Division: Pharmacy Services	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	June 25, 2009 January 11, 2010; June 15, 2012, July 7, 2022

TYGACIL® (tigecycline)

LENGTH OF AUTHORIZATION: Length of prescription (no more than 14 days); No refills.

REQUIRED LABS: Must be submitted with request and dated no later than 14 days prior to therapy (e.g. culture and/or sensitivity).

REVIEW CRITERIA:

- Patient must be ≥18 years of age.
- Documentation must show previous trial and failure of a tetracycline product unless resistance is demonstrated. If no previous trial, then clinically compelling documentation must be submitted justifying the use of this agent.
- Documentation of an infection with culture and documented sensitivity to Tygacil. The organism must not be susceptible to preferred first-line antibiotics; otherwise, submit documentation of allergies, contraindications, drug-drug interactions, or a history of intolerable side effects to susceptible preferred first-line antibiotics.
- Documentation of baseline values for liver function and blood coagulation parameters.
- **Complicated skin and skin structure infections** caused by *Escherichia coli*, *Enterococcus faecalis* (vancomycin-susceptible isolates only), *Staphylococcus aureus (MSSA)*, *Staphylococcus aureus (MRSA)*, *Streptococcus agalactiae*, *Streptococcus anginosus grp.*, *Streptococcus pyogenes,* and *Bacteroides fragilis.*
- **Complicated intraabdominal infections** caused by *Citrobacter freundii*, *Enterobacter cloacae*, *Escherichia coli*, *Klebsiella oxytoca*, *Klebsiella pneumoniae*, *Enterococcus faecalis* (vancomycin-susceptible isolates only), *Staphylococcus aureus (MSSA)*, *Streptococcus anginosus grp.*, *Bacteroides fragilis*, *Bacteroides thetaiotaomicron*, *Bacteroides uniformis*, *Bacteroides vulgatus*, *Clostridium perfringens,* and *Peptostreptococcus micros.*
- **Community-acquired pneumonia** due to penicillin-susceptible *Streptococcus pneumoniae* (including cases with concurrent bacteremia), beta-lactamase negative *Haemophilus influenzae,* and *Legionella pneumophila*.

DOSING AND ADMINISTRATION:

- Refer to product labeling at https://www.accessdata.fda.gov/scripts/cder/daf/
- Available as 50 mg lyophilized powder for reconstitution.