Agreement between drug PIs and FDA-cleared device breakpoints for 30 commonly prescribed agents (aerobes only)

Penicillins and inhib. Comb	Date of PI	Drug PI (label) MIC BPs	Cleared devices MIC BPs
penicillin G potassium - Pfizer	1/1/2006	staphylococci S $\leq$ 0.1 N. gonorrhoeae S $\leq$ 0.1 [redacted]	Use CLSI BPs for staph, streps, S. pneumoniae, enterococci that include S, I, and R criteria and different BPs for S. pneumoniae
ampicillin - Sandoz	6/1/2006	[redacted]	Use CLSI BPs for staph, streps, S. pneumoniae, enterococci
amoxicillin - Sandoz	11/1/2004	test amp with staph, enterococci, streps; amox BPs for S. pneumoniae	PI and CLSI BPs same
oxacillin - Sandoz	1/1/2004	[redacted]	use CLSI BPs for staphs
nafcillin - Baxter	9/1/2003	staphs S $\leq$ 2, R $\geq$ 4	PI and CLSI BPs same
ampicillin-sulbactam - Roerig	5/1/2006	staph and gram-negs S $\leq$ 8, I = 16, R $\geq$ 32; Haemoph S $\leq$ 2, R $\geq$ 4	PI and CLSI BPs same
amoxicillin-clavulanate - Teva	4/1/2006	gram-negs S $\leq$ 8, I = 16, R $\geq$ 32 staph and Haemoph S $\leq$ 4, R $\geq$ 8 S. pneumoniae S $\leq$ 2, I = 4, R $\geq$ 8	PI and CLSI BPs same
piperacillin - Wyeth	2/1/2004	enterics and Acinetobacter S $\leq$ 16, I - 32-64, R $\geq$ 128; Pseudomonas S $\leq$ 64, R $\geq$ 128; Enterococcus S $\leq$ 8, R $\geq$ 16	PI and CLSI BPs same
piperacillin-tazo- Wyeth	7/26/2006	same as piperacillin plus BPs for S. aureus S $\leq$ 8, R $\geq$ 16; no Enterococcus BPs	PI and CLSI BPS same except no CLSI BPs for staph

Agreement between drug PIs and FDA-cleared device breakpoints for 30 commonly prescribed agents (aerobes only)

Cephalosporins

cefazolin - GSK	4/1/2005	one set of BPs, S ≤ 16, R ≥ 64	CLSI BPs - Staph and enterics S ≤ 8, I = 16, R ≥ 32
cephalexin - Advancis	3/1/2006	one set of BPS for testing cephalothin S ≤ 8, I = 16, R ≥ 32	CLSI BPs same for staph only; no BPs for streps or Haemoph for cephalothin or cephalexin
cefotaxime - Aventis	5/1/2002	Orgs other than those below - BPs S ≤ 8, I = 16-32, R ≥ 64 Haemophilus S ≤ 2; GC S ≤ 0.5 Streptococci ≤ 0.5, I = 1, R ≥ 2	CLSI BPs for enterics, Pseudos and non-enterics and staphs S ≤ 8, I = 16-32, R > 64; Haemoph, GC, streps same as PI, except separate BPs for S. pneumo non-meningitis S ≤ 1, I = 2, R ≥ 4
ceftriaxone - Roche	1/1/2007	Orgs other than those below - BPs S ≤ 8, I = 16-32, R ≥ 64 Haemophilus S ≤ 2; GC S ≤ 0.25 Streptococci S ≤ 0.5, I = 1, R ≥ 2	CLSI BPs for enterics and staphs S ≤ 8, I = 16-32, R ≥ 64; Haemoph, GC, and S. pneumoniae same as PI, Beta streps S ≤ 0.5; viridans S ≤ 1, I = 2, R ≥ 4; S. pneumoniae non-meningitis S ≤ 1, I = 2, R ≥ 4
ceftazidime - Hospira	9/1/2005	orgs not specified S ≤ 16, R ≥ 64	CLSI BPs for enterics, staphs, pseudo and non-enterics S ≤ 8, I = 16, R ≥ 32; Haemoph ≤ 2; GC S ≤ 0.5
cefepime - BMS	12/1/2003	orgs other than those below, S ≤ 8, I = 16, R ≥ 32; Haemoph S ≤ 2, GC S, 0.5, S. pneumo S ≤ 0.5, I = 1, R ≥ 2	CLSI BPs same as PI with addition of S. pneumo non-meningitis and viridans S ≤ 1, I = 2, R ≥ 4; beta-streps S ≤ 0.5
cefoxitin - Merk/Baxter	5/1/2006	aerobes other than GC BPs S ≤ 8, I = 16, R ≥ 32; GC S ≤ 2, I = 4, R ≥	CLSI BPs same as PI for enterics, staphs, GC

