

MONTEFIORE MEDICAL CENTER
DEPARTMENT OF PHARMACY

SUBJECT: Restricted Drugs Policy, Antibiotic Restrictions

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APPROVED BY: Unified Director of Pharmacy

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The Pharmacy and Therapeutics Committee, in approving the addition of certain antibiotics to the Formulary, may restrict their use because of toxicity, and in an attempt to minimize antibiotic resistance. Monitoring of the usage of these antibiotics is the responsibility of the Antibiotic Subcommittee, the Division of Infectious Diseases, the Antibiotic Stewardship Program and the Pharmacy Department.

1. Prescribers wishing to prescribe any restricted antibiotics during designated hours of restriction (see table 1 for specific hours) should contact the designated individual, who is a member of Infectious Diseases (ID) or Antimicrobial Stewardship Program (ASP) on call for antibiotic approval.

Table 1. Hours of Restriction by Division

Division / Patient Population	Days of Restriction	Hours of Restriction
Adults: Moses, Einstein and Wakefield	7 days per week	8 AM to 10 PM
Pediatric: CHAM and NICU	7 days per week	8 AM to 11 PM

*ID consultation must still be obtained for drugs requiring mandatory consult within 24 hours

The prescriber and member of ID/ASP will discuss the most appropriate antimicrobial regimen for patient in question. If clinically indicated, member of ID/ASP will either place approval note under Antimicrobial Stewardship “Antibiotic Approval Note” in Epic or call the pharmacy and provide the following information:

- a. Name of patient
- b. Medical record number
- c. Location of patient
- d. Drug name, dosage, route, administration frequency, and duration of approval
- e. Name of antibiotic approver

If the restricted antibiotic has not been approved by a member of ID/ASP, pharmacists must call the prescriber to inform them that the antibiotic requires ID approval (so doses are not delayed) and enter as intervention (I-vent) in Epic. In instances when prescribers are unable to reach ID/ASP within one hour, prescribers must call the pharmacy and ask for two doses to be dispensed to allow for additional time to obtain approval. *A list of these incidents will be generated the*

following morning by pharmacy for follow up by a member of ID/ASP.

Pharmacists should not automatically dispense the two doses of antibiotic but should wait for the return call from prescribers indicating they were unable to reach ID/ASP. If prescribers do not call back requesting the release of the two doses, no antibiotic should be dispensed. If ID/ASP does not call the pharmacy to release the restricted antibiotics, no further medication will be dispensed.

2. In order to sufficiently treat patients overnight until stewardship hours resume, a limited number of doses of restricted Category II and III Antibiotics (table 3) can be dispensed without approval from ID/ASP if requested during non-stewardship hours (table 2). Pharmacists should remind prescribers that approval must be obtained (as outlined in Section 1) for continuation of therapy.

Table 2. Hours During Which Limited Doses May Be Dispensed

Division / Patient Population	Day	Time
Moses, Einstein and Wakefield	7 days per week	10PM – 8AM
CHAM, NICU	7 days per week	11PM – 8AM

3. Upon receipt of an order for a restricted antibiotic, pharmacists should verify the order only if ID approval has been obtained as per **Antibiotic Approval Note** in Epic.

If ID approval is pending, the medication order should not be verified, and pharmacists should follow the procedure outlined in Section 1 above.

Once ID approval is obtained, the medication order should be verified by pharmacists, and the appropriate number of doses sent to the patient unit. Pharmacists should modify the antibiotic orders to match the dose, route, frequency, and duration of approval.

4. **For category II and III antibiotics, it is the responsibility of Primary Team to ensure a sufficient duration of approval is obtained from the on-call steward until ID consult is completed to prevent missed doses.**
5. The following adjustments in restricted antibiotic therapy are **regarded as new orders and will require new approval** as described in Section 1:
 - a. Increased dose of the drug (e.g. vancomycin IV, liposomal amphotericin, etc.)
 - b. Increased frequency of administration (e.g. vancomycin IV)
 - c. Increased (extended) duration
 - d. Changing from the oral to the parenteral route of administration (e.g. azithromycin, quinolones, etc.)
6. The Director for Clinical and Educational Pharmacy Services will ensure that restricted antibiotics are approved by the responsible departments through scheduled Pharmacy Performance Improvement Initiatives.
 - 5.1 It is the responsibility of pharmacists on duty to ensure each restricted antibiotic is approved by ID or ASP in a timely fashion.
 - 5.2 The lists of Restricted Antibiotics (tables 3 - 5) are updated as necessary. They are distributed to Department of Pharmacy staff, Division of Infectious Diseases and posted on pharmacy and Infectious Diseases intranet sites

