ml	PA	\$1,117.91	Reserved for infections resistant to ALL first line antibiotics as proven by urine culture and sensitivity	
Nitroimidazole				
Metronidazole (Flagyl, Flagyl ER, Metro)	Tablets			
	Metronidazole 250 mg	--	\$4.18	--
	Metronidazole 500 mg	--	\$2.95	--
	Flagyl ER 750 mg	NF	--	--
	Capsules			
	Metronidazole 375 mg	NF	--	--
	Vaginal Gel			
	Metronidazole 0.75%	--	\$76.12	
	Injection (IV)			
	Metronidazole 500 mg/100 ml	NF	\$14.08	--
Oral Suspension				
Metronidazole 50 mg/ml	NF	--	--	
Metronidazole 100 mg/ml	NF	--	--	
Secnidazole (Solosec)	Oral Packet Secnidazole 2 g	NF	\$288.92	--
Tinidazole (Tindamax)	Tablets			
	Tinidazole 250 mg	NF	--	--
	Tinidazole 500 mg	NF	\$13.80	--
Oxazolidinone				
Linezolid (Zyvox)	Oral Suspension			
	Linezolid 100 mg/5 ml	NF	\$669.12	
	Tablets			
	Linezolid 600 mg tablet	PL, QL	\$47.03	Prescribed by Infectious Disease. Limited to 2 tablets per day.
	Injection (IV)			
	Linezolid 600 mg/ 300 ml	NF	\$210.00	--
Zyvox 600 mg/ 300 ml	NF	--		
Tedizolid (Sivextro)	Tablets			
	Sivextro 200 mg	NF	--	
	Injection (IV)			
Sivextro 200 mg	NF	--	--	

Generic Name (Brand Name)	Strength & Dosage form	Formulary Limits	Average Cost per 30 Days	Notes
Pleuromutilin				
Lefamulin (Xenleta)	Injection (IV) Lefamulin 150 mg	NF	--	
	Tablets Lefamulin 600 mg	NF	--	
Polymyxin and derivatives				
Colistimethate (Coly-Mycin M)	Injection (IV, IM) Colistimethate 150 mg	NF	--	
Polymyxin B	Injection (IV, IM) Polymyxin B 50,000 Units	NF	--	
Streptogramin				
Quinupristin/ dalfopristin (Synercid)	Injection (IV) Synercid 500 (Quinupristin 150 mg-dalfopristin 350mg)	NF	--	
Sulfonamides				
Sulfadiazine	Tablets Sulfadiazine 500 mg	NF	\$917.19	
Sulfameth/ trimethoprim (Septra, Bactrim, Bactrim DS, Sulfatrim Pediatric)	Oral Suspension Sulfa 200mg/trimeth 40 mg/5 ml	--	\$23.95	--
	Tablets			
	Sulfa 400 mg/ trimeth 80 mg	--	\$1.72	--
	Sulfa 800 mg/ Trimeth 160 mg	--	\$1.32	--
	Injection Sulfa 80 mg/ trimeth 6 mg/ ml	NF	--	--

Generic Name (Brand Name)	Strength & Dosage form	Formulary Limit	Average Cost per 30 Days	Notes
Tetracyclines				
Doxycycline (Morgidox, Vibramycin)	Capsules (Hyclate)			Non-Formulary: Alternative is doxycycline monohydrate
	Doxycycline 50 mg	NF	\$6.77	
	Doxycycline 100 mg	NF	\$8.28	
Doxycycline (Adoxa, Mondoxyne, Monodox)	Capsules (Monohydrate)			
	Doxycycline 50mg	--	\$8.61	--
	Doxycycline 75 mg	NF	--	--
	Doxycycline 100 mg	--	\$10.05	--
Doxycycline (Oracea)	Doxycycline 40 mg DR	NF	--	--
Doxycycline (Vibramycin)	Oral Suspension Doxycycline 25 mg/5 ml	NF	\$314.34	--
Doxycycline (TargaDOX, Acticlalte)	Tablets (Hyclate)			
	Doxycycline 20 mg	NF	--	--
	Doxycycline 75 mg	NF	--	--
	Doxycycline 100 mg	NF	\$7.06	--
	Doxycycline 150 mg	NF	--	--
	Tablets (Monohydrate)			

