Northwestern Memorial Hospital Restricted Antimicrobial Criteria (10/10/2019)

These criteria are based on national and local susceptibility data as well as Infectious Disease Society of America (IDSA) guideline recommendations.

Any use of restricted antimicrobials outside of specified criteria may be subject to review by the Antimicrobial Stewardship Program (ASP). The following outlines the review process:

- In case of antimicrobial use questions or clinical urgency/emergency, a prescriber may contact the ID pharmacist on call directly by paging *Pharmacist, Infectious Diseases* or *55955*.
- The ID pharmacist reviews the case and if use appears to fall outside of the restricted drug criteria, the ID pharmacist communicates with the patient's attending or ID consultant to discuss the case.
- If use falls outside of restricted criteria but the health care team feels the drug may still be beneficial, prescribers are to page Sarah Sutton, MD, NMH ASP medical director (55771), or the ASP covering physician.

Amphotericin B Deoxycholate (conventional)

Use is restricted to irrigation, inhalation per the lung transplant protocol, or special intraocular uses. Conventional amphotericin B is not to be used for intravenous treatment. For intravenous treatment with an amphotericin B product, liposomal amphotericin B (AmBisome®) should be used.

Aztreonam

Use is restricted to penicillin-allergic and cephalosporin-allergic patients who require gram-negative coverage.

Cefoxitin

Use is restricted to patients with documented rapidly growing mycobacteria (*Mycobacterium fortuitum*, *M. chelonae* and *M. abscessus*) or ID consult. For other indications, use cefazolin in combination with metronidazole.

Ceftazidime\Avibactam

Ordering of ceftazidime\avibactam is restricted to patients who are being followed by the ID consultation service and ID consultation is recommending use of this agent.

Do not use this drug when a highly-resistant Gram-negative organism is isolated in a hemodynamically stable patient in whom the only source is a symptomatic, non-complicated UTI.

Use is restricted to patients with:

- Definitive carbapenam-resistant enterobacteriaceae (CRE) infection AND failure of current first line therapies (i.e., multiple drug therapy with carbapenem +/- aminoglycoside +/- polymyxin b +/- other active agents) AND known susceptibility to ceftazidime\avibactam

- Definitive extended spectrum beta-lactamase (ESBL) resistance to all available antibiotics AND failure of current first line therapies (i.e., carbapenem) AND known susceptibility to ceftazidime\avibactam

Each order of ceftazidime\avibactam must be reviewed by the antimicrobial stewardship (ASP) pharmacist on call (pager: 55955) within 24 hours.

Ceftolozane\Tazobactam

Ordering of ceftolozane/tazobactam is restricted to patients who are being followed by the ID consultation service and ID consultation is recommending use of this agent.

Use is restricted to non-cystic fibrosis patients with:

- Definitive multidrug resistant *Pseudomonas aeruginosa* with known resistance to all available antibiotics AND known susceptibility to ceftolozane/tazobactam
- Definitive extended spectrum beta-lactamase (ESBL) resistance to all available antibiotics AND failure of current first line therapies (i.e., carbapenem) AND known susceptibility to ceftolozane/tazobactam

Each order of ceftolozane/tazobactam must be reviewed by the antimicrobial stewardship (ASP) pharmacist on call (pager: 55955) within 24 hours.

Dalfopristin/Quinupristin

Use is restricted to:

- Patients with vancomycin resistant *Enterococcus* (VRE) *faecium* infections that are unable to receive linezolid or daptomycin (due to resistance and/or intolerance).
- Patients with methicillin-resistant *Staphylococcus aureus* (MRSA) infections who are unable to receive vancomycin, linezolid, and daptomycin (due to resistance, allergy, and/or severe intolerance).

Daptomycin

Daptomycin should not be used for pneumonia as this antibiotic is inactivated by surfactant.

Use is restricted to:

- MRSA endocarditis in patients with:
    - Persistently positive blood cultures while on IV vancomycin therapy (of note, mean duration is 7 days for vancomycin-treated MRSA bacteremia in endovascular [i.e., endocarditis] infection)
      OR
    - Inability to tolerate vancomycin therapy due to allergy (excluding red man' syndrome)
      OR

    - Inability to tolerate vancomycin due to a current episode of moderate to severe acute kidney injury (AKI).
        - In many cases, vancomycin dosing may be adequately managed by pharmacy – please consult your pharmacist for recommendations.
- Systemic MRSA infections (excluding pneumonia) in patients with:
    - Inability to tolerate vancomycin therapy due to allergy (excluding red man's syndrome) OR
    - Inability to tolerate vancomycin due to a current episode of moderate to severe acute kidney injury (AKI).
        - In many cases, vancomycin dosing may be adequately managed by pharmacy – please consult your pharmacist for recommendations.
- Methicillin-susceptible *Staphylococcus aureus* (MSSA) bacteremia in patients with either of the following:
    - Allergy to beta-lactams and vancomycin therapy (excluding red man's syndrome) OR
    - Allergic to beta-lactams and inability to tolerate vancomycin due to a current episode of moderate to severe AKI.
        - In many cases, vancomycin dosing may be adequately managed by pharmacy – please consult your pharmacist for recommendations.
- VRE infections in patients allergic or resistant to penicillins and\or in patients having hematological abnormalities precluding linezolid use. Of note, Infectious Disease Consultation is strongly recommended for severe VRE infections such as endocarditis for dosing and for combination therapy recommendations.
- Gram positive cocci (GPC) bacteremia in stem-cell transplant patient with VRE colonization until culture results are available.

Dual Antifungal Therapy

Use is restricted to:

- Approval from Infectious Diseases Consultation Service with complete evaluation of the patient and clinical setting.

