

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.

<u>Department</u>	<u>Approval Sources</u> (Columbia University Medical Center)
All Adult Services	Drs. N. Bhadelia, K Brudney, N Clynes, J Dobkin, T Ellman, TM Flood, M Fordyce, A Kapur, Y Furuya, S Gandhi, R Gordon, S Hammer, J Horan, J Justman, J Kessler, C Kubin, A Lat, F Lowy, B Miko, E Morrison, J Myers, A. Nichol, M Pereira, D Rudin, U Sarwar, B Scully, M Sobieszczyk, H Tieu, S Tsiouris, A Uhlemann, K. Wright, and M Yin
All Pediatric Services	Drs. M Foca, A Gershon, C Gagliardo, P Graham, S Hymes,

NewYork-Presbyterian Hospital

Sites: All Centers

Medication Use Manual: Policy

Page 2 of 8

P LaRussa, N Neu, S Patel, P Planet, A Prince, A Ratner, L Saiman, and K Top

Department

Oncology

Approval Sources (New York Weill Cornell Center)

Bone Marrow Service (10W) – Dr. Rosemary Soave

OB/GYN

Drs. W. Ledger, R. Sassoon or S. Hockstein

Pediatrics

Drs. P Delamora, A Moscona, C Salvatore, S Toussi and Pediatric Intensive Care Unit (6S) – Full-time attendings

Surgery

Surgical Intensive Care Unit (2S) - Dr. P. Barie

Burn Unit (8W, 8S) – Drs. R. Yurt, P. Bessey, J. Gallagher

Cardiothoracic Surgery (4W) – Full-time attendings

CSS – Antiretrovirals

Drs S Ball, M Glesby, R Gulick, J Jacobs, S Jones, K Marks, S Merrick, L Siegel, H Singh, D Smith, B Stewart, C Vaamonde, M Vogler, T Wilkins and C Yoon.

All other Departments

Division of Adult Infectious Diseases Consult service via ID approval pager.

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.

AMEBICIDES

Iodoquinol PO
 Paromomycin sulfate PO

AMINOGLYCOSIDES

Gentamicin sulfate IV, INT
 Kanamycin Irrigation
 Neomycin sulfate PO
 Tobramycin sulfate IV, INH

ANTHELMINTICS

Albendazole PO
 Ivermectin PO
 Praziquantel PO
 Thiabendazole PO

ANTIFUNGALS

Amphotericin B (Adults) IV
 Griseofulvin PO
 Itraconazole (solution) PO
 Nystatin PO

ANTIMALARIAL AGENTS

Atovaquone/proguanil PO
 Chloroquine HCl IV
 Chloroquine phosphate PO
 Hydroxychloroquine sulfate PO
 Primaquine phosphate PO
 Pyrimethamine PO
 Pyrimethamine/sulfadoxine PO

ANTITUBERCULOSIS AGENTS

Capreomycin sulfate IV
 Cycloserine PO
 Ethambutol HCl PO
 Ethionamide PO
 Isoniazid PO, IV, IM
 Pyrazinamide PO

ANTIVIRALS

Acyclovir IV, PO
 Amantadine PO
 Famciclovir PO
 Oseltamivir PO
 Ribavirin PO

Rimantadine PO
 Zanamivir INH

CEPHALOSPORINS AND RELATED

Cefaclor PO
 Cefadroxil PO
 Cefixime PO
 Cefotaxime 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

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 8AM 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 zygomyceses.

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®). Zidovudine/lamivudine/abacavir (Trizivir®)

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)

<p><u>Exceptions:</u> IV to PO switch, HIV/AIDS service, patients immediate post-BMT, pancreas transplant per protocol.</p>	10C, 10S, and 10W) and the HEME/ONC peds service (NYP/C B05T and HIP-7)
Flucytosine (PO)	Polymyxin B sulfate (IV)
Foscarnet (IV)	Posaconazole (PO)
Ganciclovir (PO) <u>Exception:</u> CMV prophylaxis post-kidney and heart transplant per protocol.	Quinine sulfate (PO)
Ganciclovir (IV) <u>Exceptions:</u> solid organ transplant patients immediate post transplant for CMV prophylaxis per protocol	Quinupristin/Dalfopristin (Synercid®) (IV)
Imipenem/Cilastatin (IV)	Ribavirin (INH)
Levofloxacin (PO/IV) <u>Exceptions:</u> IV to PO switch; fever and neutropenia patients in accordance with clinical pathway (NYP/WC 10W only)	Rifampin (IV)
Linezolid (PO/IV) <u>Exception:</u> IV to PO switch	Streptomycin sulfate (IV)
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	Tigecycline (IV) Restricted for use for documented infection with (a) a carbapenem resistant gram-negative organism (eg, <i>Acinetobacter baumannii</i> , <i>Klebsiella pneumoniae</i> ; not <i>P. aeruginosa</i>) and documented tigecycline susceptibility in the lab ; (b) a multi-drug resistant gram-negative organism (not <i>P. aeruginosa</i>) where allergies/intolerance preclude the use of another agent, like beta-lactam, and the organism is tigecycline susceptible ; (c) <i>Stenotrophomonas maltophilia</i> 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
Meropenem (IV)	
Micafungin (IV)	
Palivizumab (Synagis®) (IV) – ID Attending <u>Exceptions:</u> Indications listed in the Palivizumab (Synagis®) Medication Use Guidelines	Valganciclovir (PO) <u>Exception:</u> Solid organ transplant per CMV prophylaxis protocol
Pentamidine (IV) <u>Exceptions:</u> HIV/AIDS service and for use in patients intolerant to TMP/SMX for PCP prophylaxis per protocol post-BMT (NYP/WC	Vancomycin (PO/IV) <u>Exception (IV):</u> OB/GYN for Group B Streptococcus prophylaxis in penicillin allergic patients.

Voriconazole (PO/IV)

Exception: IV to PO switch

Restricted for use in Aspergillus/mold infections and resistant Candida/yeast infections, oral therapy if preferred.

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