Doxycycline (Adoxa)	Doxycycline 50 mg	NF	--	--
	Doxycycline 75 mg	NF	--	--
	Doxycycline 100 mg	--	\$15.79	--
	Doxycycline 150 mg	NF	--	--
Doxycycline (Doryx)	Delayed Release Tablets (Hyclate)			
	Doxycycline 50 mg DR	NF	--	--
	Doxycycline 75 mg DR	NF	--	--
	Doxycycline DR 100 mg	NF	--	--
	Doxycycline DR 150 mg	NF	--	--
	Doxycycline DR 200 mg	NF	--	--
	Injection (IV) Doxycycline Hyclate 100 mg	NF	--	--
Doxycycline (Atridox 10%)	Subgingival Liquid Doxycycline hyclate 50 mg	NF	--	--
Demeclocycline	Tablets			
	Demeclocycline 150 mg	NF	\$361.87	--
	Demeclocycline 300 mg	NF	--	--
Eravacycline (Xerava)	Injection (IV) Eravacycline 50mg	NF	\$499.80	--
Minocycline (Minocin, Solodyn, Arestin)	Arestin 1 mg subgingival cartridge	NF	--	--
	Extended-release tablets			
	Minocycline XR 45 mg	NF	--	--
	Minocycline XR 90 mg	NF	--	--
	Minocycline XR 135 mg	NF	--	--
	Solodyn 55 mg	NF	--	--
	Solodyn 65 mg	NF	--	--
	Solodyn 80 mg	NF	--	--
	Solodyn 105 mg	NF	--	--
	Solodyn 115 mg	NF	--	--
	Capsules			
	Minocycline 50 mg	-	\$9.31	--
	Minocycline 75 mg	-	\$14.13	--
	Minocycline 100 mg	-	\$20.35	--
	Tablets			
	Minocycline 50 mg	NF	--	--
	Minocycline 75 mg	NF	--	--
Minocycline 100 mg	NF	--	--	
Injection (IV) Minocycline 100 mg	NF	--	--	
Omacycline (Nuzyra)	Injection (IV) Omacycline 100 mg	NF	--	--
	Tablet Omacycline 150 mg	NF	--	--
Sarecycline (Seysara)	Tablet Sarecycline 60mg, 100mg, 150mg	NF	--	--
Tetracycline	Capsules			
	Tetracycline 250 mg	NF	\$139.37	--
	Tetracycline 500 mg	PA, QL	\$80.60	Reserved for H. Pylori infection. Limited to 56 capsules per 14 days.

PA = Prior Authorization; QL = Quantity Limit; AL = Age Limit; NF = Non-formulary; SP = Specialty Pharmacy

