

New Antimicrobial Agents Approved by the U.S. Food and Drug Administration from 2007 to 2009 and New Indications for Previously Approved Agents^a

Date of approval	Trade name (form[s])	Generic name(s)	Manufacturer	Indications for use
12 Apr 2007	Altamax (topical ointment)	Retapamulin	Glaxo Group	For topical treatment of impetigo due to <i>Staphylococcus aureus</i> (methicillin susceptible) or <i>Streptococcus pyogenes</i> in adults and pediatric patients aged 9 mo or older (up to 100 cm ² in total area in adults or 2% total body surface area in children \geq 9 mo)
27 Apr 2007	AzaSite (ophthalmic solution/drops)	Azithromycin	Inspire Pharmaceuticals	For treatment of bacterial conjunctivitis caused by susceptible isolates of the following microorganisms: CDC coryneform group G, <i>H. influenzae</i> , <i>Staphylococcus aureus</i> , <i>Streptococcus mitis</i> group, and <i>Streptococcus pneumoniae</i>
21 May 2007	Tindamax (tablet)	Tinidazole	Mission Pharma	Indications expanded to include treatment of bacterial vaginosis in nonpregnant women
18 June 2007	Lexiva (tablet, oral suspension)	Fosamprenavir calcium	GlaxoSmithKline	Indications expanded to include children \geq 2 yr of age, in combination with other antiretroviral agents for treatment of HIV-1 infection
6 Aug 2007	Selzentry (tablet)	Maraviroc	ViiV Healthcare	In combination with other antiretroviral drugs, for treatment-experienced adult patients infected with only CCR5-tropic HIV-1 detectable virus who have evidence of viral replication and HIV-1 strains resistant to multiple antiretroviral agents
14 Sep 2007	Levaquin (tablet, oral solution, injection)	Levofloxacin	Ortho-McNeil Pharmaceuticals	Indications expanded to include complicated urinary tract infections (mild to moderate) due to <i>Enterococcus faecalis</i> , <i>Enterobacter cloacae</i> , <i>Escherichia coli</i> , <i>Klebsiella pneumoniae</i> , <i>Proteus mirabilis</i> , or <i>Pseudomonas aeruginosa</i> and acute pyelonephritis caused by <i>E. coli</i> , including cases with concurrent bacteremia
28 Sep 2007	Lamsil (oral granules)	Terbinafine hydrochloride	Novartis	For treatment of tinea capitis in patients 4 yr of age or older
12 Oct 2007	Doribax (injectable)	Doripenem	Ortho-McNeil Janssen	For treatment of complicated intra-abdominal infections caused by <i>E. coli</i> , <i>K. pneumoniae</i> , <i>P. aeruginosa</i> , <i>Bacteroides caccae</i> , <i>Bacteroides fragilis</i> , <i>Bacteroides thetaiotaomicron</i> , <i>Bacteroides uniformis</i> , <i>Bacteroides vulgatus</i> , <i>Streptococcus intermedius</i> , <i>Streptococcus constellatus</i> , and <i>Peptostreptococcus micros</i> and for treatment of complicated urinary tract infections, including pyelonephritis caused by <i>E. coli</i> , including cases with concurrent bacteremia, <i>K. pneumoniae</i> , <i>P. mirabilis</i> , <i>P. aeruginosa</i> , and <i>Acinetobacter baumannii</i>
12 Oct 2007	Isentress (tablet)	Raltegravir potassium	Merck Sharp & Dohme	For treatment of HIV-1 infection in treatment-experienced adult patients, in combination with other antiretroviral agents
19 Dec 2007	Hepsera (tablets)	Adefovir dipivoxil	Gilead Sciences	Indications expanded to include patients 12 yr of age or older for treatment of chronic hepatitis B with evidence of active viral replication and either evidence of persistent elevations in alanine aminotransferase or aspartate transaminase or histologically active disease