- Probable or proven invasive aspergillosis in a hematologic malignancy or stem cell transplant patient (echinocandin plus azole antifungal only).

Ertapenem

Restricted to a single dose prior to discharge in patients who are to receive ertapenem as home parenteral antibiotic therapy.

Fidaxomicin

Use is restricted to the treatment of *Clostridioides difficile*-associated diarrhea, restricted to ID consultation only, for inpatients who have had CDI recurrence after standard vancomycin followed by extended pulse dose oral vancomycin therapy. Prior authorization is necessary to ensure continuity of care.

Imipenem

Use is restricted to patients with documented infections resistant to all other potentially effective antimicrobials on formulary, including meropenem.

Isavuconazole

Use is restricted to:

- Antifungal prophylaxis for highly immunocompromised patients such as stem cell transplant patients.

- Probable or proven invasive Mucormycosis in patients who are failing liposomal amphotericin B treatment or who are experiencing complications that preclude its use.

AND

- Approval from Infectious Diseases Consultation Service with complete evaluation of the patient and clinical setting.

Linezolid

Use is restricted to:

- MRSA infections in patients with:
    - Inability to tolerate vancomycin due to allergy (excluding red man's syndrome)
      OR
    - Inability to tolerate vancomycin due to a current episode of moderate to severe AKI.
        - In many cases, vancomycin dosing may be adequately managed by pharmacy – please consult your pharmacist for recommendations.
- Culture-documented MRSA pneumonia.
- Empiric use for suspected MRSA hospital acquired, ventilator associated, or health care associated pneumonia in a critically ill patient. Subsequent documentation of MRSA from culture is required for linezolid continuation beyond 72 hours.
- Empiric use for suspected MRSA pneumonia in hemodynamically stable (floor) patients with:
    - Cystic fibrosis patients
      OR
    - Inability to tolerate vancomycin due to allergy (excluding red man's syndrome)
      OR
    - Inability to tolerate IV vancomycin therapy due to a current episode of moderate to severe AKI.

        - In many cases, vancomycin dosing may be adequately managed by pharmacy – please consult your pharmacist for recommendations.
- GPC bacteremia in a febrile neutropenic patient with VRE colonization until culture results available.
- Documented or strongly suspected systemic VRE infections that are:
    - Also ampicillin-resistant
      OR
    - Ampicillin-susceptible in patients allergic to penicillins.
- Documented VRE in the urine of:
    - A pregnant patient
      OR
    - An immunocompromised (neutropenic or transplant) patient
      OR
    - An immunocompetent patient with systemic symptoms such as dysuria, fever, elevated WBC, and rigors.
        - <u>Asymptomatic bacteriuria in an immunocompetent patient should not be treated.</u>

Meropenem

Use is restricted to:

- Patients with a positive blood, deep respiratory (BAL), or other clinically significant sterile site culture with an ESBL producing organism (floor or ICU patient).
- Empiric use in critically ill ICU patients with prior documentation of ESBL organism.
- Critically ill ICU patients failing > 72 hours of cefepime or piperacillin/tazobactam therapy.

Micafungin

Use is restricted to patients with:

- Documented or suspected aspergillosis who are refractory or intolerant to amphotericin products and voriconazole.
- Empiric antifungal therapy when necessary in neutropenic patients who remain febrile despite broad spectrum antibiotic therapy for greater than 3 days.
- Empiric use in patients with yeast bloodstream infections. If *Candida albicans* is identified, micafungin should be deescalated to fluconazole.
- Suspected candidiasis in patients with recent azole exposure, moderately severe to severe illness, or high risk of *C. glabrata* or *C. krusei.*
- Candida isolates that have documented clinical or microbiologic resistance to fluconazole.

Micafungin should not be used for fungal urinary tract infections as this drug is not excreted in the urine.

Oxacillin

Use is restricted to:

- Infectious Diseases consultation
- MSSA meningitis
- MSSA CNS parenchymal abscess

Tigecycline

Use is restricted to Infectious Diseases consultation only.

Posaconazole

Use is restricted to:

- Infectious Diseases consultation
- Continuation of outpatient posaconazole therapy
- Lung transplant patients
- Fungal prophylaxis for solid organ transplant patients

Meropenem-Vaborbactam

Ordering of meropenem-vaborbactam is restricted to patients who are being followed by the ID consultation service and ID consultation is recommending use of this agent.

Do not use this drug when a highly-resistant Gram-negative organism is isolated in a hemodynamically stable patient in whom the only source is a symptomatic, non-complicated UTI.

Use is restricted to patients with:

- Definitive extended spectrum beta-lactamase (ESBL) resistance to all available antibiotics AND failure of current first line therapies (i.e., carbapenem) AND known susceptibility to meropenem-vaborbactam
- Definitive carbapenam-resistant enterobacteriaceae (CRE) infection AND failure of current first line therapies (i.e., multiple drug therapy with carbapenem +/- aminoglycoside +/- polymyxin b +/- other active agents) AND known susceptibility to meropenem-vaborbactam

Each order of meropenem-vaborbactam must be reviewed by the antimicrobial stewardship (ASP) pharmacist on call (pager: 55955) within 24 hours.

Voriconazole

Use is restricted to:

- Fungal prophylaxis in high-risk bone marrow transplant patients

- Patients with documented or strongly suspected invasive aspergillosis.

NON-FORMULARY ANTIMICROBIAL AGENTS

Non-formulary antimicrobial agents must go through the non-formulary request process regardless of who is requesting use of the agent.

Please page the ID pharmacist on call (55955) to initiate the non-formulary process for an antimicrobial agent.

ANTI-INFECTIVE SHORTAGES

When an anti-infective agent is unavailable or in severely limited supply, ASP may alter the NMH formulary restrictions temporarily and notify health care workers of alternative agents for specific indications.