Generic Name (Brand Name)	Strength & Dosage form	Formulary Limits	Average Cost per 30 Days	Notes
Monobactam				
Aztreonam (Azactam, Cayston)	IV solution (IV, IM)			
	Aztreonam 1 gram	NF	--	--
	Aztreonam 2 gram	NF	--	--
	Inhalation Solution			
	Cayston 75 mg/ml	NF	\$9,384.83	--
Miscellaneous				
Clofazimine	Clofazimine 50 mg capsule	NF	--	--
Dapsone	Tablets			
	Dapsone 25 mg	--	\$58.77	--
	Dapsone 100 mg	--	\$42.32	--
Fosfomycin (Monurol)	Monurol 3 gm oral packets	NF	\$633.04	--
Methenamine (Hiprex)	Tablets			
	Methenamine hippurate 1 gram	--	\$63.09	--
	Methenamine mandelate 0.5 gram	--	\$36.98	--
	Methenamine mandelate 1 gram	--	--	--
Trimethoprim (Primsol)	Oral solution			
	Primsol 50 mg/5 ml	--	--	--
	Tablets			
	Trimethoprim 100 mg	--	\$12.87	--
Monoclonal Antibody				
Bezlotoxumab (Zinplava)	IV solution 1000mg/40 ml (40ml)	PA	--	See Coverage Criteria
Antitubercular Agents				
Isoniazid	Solution			
	Isoniazid 50 mg/5mL	--	\$313.83	--
	Tablet			
	Isoniazid 100 mg	--	\$5.57	--
	Isoniazid 300 mg	--	\$4.38	--
Ethambutol	Tablet			
	Ethambutol 100 mg	--	\$18.44	--
	Ethambutol 400 mg	--	\$52.57	--
Pyrazinamide	Tablet			
	Pyrazinamide 500 mg	--	\$205.21	--
Rifampin	Capsule			
	Rifampin 150 mg	--	\$70.02	--
	Rifampin 300 mg	--	\$35.83	--
Rifapentine (Priftin)	Tablet			
	Rifapentin 150 mg	QL	\$83.71	Limited to 32 tablets per 30 days.
Rifabutin (Mycobutin)	Capsule			

	Rifabutin 150 mg	PA	\$713.59	See Coverage Criteria
Bedaquiline (Sirturo)	Tablet			
	Sirturo 20 mg tablet	PA	--	See Coverage Criteria
	Sirturo 100 mg tablet	PA	--	See Coverage Criteria

PA = Prior Authorization; QL = Quantity Limit; AL = Age Limit; NF = Non-formulary; SP = Specialty Pharmacy

EVALUATION CRITERIA FOR APPROVAL/EXCEPTION CONSIDERATION

Below are the coverage criteria and required information for each agent. These coverage criteria have been reviewed & approved by the HPSJ Pharmacy & Therapeutics (P&T) Advisory Committee. For conditions not covered under this Coverage Policy, HPSJ will make the determination based on Medical Necessity as described in HPSJ Medical Review Guidelines (UM06).

Topical Antibiotics
<i>Bacitracin, Bacitracin-Polymyxin B (Polysporin), Bactroban, Chlorhexidine gluconate (Peridex), Clindamycin phosphate (Cleocin, Cleocin T), Clindamycin vaginal cream (Vandazole), Clindamycin vaginal suppository, Erythromycin (Ery-Pads), Gentamicin Sulfate, Iodoquinol/hydrocortisone (Dermazene), Metronidazole (Metrogel, Metro lotion, Noritate), Mupirocin (Bactroban, Centany), Neomycin-bacitracin-polymyxin (Neosporin, Triple antibiotics), Neomycin-bacitracin-polymyxin, Neomycin-polymyxin-prmoxine (Neosporin Plus), Neomycin-polymyxin-hydrocortisone (Cortisporin), Silver Sulfadiazine (SSD)</i>

Chlorhexidine gluconate oral rinse; Clindamycin phosphate vaginal suppository, cream; Metronidazole cream, gel, vaginal gel, lotion; Mupirocin ointment

- Coverage Criteria:** None
- Limits:** None
- Required Information for Approval:** N/A
- Other Notes:** None
- Non-Formulary:** Bactroban cream: Bactroban Nasal Ointment: Iodoquinol/hydrocortisone cream; Metronidazole 1% Cream (Noritate): Cortisporin Cream/Ointment

Penicillins
<i>Amoxicillin (Moxatag), Amoxicillin/potassium clavulanate (Augmentin), Ampicillin, Ampicillin-sulbactam (Unasyn), Dicloxacillin, Nafcillin (Nallpen), Oxacillin (Bactocill), Penicillin G benzathine (Bicillin L-A), Penicillin G (Pfizerpen-G), Penicillin V Potassium, Piperacillin/tazobactam (Zosyn)</i>

