TITLE: ANTIBIOTIC CONTROL PROGRAM REGULATIONS

POLICY:
Based on recommendations from the Subcommittee on Anti-Infective Use, the Committee on Infections and the Formulary and Therapeutics Committee, it has been established that an antimicrobial control program will be instituted to promote efficacious use of antimicrobial agents within the institution.

PURPOSE:
The goals of the program include:

1. Promotion of optimal patient care by assisting clinicians with antimicrobial selection.
2. Promotion of the safe use of antimicrobials by assisting clinicians in the selection of dosing regimens for various antimicrobials.
3. Provision of a model of rational antimicrobial prescribing for use as an educational tool within the institution.
4. Providing optimal antimicrobials therapy while assuring maximal patient safety at minimal expense to the institution.

With these goals in mind, the control program has been developed to assure the quality of antimicrobials prescribing. The system will operate by permitting general use of selected antimicrobials while requiring communication with various advisory sources prior to prescribing other selected antimicrobials and/or dosing regimens.

APPLICABILITY:
All Centers

PROCEDURE:
All agents used within this institution have been grouped into the three classes of antimicrobials defined and outlined below.

Class I: Antimicrobials approved for general use.
Class II: Antimicrobials approved for general use providing pre-determined dosing parameters are not exceeded.
Class III: Antimicrobials requiring approval from the Divisions of Adult or Pediatric Infectious Diseases approval sources regardless of dose.

<table>
<thead>
<tr>
<th>Department</th>
<th>Approval Sources</th>
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<tbody>
<tr>
<td>All Pediatric Services</td>
<td>Drs. M Foca, A Gershon, C Gagliardo, P Graham, S Hymes,</td>
</tr>
</tbody>
</table>
Emergency Dispensing
IN THE CASE OF AN EMERGENCY AND IF AN ATTEMPT TO CONTACT AN APPROVAL SOURCE IS UNSUCCESSFUL, THE DEPARTMENT OF PHARMACY WILL DISPENSE ONE (1) EMERGENCY DOSE. AN ATTEMPT TO OBTAIN APPROVAL IS DEEMED UNSUCCESSFUL IF A RESPONSE FROM AN APPROVAL SOURCE IS NOT RECEIVED WITHIN A REASONABLE TIME. AN ORDER WRITTEN AS: “FIRST DOSE STAT, EMERGENCY APPROVAL” WILL BE ACCEPTED FOR THE DISPENSING OF ONE DOSE, AFTER WHICH APPROVAL IS NECESSARY FOR SUBSEQUENT DOSES.

***NOTE: Emergency dispensing without approval will be documented and closely monitored by the Department of Pharmacy and the Division of Infectious Diseases for appropriateness and adherence to antibiotic control program policy.***
Class I: Antimicrobials approved for general use.

