New Drug Approvals

Generic Name (Trade Nameâ€"Company)	**Uses**/Notes
June 27, 2018	
Plazomicin	Achaogen announced FDA approval of plazomicin, an I.V. infusion administered once daily, for adults aged 18 years and older with complicated urinary tract infections (cUTI), including pyelonephritis, caused by Enterobacteriaceae bacteria (*Escherichia coli, Klebsiella pneumoniae, Proteus mirabilis,* and *Enterobacter cloacae*). The drug is for patients who have limited or no alternative treatment options. Plazomicin was engineered to overcome aminoglycoside-modifying enzymes, the most common aminoglycoside-resistance mechanism in Enterobacteriaceae, and has in vitro activity against extended-spectrum beta-lactamase (ESBL)–producing, aminoglycoside-resistant, and carbapenem-resistant isolates. CDC has characterized ESBL-producing Enterobacteriaceae as a "serious threat" and CRE as "nightmare bacteria"—immediate public health threats that require urgent and aggressive action. Approval was supported in part by data from the EPIC (Evaluating Plazomicin In cUTI) clinical trial, the first randomized controlled study of once-daily aminoglycoside therapy for treatment of cUTI, including pyelonephritis. As only limited clinical safety and efficacy data for plazomicin are currently available, plazomicin is reserved for use in cUTI patients who have limited or no alternative treatment options. To reduce the development of drug-resistant bacteria and maintain effectiveness of plazomicin and other antibacterial drugs, plazomicin should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible microorganisms. On the potential indication for plazomicin to treat bloodstream infection (BSI), FDA issued a Complete Response Letter (CRL) stating that the CARE study

(Zemdri—Achaogen)

New drug targets complicated urinary tract infections in adults

does not provide substantial evidence of effectiveness of plazomicin for this indication. The company intends to meet with FDA to determine whether there is a feasible resolution to address the CRL.

Achaogen will work with hospitals, providers, and insurers to ensure patients are able to receive this treatment. Patients, physicians, pharmacists, or other health professionals with questions about plazomicin should contact 1-833-252-6400 or visit www.ZEMDRI.com.

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