Amoxicillin chewable tablets, oral suspension, capsules, tablets

- Coverage Criteria:** None
- Limits:** None
- Required Information for Approval:** N/A
- Other Notes:** None
- Non-Formulary:** Amoxicillin/potassium clavulanate suspension (125/31.25, 250/62.5): Amoxicillin/ potassium clavulanate 1000 mg/ 62.5 mg: All strengths of chewable Augmentin tablets:

Ampicillin injection solution, Ampicillin/sulbactam (Unasyn):
Nafcillin (Nallpen), All Injectable Penicillin: Piperacillin/tazobactam (Zosyn):
All Penicillin Injections except Penicillin G Procaine 600,000 unit/1mL
All Piperacillin/tazobactam Injections

Cephalosporins - 1st generation
<i>Cefadroxil (Duricef), Cefazolin (Ancef), Cephalexin (Keflex)</i>

Cephalexin (Keflex) suspension, capsules (250 mg, 500 mg)

- Coverage Criteria:** None
- Limits:**
 - o Cefazolin in Dextrose 1G/50mL, 2G/50mL frozen piggyback: Limited to a 7-day supply at a time.
- Required Information for Approval:** N/A
- Other Notes:** None
- Non-Formulary:** All strengths of Cefadroxil, and Cefazolin, Cephalexin 333mg and 750 mg Capsules, and Cephalexin Tablets

Cephalosporins – 2nd generation

Cefaclor (Ceclor), cefotetan (Cefotan), Cefoxitin (Mefoxin), Cefprozil (Cefzil), Cefuroxime (Ceftin, Zinacef)

Cefaclor (Ceclor) suspension, capsules; Cefuroxime (Ceftin) tablets

- Coverage Criteria:** None
- Limits:** None
- Required Information for Approval:** N/A
- Other Notes:** None
- Non-Formulary:** Cefaclor XR tablets; Cefotetan , Cefoxitin , Cefprozil, Cefuroxime oral suspensions and injections

Cephalosporins – 3rd generation

Cefdinir (Omnicef), Cefditoren (Spectracef), Cefixime (Suprax), Cefotaxime (Claforan), Cefpodoxime (Vantin), Ceftazidime (Fortaz, Tazicef), Ceftazidime/avibactam (Avycaz), Ceftibuten (Cedax), Ceftriaxone (Rocephin)

Cefdinir (Omnicef)

- Coverage Criteria:** Cefdinir is step therapy to 1 course of generic first-line antibiotics within the last 90 days.
- Limits:**
 - Ceftriaxone in Dextrose 1G/50mL, 2G/50mL frozen piggyback: Limited to a 7-day supply at a time.
 - Ceftriaxone 250mg, 500mg, 1G injection: Limited to 1 fill per 365 days.
- Required Information for Approval:** For cefdinir, prescription fill history of first-line antibiotic in the last 90 days.
- Other Notes:** None
- Non-Formulary:** Cefditoren, Cefixime , Cefotaxime, Cefpodoxime, Ceftazidime, Ceftibuten, Cefiderocol

Cephalosporins – 4th generation

Cefepime (Maxipime)

- Non-Formulary:** Cefepime, Cefiderocol

Cephalosporins – 5th generation

Ceftaroline (Teflaro)

- Non-Formulary:** Ceftaroline

Combination Cephalosporins

Ceftazidime/avibactam (Avycaz), Ceftolozane/Tazobactam (Zerbaxa)

- Non-Formulary:** Ceftazidime/avibactam, Ceftolozane/Tazobactam

Carbapenems

Doripenem (doribax), Ertapenem (Invanz), Imipenem/cilastatin (Primaxin), Meropenem (Merrem)

- Non-Formulary:** Doripenem, Ertapenem Imipenem/cilastatin

Aminoglycosides

Amikacin, Gentamicin, Neomycin, Tobramycin

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
- Other Notes:** Tobramycin 300 mg/ 5 ml Inhalation Solution is dispensed through HPSJ designated specialty pharmacy only
- Non-Formulary:** Amikacin, Gentamicin 80 mg/ml injection, Tobramycin, Tobi Podhaler