Agreement between drug PIs and FDA-cleared device breakpoints for 30 commonly prescribed agents (aerobes only)

Carbapenems

imipenem - Merck	1/1/2007	[redacted]	CLSI and PI BPs same except for S. pneumo S $\leq$ 0.25, I = 0.5, R $\geq$ 1
Meropenem - AstraZeneca	8/1/2006	BPs for enterics, Pseudomonas, staph S $\leq$ 4, I = 8, R $\geq$ 16; [redacted] S $\leq$ 0.5	CLSI and PI BPs same except for S. pneumo S $\leq$ 0.12, I = 0.25, R $\geq$ 0.5;
ertapenem - Merck	8/10/2006	BPs for enterics and staphs S $\leq$ 2, I = 4, R $\geq$ 8; streps S $\leq$ 1 Haemoph S $\leq$ 0.5	CLSI and PI BPs the same

Aminoglycosides

gentamicin - Hospira	8/1/2005	[redacted]	CLSI MIC BPs for enterics, Pseudomnas, other non-fermenters, Acinetobacter, staphs, enterococci
tobramycin - Hospira	7/1/2006	orgs not specified for BPs S $\leq$ 4, I = 8 R $\geq$ 16	CLSI BPs same as PI for enterics, Pseudomonas and non-enterics, staphs
amikacin - Hospira	2/1/2006	[redacted]	CLSI BPs for enterics, Pseudomonas and non-enterics, staphs

Agreement between drug PIs and FDA-cleared device breakpoints for 30 commonly prescribed agents (aerobes only)

Flouroquinolones

ciprofloxacin - Teva	11/1/2006	BPs for enterics, Pseudomonas, staph, streps S $\leq$ 1, I = 2, R $\geq$ 4; Haemoph S $\leq$ 1; GC S $\leq$ 0.06, I= 0.12-0.5, R $\geq$1	CLSI BPs same as PI except no BPs for streps
levofloxacin - Ortho McNeill	6/23/2006	BPs for enterics, Pseudomonas, staphs enterococci, S. pneumoniae, GAS S $\leq$ 2, I=4, R $\geq$ 8 Haemoph S $\leq$ 2	CLSI BPs same as PI for enterics, pseudo, S. pneumoniae, GAS, entero PI BPs used for staph
moxifloxacin - Bayer	7/1/2005	BPs for enterics and staphs S $\leq$ 2, I = 4, R $\geq$ 8; Haemoph S $\leq$ 1; streps S $\leq$ 1, I = 2, R $\geq$ 4	CLSI BPs same as PI except staphs S $\leq$ 0.5, I = 1, R $\geq$ 2

Agreement between drug PIs and FDA-cleared device breakpoints for 30 commonly prescribed agents (aerobes only)

Other agents

erythromycin - Abbott	6/1/2006	orgs not specified for BPs of S ≤ 0.5, I = 1-4, R ≥ 8	CLSI BPs same as PI for staph and enterococci; CLSI BPs of S≤ 0.25, I = 0.5, R ≥ 1 for streps - note eryth tested to represent azith and clarith in many devices
trimethoprim-sulfa - AR Sci	3/1/2006	BPs for enterics and staphs S ≤ 2, R ≥ 4; for Haemoph and S. pneumo S ≤ 0.5, I = 1-2, R ≥ 4	CLSI BPs same as PI
vancomycin - Hospira	10/1/2006	orgs not specified for BPs of S ≤ 4, I = 8, R ≥ 16	CLSI BPs of S ≤ 4, I = 8-16, R ≥ 32 for staphs and enterococci cleared for use in devices; BP for streps of S ≤ 1; newer CLSI BPS of S ≤ 2, I = 4-8, R ≥ 16 for S. aureus not cleared
vancomycin - Baxter plastic	5/1/2003	orgs not specified for BPs of S ≤ 4, I = 8-16, R ≥ 32	same as above
doxycyline - Pfizer	1/1/2006	no BPs provided with most generics; Vibramycin BPs S ≤ 2, I = 4, R ≥ 8	CLSI BPs for enterics, non-enteric gram-negs, staphs, enterococci BPs S < 4, I = 8, R > 16
nitrofurantoin - Proctor & Gam	2/1/2006	orgs not specified for BPs of S ≤ 32, I = 64, R ≥ 128	CLSI BPs same as PI for enterics, staphs, enterococci

Sources for PI BP data shown above was one of the following websites, except cefotaxime which was a drug vial insert

http://www.accessdata.fda.gov/scripts cder/drugsatfda/index.cfm

http://dailymed.nlm.nih.gov/ dailymed/about.cfm