<table>
<thead>
<tr>
<th>Class</th>
<th>Medication</th>
<th>Route</th>
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</thead>
<tbody>
<tr>
<td>AMEBICIDES</td>
<td>Iodoquinol</td>
<td>PO</td>
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<tr>
<td></td>
<td>Paromomycin sulfate</td>
<td>PO</td>
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<tr>
<td>AMINOGLYCOSIDES</td>
<td>Gentamicin sulfate</td>
<td>IV, INT</td>
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<td></td>
<td>Kanamycin</td>
<td>Irrigation</td>
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<td></td>
<td>Neomycin sulfate</td>
<td>PO</td>
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<td></td>
<td>Tobramycin sulfate</td>
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<td>ANTHELMINTICS</td>
<td>Albendazole</td>
<td>PO</td>
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<td></td>
<td>Ivermectin</td>
<td>PO</td>
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<td></td>
<td>Praziquantel</td>
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<td></td>
<td>Thiabendazole</td>
<td>PO</td>
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<td>ANTIFUNGALS</td>
<td>Amphotericin B (Adults)</td>
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<tr>
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<td>Griseofulvin</td>
<td>PO</td>
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<td></td>
<td>Itraconazole (solution)</td>
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<td></td>
<td>Nystatin</td>
<td>PO</td>
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<tr>
<td>ANTIMALARIAL AGENTS</td>
<td>Atovaquone/proguanil</td>
<td>PO</td>
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<tr>
<td></td>
<td>Chloroquine HCl</td>
<td>IV</td>
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<td>Chloroquine phosphate</td>
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<td></td>
<td>Hydroxychloroquine sulfate</td>
<td>PO</td>
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<td></td>
<td>Primaquine phosphate</td>
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<td></td>
<td>Pyrimethamine</td>
<td>PO</td>
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<td></td>
<td>Pyrimethamine/sulfadoxine</td>
<td>PO</td>
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<td>ANTITUBERCULOSIS AGENTS</td>
<td>Capreomycin sulfate</td>
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<td>Cycloserine</td>
<td>PO</td>
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<td>Ethambutol HCl</td>
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<td>Ethionamide</td>
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<td></td>
<td>Isoniazid</td>
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<td>Pyrazinamide</td>
<td>PO</td>
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<td>ANTIVIRALS</td>
<td>Acyclovir</td>
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<td>Amantadine</td>
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<td></td>
<td>Famciclovir</td>
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<td></td>
<td>Oseltamivir</td>
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<td></td>
<td>Ribavirin</td>
<td>PO</td>
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Rimantadine PO  
Zanamivir INH  
CEPHALOSPORINS AND RELATED  
Cefaclor PO  
Cefadroxil PO  
Cefixime PO  
Ceftotaxime sodium (Peds) IV  
Cefpodoxime PO  
Cefprozil PO  
Cefuroxime axetil PO  
Cefuroxime sodium IV  
Cephalexin PO  
CLINDAMYCIN  
Clindamycin PO, IV  
MACROLIDES  
Azithromycin PO  
Clarithromycin PO  
Erythromycin base PO  
Erythromycin ethylsuccinate PO  
Erythromycin stearate PO  
Erythromycin lactobionate IV  
PENICILLINS  
Amoxicillin PO  
Amoxicillin / clavulanate PO  
Ampicillin sodium IV  
Dicloxacillin sodium PO  
Oxacillin IV  
Penicillin G benzathine IM  
Penicillin G procaine IM  
Penicillin G sodium IV  
Penicillin G potassium IV  
Penicillin V potassium PO  
RIFAMPIN AND RIFABUTIN  
Rifabutin PO  
Rifampin PO  
SULFONAMIDES  
Sulfadiazine PO  
Sulfamethoxazole/trimethoprim PO, IV  
Sulfasalazine PO
**TETRACYCLINES**
Demeclocycline PO  
Doxycycline calcium PO  
Doxycycline hyclate IV  
Minocycline HCl PO  
Tetracycline HCl PO  

**MISCELLANEOUS ANTIBIOTICS**
Atovaquone PO  
Bacitracin IV  
Colistimethate sodium INH  
Dapsone PO  
Metronidazole PO  
Spectinomycin HCl IV  

**URINARY ANTI-INFECTIVES**
Methenamine hippurate PO  
Nitrofurantoin Suspension PO  
Nitrofurantoin Monohyd Macrystals PO  
Trimethoprim PO  

**KEY:** PO = oral tablet, capsule, or liquid  
IV = intravenous  
IM = intramuscular  
INT = intrathecal  
INH = inhalation
Class II: Antimicrobials approved for general use providing pre-determined dosing parameters are not exceeded. If predetermined parameters are exceeded, the prescribing physician must get approval from the appropriate advisory source.

NOTE: IF PREDETERMINED PARAMETERS ARE EXCEEDED, APPROVAL MUST BE OBTAINED. DURING OVERNIGHT HOURS, THE DEPARTMENT OF PHARMACY WILL DISPENSE EMERGENT DOSES BETWEEN 10 PM AND 8 AM. SUFFICIENT QUANTITY WILL BE DISPENSED TO MAINTAIN THE PATIENT UNTIL 8 AM THE FOLLOWING MORNING, AFTER WHICH APPROVAL WILL BE NECESSARY FOR SUBSEQUENT DOSES. INFECTIOUS DISEASES PHYSICIANS ARE AVAILABLE AT ALL HOURS FOR CONSULTATION IF NECESSARY.