Cyclic lipopeptide*Daptomycin (Cubicin)*

- Non-Formulary:** Daptomycin (Cubicin)

Fluoroquinolones*Ciprofloxacin (Cipro), Gemifloxacin (Factive), Levofloxacin (Levaquin), Moxifloxacin (Avelox), Ofloxacin***Ciprofloxacin, Levofloxacin:**

- Coverage Criteria:** Levofloxacin oral solution & tablets are restricted to patients age 18 & older.
- Limits:**
 - **Ciprofloxacin 100 mg, 250 mg tablets:** 28 tablets per month
 - **Ciprofloxacin 250 mg/5ml oral suspension:** 300 ml per month
 - **Ciprofloxacin 500 mg/5 ml oral suspension:** 150 ml per month
 - **Levofloxacin 25 mg/5 ml oral solution:** 280 ml per month
 - **Levofloxacin tablets:** Limit 14 tablets per month
- Required Information for Approval:** N/A
- Other Notes:** None
- Non-Formulary:** Ciprofloxacin ER 500 mg and 1000 mg tablets, Ciprofloxacin Injection, Gemifloxacin, Levofloxacin Injection, Moxifloxacin, Ofloxacin

Glycopeptide*Vancomycin (Firvanq, Vancocin)***Vancomycin (Firvanq) 25mg/ml and 50mg/ml oral suspension**

- Coverage Criteria:** Vancomycin (Firvanq) oral suspension is reserved for Clostridium difficile infections as evidenced by C. diff toxin assay or C. diff DNA PCR
- Limits:** None
- Required Information for Approval:** Positive (detected) C. diff toxin on assay or DNA PCR
- Other Notes:** None

Non-Formulary: First-Vancomycin**Vancomycin (Vancocin) capsules (125 mg)**

- Coverage Criteria:** Vancomycin 125 mg capsules are reserved for Clostridium difficile infections as evidenced by C. diff toxin assay or C. diff DNA PCR.
- Limits:** None
- Required Information for Approval:** Positive (detected) C. diff toxin on assay or DNA PCR
- Other Notes:** tapered and pulsed dose regimen = Vancomycin 125mg four times daily for 10 to 14 days followed by twice daily for 7 days, then once daily for 7 days, and finally once daily every 2-3 days for 2 to 8 weeks.
- Non-Formulary:** First-Vancomycin

Glycylcycline*Tigecycline (Tygacil)*

- Non-Formulary:** Tigecycline (Tygacil)

Lincosamide*Clindamycin (Cleocin HCl, Cleocin Palmitate, Cleocin Phosphate), Lincomycin (Lincocin)***Clindamycin (Cleocin) capsules, oral solution**

- Coverage Criteria:** None
- Limits:** None
- Required Information for Approval:** N/A
- Other Notes:** None
- Non-Formulary:** Clindamycin Injection, Lincomycin

Macrolides

Azithromycin (Zithromax), Clarithromycin (Biaxin), Erythromycin (EryPed, Ery-Tab, Erythrocin, E.E.S., PCE), Fidaxomicin (Difcid)

Azithromycin: Clarithromycin oral suspension (250 mg/5 ml), tablets

- Coverage Criteria:** None
- Limits:** Erythromycin with a limit of 1 fill per 365 days
- Required Information for Approval:** : For continuation beyond one fill, submit PA with clinic notes documenting indication, previous therapies tried, and treatment plan
- Other Notes:** For gastroparesis, metoclopramide must be tried first.
- Non-Formulary:** Clarithromycin 125 mg/5 ml oral suspension, Clarithromycin XL 500 mg tablets, EryPed 400 mg/5ml oral suspension, Difcid

Fidaxomicin (Difcid) 200mg tablets

- Coverage Criteria:** Fidaxomicin (Difcid) is reserved for Clostridium difficile infections as evidenced by C. diff toxin assay or C. diff DNA PCR.
- Limits:** 20 tablets per fill for initial or recurrent infections.
- Required Information for Approval:** Positive (detected) C. diff toxin on assay or DNA PCR
- Other Notes:** Recurrent C. diff infections- Fidaxomicin 200mg by mouth twice daily for 10 days, OR twice daily for 5 days followed by once every other day for 20 days.

