	"Facility Name" Policy and Procedure		
Title: Protected Antimicrobial Use		**Control No.:**	**Version: 1**
Replaces: Not Set			
Policy Owner:			
Reviewers:			
Approvers: Infection Control Committee (Chairman), Medical Staff P.I. Committee (Chairman) Infection Control, Medical Staff Office		**Date Approved: 10/13/2016**	**Date Last Reviewed: 10/13/2016**

Purpose: This protected antimicrobial use policy has been developed by the Antimicrobial Stewardship committee in order to decrease the inappropriate use of antimicrobials which leads to the emergence of resistant bacteria, an increase in the risk of harm from side effects, and infection with multi-resistant bacteria. This policy aims to:

- Promote the appropriate use of protected antimicrobials at our facility by initiating review at order entry by pharmacy
- Reduce the development of resistance via the promotion of appropriate antimicrobial prescribing
- Promote awareness and compliance among all medical, nursing, and pharmacy staff with correct antimicrobial prescribing procedures as an essential part of routine clinical practice
- Identify the antimicrobials protected at our facility and outline requirements for prescribing these agents

Policy: The following antimicrobials are included in the protected list by the Antimicrobial Stewardship committee for reasons involving drug safety, efficacy, and expense:
Tigecycline (Tygacil)
Ceftaroline (Teflaro)
Ceftazidime/Avibactam (Avycaz)
Ortivancin (Orbactiv)
Colistimethate (Colistin)
Daptomycin (Cubicin)

Procedure: The following applies to all adult patients 18 years of age or greater. Upon order placement the pharmacist will review the patient's profile to determine antimicrobial appropriateness.

1. If the patient meets criteria for the ordered antimicrobial, the order will be entered with an intervention stating the inclusion criteria.
2. If the patient does not meet inclusion criteria, a phone call will be placed to the ordering physician by the pharmacist. At this time the ordering physician will either provide evidence based information supporting the criteria for use, or discontinue the medication.
3. If the ordering physician has no further information to support the order yet still wants to proceed then the Infectious Disease Physician on staff or one of the Utilization Management committee physicians will be contacted by the pharmacist to discuss the case.

After-hours ordering:

1. If the order is placed after hours, the pharmacist will profile the order and send the doses. That pharmacist will document an intervention and the protected antimicrobial order will be reviewed for inclusion criteria within 24 hours of the order being placed.

Protected Antimicrobial criteria:

- Tygecycline (Tygacil): Indicated for culture-directed therapy of multi-drug resistant infections for which there may not be other therapy choices. Approved uses: community acquired pneumonia, infections of the skin or subcutaneous tissue, and complicated infectious diseases of the abdomen. Tygecycline is also only bacteriastatic.
  *restricted due to increase in mortality and should be restricted to situations when alternative treatments are not suitable.

- Ceftaroline (Teflaro): Indicated for the treatment of community acquired pneumonia and infections of the skin and or subcutaneous tissue in patients who have failed Vancomycin treatment or are intolerant to Vancomycin.

  *restricted due to non-inferior cure rates for complicated skin and skin structure infections compared to Vancomycin and non-inferior cure rates for CAP when compared to Rocephin.

- Ceftazidime/Avibactam (Avycaz): Indicated for the treatment of multi-drug resistant organisms in the urinary tract or abdomen along with metronidazole

  *restricted due to MSPIC approval only for pathogens that are resistant to carbapenem antibiotics as well as the risk of anti-microbial resistance development. This medication is also a high cost medication.

- Ortavancin (Orbactiv): Indicated for the outpatient treatment of skin and skin structure infections caused by susceptible isolates of gram-positive microorganisms including Staph, MRSA, Strep and Enterococcus faecalis.

  *restricted due to reimbursement being only in the outpatient setting as well as high medication cost.

- Colistimethate (Colistin): Indicated for the treatment of difficult to treat multi-drug resistant Gram-negative pathogens (e.g. P. aeruginosa, Acinetobacter sp., and carbapenem-resistant Enterobacteriaceae).

  *restricted to salvage therapy due to risk of nephrotoxicity and neurotoxicity.

- Daptomycin (Cubicin): Indicated as an alternative for patients failing or intolerant to vancomycin or for culture directed therapy of serious vancomycin resistant Enterococcus (VRE) infections.

  *restricted due to the narrow spectrum of use and contraindicated in pneumonia due to increased mortality.

Supportive Data: Antibiotic resistance is the ability of microbes to resist the effects of drugs- that is, the germs are not killed, and their growth is not stopped. The use of antibiotics is the single most important factor leading to antibiotic resistance therefore simply using antibiotics creates resistance. Antibiotics should only be used to manage infections, should be optimally dosed, and only prescribed when needed. According to the CDC each year in the United States, at least 2 million people become infected with bacteria that are resistant to antibiotics and at least 23,000 people die each year as a direct result of these infections.

Tgmc antibiogram: http://tgmc/pharmacy/antibiogram.pdf

References:

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