Ampicillin/Sulbactam (IV): Provided the dosing regimen of 3 g IV Q6H is not exceeded

Aztreonam (IV): Provided the dosing regimen of 1 g IV Q8H is not exceeded

Cefazolin (IV): Provided the dosing regimen of 1 g IV Q8H is not exceeded

Cefoxitin (IV): Provided the dosing regimen of 2 g IV Q6H is not exceeded or the period for surgical prophylaxis does not exceed 24 hours

Ceftriaxone (IV): Provided the dosing regimen of 1 g IV Q24H is not exceeded

Exception: Pediatrics

Metronidazole (IV): Provided the dosing regimen of 500 mg IV Q8H is not exceeded

Piperacillin/Tazobactam (IV): Provided the dosing regimen of 4.5 g IV Q8H is not exceeded

Exception: 4.5 g IV Q6H for fever and neutropenia patients in accordance with clinical pathway (NYP/WC 10C, 10S and 10W, NYP/C M6HN, B05T), ICUs and patients post lung transplantation per protocol (NYP/C).

Valacyclovir (PO): Provided the dosing regimen of 1 g PO Q8H is not exceeded

Exception: Adult bone marrow/stem cell transplant patients for CMV prophylaxis per protocol
**Class III:** Antibiotics requiring approval from the appropriate advisory source regardless of dose.

NOTE: Approval must be obtained prior to the use of these agents. The Department of Pharmacy will dispense emergent doses between 10 PM and 8 AM. Sufficient quantity will be dispensed to maintain the patient until 8 AM the following morning, after which approval will be necessary for subsequent doses. Infectious Diseases physicians are available at all hours for consultation if necessary.

Amikacin (IV)
- **Exceptions:** Class I NYP/WC for use in the Pediatric ICU (6S) and 8W (Burn Unit) only.

Amphotericin B (IV)
- Approval required for pediatric use only

Lipid Amphotericin B (Abelcet®) (IV)
- **Exception:** Lung transplant; mechanically ventilated 100 mg x 4 days, then 100 mg qweek* or non-ventilated 50 mg x 4 days then 50 mg qweek* per protocol. Heart transplant 50 mg qweek* per protocol.
- *Qweek doses only to be dispensed on Tuesday or Friday

Liposomal Amphotericin B (Ambisome®) (IV)
- Restricted for prophylaxis in pediatric allogeneic HSCT/BMT patients at 1.5 mg/kg daily and treatment of pediatric patients with fungal infections at a maximum of 3 mg/kg daily. Maximum dose may be increased to 10 mg/kg daily if managing CNS disease or zygomycoses.

Antiretrovirals (PO/IV)
- abacavir, abacavir/lamivudine (Epzicom®), atazanavir, darunavir, delavirdine, didanosine, efavirenz, efavirenz/emtricitabine/tenofovir (Atripla®), emtricitabine, emtricitabine/tenofovir (Truvada®), enfuvirtide, entecavir, etravirine, fosamprenavir, indinavir, lamivudine, lopinavir/ritonavir (Kaletra®), maraviroc, nelfinavir, nevirapine, raltegravir, ritonavir, saquinavir (Invirase®), stavudine, tenofovir, tipranavir, zidovudine, zidovudine/lamivudine (Combivir®).
- **Exceptions:** HIV AIDS service; NYP/WC: Refer to CSS Attending Policy
- Lamivudine (100 mg PO once daily), entecavir, and tenofovir: approval by hepatology/gastroenterology attendings

Azithromycin (IV)
- Restricted for use in patients that are NPO including medications
- **Exceptions:** Emergency department, ICUs, and OB/GYN

Chloramphenicol (IV)

Cefepime (IV)

Ceftazidime (IV)

Cidofovir (IV)
- **Exception:** HIV/AIDS service

Ciprofloxacin (PO/IV)
- Restricted to Pediatric patients only

Colistimethate sodium (IV)

Cytomegalovirus immune globulin (CMV-IG)
- Refer to guidelines for use

Daptomycin (IV)
- Restricted for use as a 2nd or 3rd line agent for the treatment of Gram (+) infections in patients who are intolerant and/or resistant to both vancomycin and linezolid.