Nitrofurantoin derivatives

Nitrofurantoin (Furadantin, Macrobid, Macrodantin)

Nitrofurantoin:

- Coverage Criteria:** Nitrofurantoin suspension is reserved for infections resistant to ALL first line antibiotics as proven by urine culture and sensitivity.
- Limits:** None
- Required Information for Approval:** Urine culture & sensitivity results for Nitrofurantoin suspension
- Other Notes:** None
- Non-Formulary:** Nitrofurantoin macrocrystal 25 mg capsules

Nitroimidazoles

Metronidazole (Flagyl, Flagyl ER, Metro), Tinidazole (Tindamax)

Metronidazole tablets

- Coverage Criteria:** None
- Limits:** None
- Required Information for Approval:** N/A
- Other Notes:** None
- Non-Formulary:** Metronidazole 375 mg capsules, oral suspensions, Flagyl ER 750 mg tablets, IV solution, Tinidazole, Solosec

Oxazolidinones

Linezolid (Zyvox), Tedizolid (Sivextro)

Linezolid (Zyvox) tablets

- Coverage Criteria:** None
- Limits:**
 - Prescriber limited to Infectious Disease.
 - Limited to 2 tablets per day.
- Required Information for Approval:**
- Other Notes:** linezolid is generally reserved for treatment of infections due to drug-resistant organisms (eg, MRSA, VRE) due to risk of drug resistance
- Non-Formulary:** Linezolid Injection, oral suspension; Tedizolid

Polymyxin and derivatives

Colistimethate (Coly-Mycin M); Polymyxin B

- Non-Formulary:** Colistimethate (4Coly-Mycin M); Polymyxin B

Streptogramin

Quinupristin/dalfopristin (Synercid)

- Non-Formulary:** Quinupristin/dalfopristin (Synercid)

Sulfonamides

Sulfadiazine, Sulfamethoxazole/trimethoprim (Septra, Bactrim, Bactrim DS, Sulfatrim Pediatric)

Sulfamethoxazole/trimethoprim (Septra, Bactrim, Bactrim DS, Sulfatrim)

- Coverage Criteria:** None
- Limits:** None
- Required Information for Approval:** N/A
- Other Notes:** None
- Non-Formulary:** Sulfamethoxazole/trimethoprim injections, Sulfadiazine

Tetracyclines

Demeclocycline, Doxycycline Adoxa, Atridox, Doryx, Monodox, Oracea, Vibramycin), Minocycline (Minocin, Solodyn, Arestin), Tetracycline

Doxycycline monohydrate tablets (100 mg), capsules (50 mg, 100 mg); Minocycline capsules

- Coverage Criteria:** None
- Limits:** None
- Required Information for Approval:** N/A
- Other Notes:** None
- Non-Formulary:**
- All other dosage forms and strengths of Doxycycline **EXCEPT** Doxycycline Monohydrate 50 mg and 100 mg capsules, and Doxycycline Monohydrate 100 mg Tablets. All dosage forms and strengths of Minocycline **EXCEPT** Minocycline 50 mg, 75 mg, and 100 mg capsules.
- Demeclocycline, Nuzyra, Seysara

Tetracycline 500mg capsules

- Coverage Criteria:** PA required. Reserved for patients with a positive Helicobacter pylori infection.
- Limits:** Limited to 56 capsules per 14 days.
- Required Information for Approval:** Positive lab results confirming H. pylori infection.
- Non-Formulary:** Tetracycline 250mg capsules

Monobactam and Other antibiotics

Aztreonam (Azactam, Cayston), Clofazimine, Dapsone, Fosfomycin (Monurol), Methenamine (Hiprex), Trimethoprim (Primsol)

Dapsone, Methenamine (Hiprex)

- Coverage Criteria:** None
- Limits:** None
- Required Information for Approval:** N/A
- Other Notes:** None
- Non-Formulary:** Aztreonam, Clofazimine, Fosfomycin (Monurol)

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.