Table 3. Restricted Antimicrobial List for Moses/Einstein/Wakefield (Adults) as of December of 2023

ANTIMICROBIAL	ROUTE	COMMENTS
CATEGORY I – ID or stewardship approval is required 24h/day & 7-days per week. Ideally, these are not started overnight, but may be required in certain circumstances. ID consult must be obtained within 24 hours of the first dose.		
Amikacin	Inhalation	None
Amphotericin B deoxycholate	IV	None
Amphotericin B (liposomal)	IV, Inhalation	Ambisome is the Amphotericin B lipid formulation available at Montefiore
Artemether/lumefantrine	PO	None
Artesunate*	IV	None
Cefiderocol	IV	None
Ceftazidime/avibactam*	IV	None
Ceftolozane/tazobactam	IV	None
Cidofovir	IV	None
Colistin*	Inhalation	None
Daptomycin	IV	None
Eravacycline	IV	None
Fidaxomicin	PO	None
Foscarnet	IV	None
Imipenem/cilastatin/relebactam*	IV	None
Isavuconazole*	IV, PO	None
IVIG	IV	Need ID approval/consult for any ID indications (i.e. <i>C. difficile</i> colitis, group A streptococcal or MRSA toxic shock syndrome).
Letermovir*	IV, PO	None
Maribavir	PO	None
Meropenem/vaborbactam	IV	None
Pentamidine	IV	None
Peramivir*	IV	None
Polymyxin B	IV	None
Pyrimethamine	PO	None
Ribavirin*	Inhalation	None
CATEGORY II – ID or stewardship approval must be requested from 8am-10pm, but 1-2 doses may be dispensed from 10pm-8am without approval. ID consult must be obtained within 24 hours of the first dose (see meropenem exception below).		
Ceftaroline	IV	None
Ertapenem	IV, IM	
Linezolid	IV, PO	None (patients are automatically switched to the oral formulation when able to take oral medications).
Meropenem	IV	ID consult required within 24h of first dose on weekdays. On weekends, ID consult can be ordered within 48 hours or Monday morning; but it is the responsibility of the Primary Team to ensure a sufficient duration of approval is obtained from on-call steward to prevent missing doses while awaiting ID consult.
Micafungin	IV	ID consultation/approval is not required for 50 mg/day for antifungal prophylaxis in allogeneic stem cell patients.
Posaconazole	IV*, PO	ID consult and approval are not required for prophylaxis for AML/high risk MDS on induction or consolidation therapy with ANC<500, or allogeneic stem cell patient with GVHD or receiving alemtuzumab or high dose steroids. Please note: suspension and extended-release tablet dosing are NOT interchangeable.
Voriconazole	IV, PO	ID consult is not required for lung transplant prophylaxis and approval is not required for 1 st dose of 200 mg IV ordered for surgical prophylaxis of fresh lung transplant.