Fluconazole (PO/IV)
Exceptions: IV to PO switch, HIV/AIDS service, patients immediate post-BMT, pancreas transplant per protocol.

Flucytosine (PO)

Foscarnet (IV)

Ganciclovir (PO)

Exception: CMV prophylaxis post-kidney and heart transplant per protocol.

Ganciclovir (IV)

Exceptions: solid organ transplant patients immediate post transplant for CMV prophylaxis per protocol

Imipenem/Cilastatin (IV)

Levofloxacin (PO/IV)

Exceptions: IV to PO switch; fever and neutropenia patients in accordance with clinical pathway (NYP/WC 10W only)

Linezolid (PO/IV)

Exception: IV to PO switch

Live Vaccines

Measles, MMR, MMRV, rotavirus, rubella, typhoid, varicella

Restricted for use in select patients immediately prior to discharge.

Exception OB/GYN patients receiving MMR immediately prior to discharge

Meropenem (IV)

Micafungin (IV)

Palivizumab (Synagis®) (IV) – 1D Attending

Exceptions: Indications listed in the Palivizumab (Synagis®) Medication Use Guidelines

Pentamidine (IV)

Exceptions: HIV/AIDS service and for use in patients intolerant to TMP/SMX for PCP prophylaxis per protocol post-BMT (NYP/WC 10C, 10S, and 10W) and the HEME/ONC peds service (NYP/C B05T and HIP-7)

Polymyxin B sulfate (IV)

Posaconazole (PO)

Quinine sulfate (PO)

Quinupristin/Dalfopristin (Synercid®) (IV)

Ribavirin (INH)

Rifampin (IV)

Streptomycin sulfate (IV)

Tigecycline (IV)

Restricted for use for documented infection with (a) a carbapenem resistant gram-negative organism (eg, Acinetobacter baumannii, Klebsiella pneumoniae; not P. aeruginosa) and documented tigecycline susceptibility in the lab; (b) a multi-drug resistant gram-negative organism (not P. aeruginosa) where allergies/intolerance preclude the use of another agent, like beta-lactam, and the organism is tigecycline susceptible; (c) Stenotrophomonas maltophilia in patients unable to tolerate or resistant to TMP/SMX and documented tigecycline susceptibility in the lab; (d) Severe deep-seated infections (eg, osteomyelitis) caused by MRSA where the addition of a second agent, like oral minocycline or I.V. tetracycline, added to vancomycin therapy may be useful.

Valganciclovir (PO)

Exception: Solid organ transplant per CMV prophylaxis protocol

Vancomycin (PO/IV)

Exception (IV): OB/GYN for Group B Streptococcus prophylaxis in penicillin allergic patients.
Voriconazole (PO/IV)  
Restricted for use in Aspergillus/mold infections and resistant Candida/yeast infections, oral therapy if preferred.  

**Exception:** IV to PO switch  

ALL NON-FORMULARY ANTIBIOTICS REQUIRE APPROVAL PRIOR TO USE  
The enhanced communications between the prescribing physicians, Divisions of Infectious Diseases, department chairpersons and the Department of Pharmacy will provide essential data regarding antibiotic prescribing patterns. This data can be used to further enhance educational efforts within the institution while assuring the quality and safety of antibiotic use for our population.  

**RESPONSIBILITY:**  
Joint Subcommittee on Anti-Infective Use  

**POLICY DATES:**  
Issued: December 1999  
Reviewed: March 2011  
Revised: February 2011  
Medical Board Approval: May 2011