Antitubercular Agents

Isoniazid, Pyrazinamide, Ethambutol, Rifampin, Rifapentine (Priftin), Rifabutin (Mycobutin), Bedaquiline (Sirturo)

Isoniazid, Pyrazinamide, Ethambutol, Rifampin

- Coverage Criteria:** None
- Limits:** None

Rifapentine (Priftin)

- Coverage Criteria:** None
- Limits:** Limited to 32 tablets per 30 days.
- Required Information for Approval:** None

Rifabutin (Mycobutin)

- Coverage Criteria:**
 - o For treatment of tuberculosis, Mycobutin (rifabutin) is reserved for patients on medications regimens that prohibit use of rifampin due to interactions that cannot be avoided by dose adjustment.
 - o For Mycobacterium avium complex (MAC) prophylaxis Mycobutin (rifabutin) is reserved for HIV+ patients with CD4 count < 50 cells/ μ L who cannot use Azithromycin or Clarithromycin due to intolerance or interactions that cannot be avoided by dose adjustment. Therapy will be discontinued when CD4 count is > 100 cells/ μ L for more than 3 months.
- Limits:** None
- Required Information for Approval:**
 - o If for tuberculosis:
 - Positive diagnosis of Tuberculosis
 - Drugs that interact with rifampin
 - o If for Mycobacterium avium complex (MAC) prophylaxis in HIV+ patients
 - CD4 count
 - History of intolerance to Azithromycin or Clarithromycin
 - Allergic reactions to Azithromycin or Clarithromycin

Bedaquiline (Sirturo)

- Coverage Criteria:** Approval is determined by medical necessity criteria. Restricted to specialty pharmacy.
- Limits:** None
- Required Information for Approval:**
 - Diagnosis of multi-drug resistant tuberculosis
 - Directly observed therapy must be part of the treatment plan
- Other Notes:** Overall quality of evidence for use is low or insufficient, must consider that benefits outweigh potential of risks.

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

EVALUATION CRITERIA FOR APPROVAL/EXCEPTION CONSIDERATION

For agents that do not have established prior authorization criteria or agents that are “Non-Formulary.” HPSJ will make the determination based on the **Infectious Diseases Society of America (IDSA) or Centers for Disease Control and Prevention (CDC) Guidelines** and **Medical Necessity criteria** as described in HSPJ Medical Review Guidelines (UM06)—*see below for details*.

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, please submit a pharmacy authorization.** For all other administration settings (including buy-and-bill), please submit a UM authorization.

How to submit a pharmacy prior authorization form for review:

1. Submit request through HPSJ's Pharmacy Medication Prior Authorization Request form which can be obtained from www.hpsj.com.
2. Include clinic notes documenting diagnosis, past treatment history, and any pertinent laboratory tests.
3. Fax both the completed prior authorization form and the clinic documents to HPSJ Pharmacy Department: 209.762.4704.

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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

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

<ul style="list-style-type: none"> ⊞ Please refer to Eye & Ear Inflammatory Disorders Coverage Policy for coverage criteria of ophthalmic antibiotic medications. ⊞ Please refer to Acne Coverage Policy for coverage criteria of topical antibiotics used for acne. ⊞ Please refer to Wound Care Coverage Policy for coverage criteria of topical antibiotics used for wound care. ⊞ Please refer to Digestive Disorders Coverage Policy for coverage criteria of combination products used for H. pylori infections. ⊞ Please refer to Liver Disease Coverage Policy for coverage criteria of rifaximin (Xifaxan).
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