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18 Jan 2008	Intence (tablet)	Etravirine	Tibotec	For treatment, in combination with other antiretroviral agents, of HIV-1 infection in antiretroviral treatment-experienced adult patients who have evidence of viral replication and HIV-1 strains resistant to a nonnucleoside reverse transcriptase inhibitor and other antiretroviral agents
22 Jan 2008	Mycamine (infusion)	Micafungin	Astellas	Indications expanded to include treatment of patients with candidemia, acute disseminated candidiasis, <i>Candida</i> peritonitis, and abscesses
23 Jan 2008	Moxatag (extended-release tablet)	Amoxicillin (extended release)	MiddleBrook Pharmaceuticals	For treatment of tonsillitis and/or pharyngitis caused by <i>Streptococcus pyogenes</i> in adults and pediatric patients 12 yr of age or older
25 Mar 2008	Reyataz (capsule)	Atazanavir sulfate	Bristol-Myers Squibb	Use extended to include pediatric patients at least 6 yr of age
5 May 2008	Levaquin (tablet, oral solution, injection)	Levofloxacin	Ortho-McNeil Janssen	Use extended to include pediatric patients at least 6 mo of age, after exposure to inhalational anthrax to reduce the incidence or progression of disease following exposure to aerosolized <i>Bacillus anthracis</i>
20 Jun 2008	Kaletra (tablet, oral solution)	Lopinavir and ritonavir	Abbott Laboratories	Use extended to include pediatric patients at least 14 days of age
23 Jun 2008	Aptivus (capsule, oral solution)	Tipranavir	Boehringer-Ingelheim Pharmaceuticals	Coadministered with ritonavir, use extended to treatment of HIV-1-infected pediatric patients (aged 2 to 18 yr) who are treatment-experienced and infected with HIV-1 strains resistant to more than one protease inhibitor, in combination with antiretroviral regimens
24 Jun 2008	Viramune (tablet, oral suspension)	Nevirapine	Boehringer-Ingelheim Pharmaceuticals	Dosing recommendations extended for pediatric patients at least 15 days of age
29 Jul 2008	Candidas (injection)	Caspofungin acetate	Merck Research Laboratories	Use extended to include pediatric population ≥ 3 mo to 16 yr of age
11 Aug 2008	Viread (tablet)	Tenofovir disoproxil fumarate	Gilead Sciences	New indication: for the treatment of chronic hepatitis B infection in adults
3 Sep 2008	Valtrex (caplet)	Valacyclovir hydrochloride	GlaxoSmithKline	Use extended to treatment of chickenpox in immunocompetent pediatric patients 2 to <18 yr of age
7 Oct 2008	Zmax (powder for oral suspension)	Azithromycin extended release	Pfizer	Use extended to pediatric patients 6 mo or older for treatment of community-acquired pneumonia caused by <i>Chlamydia pneumoniae</i> , <i>Haemophilus influenzae</i> , <i>Mycoplasma pneumoniae</i> , or <i>S. pneumoniae</i> in patients appropriate for oral therapy
21 Oct 2008	Prezista (tablet)	Darunavir ethanolate	Centocor Ortho	Use expanded to include, in combination with ritonavir and other antiretroviral agents, the treatment of HIV-1 in antiretroviral treatment-naïve adults
11 Dec 2008	PegIntron	Peginterferon alfa-2B	Schering	Use extended to include PegIntron in combination with Rebetol (ribavirin) for treatment of chronic hepatitis C in patients ≥ 3 yr of age with compensated liver disease previously untreated with alpha interferon
18 Dec 2008	Prezista (tablet)	Darunavir ethanolate	Centocor Ortho	Use extended to include, in combination with ritonavir and other antiretroviral agents, the treatment of HIV-1 infection in pediatric patients ≥ 6 yr of age
2 Feb 2009	Combivir (tablet)	Zidovudine and lamivudine	ViiV Healthcare	Allows for the use of the combination tablet in children weighing ≥ 30 kg, in combination with other antiretrovirals for treatment of HIV-1 infection

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20 Mar 2009	Tygacil (injection)	Tigecycline	Wyeth Pharmaceuticals	Indications expanded to include treatment of community-acquired bacterial pneumonia caused by <i>S. pneumoniae</i> (penicillin-susceptible isolates), including cases with concurrent bacteremia, <i>H. influenzae</i> (β -lactamase-negative isolates), and <i>L. pneumophila</i> ; list of indicated organisms also expanded for the indications approved earlier
7 Apr 2009	Coartem (tablet)	Artemether and lumefantrine	Novartis	For treatment of acute, uncomplicated malaria due to <i>Plasmodium falciparum</i> in patients ≥ 5 kg body weight
28 May 2009	Besivance (ophthalmic suspension)	Besifloxacin hydrochloride	Bausch & Lomb	For treatment of bacterial conjunctivitis caused by susceptible isolates of the following bacteria: CDC coryneform group G, <i>Corynebacterium pseudodiphtheriticum</i> , <i>Corynebacterium striatum</i> , <i>H. influenzae</i> , <i>Moraxella lacunata</i> , <i>S. aureus</i> , <i>Staphylococcus epidermidis</i> , <i>Staphylococcus hominis</i> , <i>Staphylococcus lugdunensis</i> , <i>S. mitis</i> group, <i>Streptococcus oralis</i> , <i>S. pneumoniae</i> , and <i>Streptococcus salivarius</i>
8 Jul 2009	Isentress (tablet)	Raltegravir	Merck	Use expanded to include treatment-naïve (in addition to treatment-experienced) individuals, in combination with other antiretrovirals, for treatment of adults with HIV-1 infection
31 Jul 2009	Xerese (topical cream)	Acyclovir and hydrocortisone	Medivir	For early treatment of recurrent herpes labialis (cold sores) to reduce the likelihood of ulcerative sores and to shorten lesion healing time in adults and adolescents ≥ 12 yr old (information from the label of 12 May 2010)
28 Aug 2009	Valcyte (tablet, powder for oral solution)	Valganciclovir hydrochloride	Roche Palo Alto	For prevention of cytomegalovirus disease in pediatric kidney and heart transplant patients ≥ 4 mo of age at high risk of such disease
11 Sep 2009	Vibativ (for injection)	Telavancin hydrochloride	Theravance	For treatment of adult patients with complicated skin and skin structure infections caused by susceptible isolates of the following: <i>S. aureus</i> (including methicillin-susceptible and -resistant isolates), <i>S. pyogenes</i> , <i>Streptococcus agalactiae</i> , <i>Streptococcus anginosus</i> group (includes <i>S. anginosus</i> , <i>S. intermedius</i> , and <i>S. constellatus</i>), or <i>E. faecalis</i> (vancomycin-susceptible only)
15 Sep 2009	Zirgan (ophthalmic gel)	Ganciclovir	Sirion Therapeutics	For treatment of acute herpetic keratitis (dendritic ulcers)

^a Information obtained from <http://www.accessdata.fda.gov/scripts/cder/drugsatfda/>, accessed June 2010.