CATEGORY III – ID or stewardship approval must be requested from 8am-10pm, but one or two doses may be dispensed from 10pm-8am without approval when being given to adults.		
Acyclovir	IV	Approval is not required for 250 mg IV q12h prophylaxis in stem cell recipients unable to take oral valacyclovir.
Albendazole	PO	None
Amikacin	IV, IM	None
Azithromycin	IV	Approval is not required for single dose 500mg for Caesarian section during L&D. Approval not required for 1 st dose ordered via Severe Sepsis Protocol.
Aztreonam	IV	Approval not required for 1 st dose ordered via Severe Sepsis Protocol.
Cefepime	IV	<p>Moses/Einstein: approval is exempt for oncology patients in NW 2 (Moses) and 11S (Einstein) and patients in critical care units (not step-down patients).</p> <p>Wakefield: approval is not required for the initial 72 hours.</p> <p>For all campuses: approval is not required for 1st dose ordered via Severe Sepsis Protocol.</p>
Ceftriaxone	IV	Only >2g/day requires ID/ASP approval (i.e. meningitis 2g IV q12h)
Ciprofloxacin	IV	Approval is not required for 1 st dose ordered via Severe Sepsis Protocol. Patients are automatically switched to the oral formulation when able to take oral medications.
Fluconazole	IV, PO	Approval is not required for HIV patients, for prophylaxis in stem cell recipients receiving up to 400 mg/day, for first 7 days of 200 mg IV ordered for surgical prophylaxis of fresh dual kidney/pancreas transplant, and for single 150 mg PO dose for candidal vaginitis. Patients are automatically switched to the oral formulation when able to take oral medications.
Flucytosine	PO	None
Fosfomycin*	PO	None
Ganciclovir	IV	None
Itraconazole	PO	None
Ivermectin	PO	None
Levofloxacin	IV, PO	Approval is not required for oral doses ≤500 mg daily and IV formulation for prophylaxis doses in stem cell recipients. Patients are automatically switched to the oral formulation when able to take oral medications.
Oseltamivir	PO	Approval is required for influenza prophylaxis, treatment duration >5 days, or no positive lab result for influenza.
Piperacillin/tazobactam	IV	<p>Moses/Einstein: approval is required only for patients in the Emergency Room and on Vascular Surgery.</p> <p>Wakefield: approval is not required for the initial 72 hours.</p> <p>For all campuses: approval is not required for 1st dose ordered via Severe Sepsis Protocol.</p>
Remdesivir	IV	
Ribavirin	PO	None
Tobramycin	Inhalation	Approval is not required for post lung transplant.
Vancomycin	IV, PO, Rectal	Approval is not required for the initial 72 hours of PO and IV therapy, however, approval is still required for <i>C. difficile</i> prophylaxis or any oral dose >125 mg. Approval is not required for IV therapy for peri-operative LVAD surgery prophylaxis x 48 hours.

*Nonformulary antimicrobials

Table 4. Restricted Antimicrobial List for (CHAM/NICU Pediatrics) as of June 2023

ANTIMICROBIAL	ROUTE	EXEMPTIONS
Acyclovir	IV, oral	One dose exceptions are the emergency room for fever in baby < 8 weeks, severe sepsis and possible meningitis
Albendazole	Oral	None
Amantadine	Oral	None
Amikacin	IV, IM	One dose exception for severe sepsis
Amphotericin B deoxycholate	IV	None
Amphotericin B lipid complex	IV	None
Artesunate	IV	None, coordination with the clinical manager
Aztreonam	IV	One dose exception for severe sepsis.
Cefepime	IV	Approvals are exempt on CHAM 9, CHAM 10, and NICU. One dose exceptions are for severe sepsis, possible meningitis, and febrile neutropenia (in ER only)
Ceftaroline	IV	None
Ceftazidime-Avibactam	IV	None
Ceftolozane-Tazobactam	IV	None
Cefiderocol	IV	None
Chloramphenicol	IV	The oral formulation is no longer made in the U.S. and is unavailable.
Cidofovir	IV	None
Ciprofloxacin	Oral, IV	One dose exception for severe sepsis
Clarithromycin	Oral	None
Clindamycin	IV	None
Colistin Nebulizer	Inhalation	None
Daptomycin	IV	None
Fluconazole	Oral, IV	NICU Only: Approval is not required in neonates using doses of 3mg/kg q72h.
Flucytosine	Oral	None
Foscarnet	IV	None
Ganciclovir	IV	None
Imipenem/Cilastatin/Relebactam	IV	None
Itraconazole	Oral	None
Letermovir	Oral, IV	None
Levofloxacin	Oral, IV	One dose exception for severe sepsis
Linezolid	Oral, IV	One dose exception for severe sepsis
Maribavir	Oral, IV	None
Meropenem	IV	One dose exception for severe sepsis
Meropenem-vaborbactam	IV	None
Metronidazole	IV	None
Micafungin	IV	None
Omadacycline	IV	None
Oseltamivir	Oral	For treatment, answer choices in the EPIC ordering set are mandatory
Palivizumab	IM, IV	None, must be evaluated by an ASP member from 8 a.m. – 5 p.m. Monday through Friday
Pentamidine	IV, inhalation	None
Polymyxin B	IV	None
Ribavirin	Oral, inhalation	None
Piperacillin-Tazobactam	IV	Approval not required for 48 hours
Posaconazole	Oral, IV	None
Remdesivir	IV	None
Rimantadine	Oral	None
Tigecycline	IV	None
Tobramycin	IV, IM, inhalation	IV, IM: For <i>Pseudomonas aeruginosa</i> infections only
Valganciclovir	PO	None
Vancomycin	IV, oral, rectal	IV: One dose exceptions are for severe sepsis and possible meningitis
Voriconazole	Oral, IV	None

