Pharmacy and Therapeutics Committee Approvals, October 2008

P&T Date: October 7, 2008

AGENDA ITEM	P&T COMMITTEE DECISION	COMMENTS
• **DEXRAZOXANE (TOTECT KIT®)**	**RETAIN NON-FORMULARY STATUS. KIT AVAILABLE FOR BORROWING FROM THE OUTPATIENT CANCER CENTER**	• ***Indication:*** Treatment of extravasation resulting from IV anthracycline chemotherapy (includes daunorubicin, doxorubicin, epirubicin, idarubicin, ifosfamide, mitomycin C). • ***Mechanism of Action:*** Although not clearly understood, evidence suggests reversible inhibition of topoisomerase II may be responsible for diminishing tissue damage resulting from anthracycline extravasation • ***Adverse effects:*** >5% incidence of: pyrexia, injection site pain, fatigue, peripheral edema, nausea, alopecia, dyspnea, pneumonia • ***Contraindications:*** None known • ***Precautions:*** Additive cytotoxicity may occur and may result in leucopenia, neutropenia, and thrombocytopenia; reversible LFT elevations may occur. Dose should be reduced by 50% when Clcr <40ml/min. Do not use DMSO in patients receiving dexrazoxane for anthracycline-induced extravasation. Pregnancy category D; unknown if excreted into breast milk
• **ALVIMOPAN (ENTEREG®)**	**RETAIN NON-FORMULARY STATUS**	• ***Indication:*** Treatment of post-operative ileus following partial large or small bowel resection surgery with anastomosis • ***Mechanism of Action:*** Selective peripheral mu-opioid receptor antagonism, thereby increasing motility. Does not cross the blood-brain barrier and does not reverse the central analgesic effect of mu-receptor agonists • ***Adverse effects:*** Most common: hypokalemia, dyspepsia, anemia, back pain, urinary retention. Serious adverse effects (causal relationship not definitively established): increase in cardiovascular events, including myocardial infarctions • ***Contraindications:*** Contraindicated in patients receiving therapeutic doses of opioids for > 7 days immediately prior to taking alvimopan or in patients allergic to alvimopan • ***Precautions:*** Use not recommended in complete bowel obstruction correction surgery. Use caution when administering to patients with history of cardiovascular events. Use has not been evaluated in pediatrics. Do not use in patients with severe hepatic impairment or end-stage renal disease; monitor use closely in patients with mild to moderate hepatic impairment. Pregnancy category B; unknown if excreted into human breast milk
• **RISPERIDONE LONG-ACTING (RISPERDAL® CONSTA®)**	**RETAIN NON-FORMULARY STATUS. RESTRICTED USE ON A CASE-BY-CASE BASIS**	• ***Indication:*** Treatment of schizophrenia • ***Mechanism of Action:*** Combination of dopamine Type 2 and serotonin Type 2 receptor antagonism as well as alpha 1 and 2, and histaminergic receptor antagonism • ***Adverse effects:*** Most common: tremor, akathisia, somnolence, dyspepsia, constipation, xerostomia, fatigue, weight gain. Neuroleptic malignant syndrome and tardive dyskinesias have been reported. Orthostatic hypotension, hyperglycemia, and increased prolactin levels • ***Contraindications:*** Known hypersensitivity to the product or any of its

		components • ***Precautions:*** Use with caution in patients with known cardiovascular disease, diabetes, or seizure disorders, the elderly, and patients with renal or hepatic impairment. Boxed warning re: increased mortality (due to cerebrovascular events, including stroke) in elderly patients with dementia-related psychosis. Pregnancy category C; use not recommended during and for at least 12 weeks following last Consta® injection in nursing mothers
• **REGADENOSON (LEXISCAN®)**	**APPROVAL FOR USE IN A TEST-OF-CHANGE FOR RADIONUCLIDE MYOCARDIAL PERFUSION IMAGING PROCEDURES ONLY, UTILIZING LEXISCAN® PROTOCOLS IN PATIENTS MEETING SPECIFIC RESTRICTIONS**	• ***Indication:*** Pharmacologic stress agent for radionuclide myocardial perfusion imaging in patients unable to undergo adequate exercise stress • ***Mechanism of Action:*** A_{2A} adenosine receptor agonism, leading to coronary vasodilation and increased coronary blood flow • ***Adverse effects:*** Most common: shortness of breath, rhythm/conduction abnormalities, headache, flushing, chest discomfort, dizziness, and nausea – most occurring and abating within 15 minutes • ***Contraindications:*** Contraindicated in patients with second or third degree AV block or sinus node dysfunction unless patient has a functioning artificial pacemaker • ***Precautions:*** Methylxanthines may interfere with vasodilatory effects of regadenoson, therefore, withhold methlxanthines for at least 12 hours prior to scheduled radionuclide MPI. Dipyridamole may increase activity of regadenoson, therefore, when possible, withhold dipyridamole for at least two days prior to regadenoson administration. Pregnancy category C; unknown if excreted into human breast milk – based on pharmacokinetics, drug should be cleared 10 hours after administration
• **FORMULARY CHANGES**		• **Replacement of Hextend® (6% hetastarch in lactated electrolyte solution) with Hespan® (6% hetastarch in saline)** • **Fomepizole (Antizol®; antidote for ethylene glycol toxicity) – added to formulary**
• **AUTOMATIC SUBSTITUTIONS**		• **Artificial saliva (Roxane) automatically substituted TO MouthKote® at same dose and frequency** • **Lovenox 40 mg SQ daily automatically substituted TO Fragmin 5000 international units daily for acutely medically ill patients with severely restricted mobility** • ***** In shortage situations ONLY ***** **Prochlorperazine (Compazine®) injection 5 or 10 mg IV automatically substituted TO ondansetron 4 mg IV at the same frequency**
• **DEAR DOCTOR LETTERS**		**A copy (a permanent part of the Medical Record) will be placed in the Progress Notes section when a new order for the following is received:** • **Abacavir (Ziagen®) – fatal hypersensitivity reactions (HLA-B*5701)**  Appendix B - Abacavir Dear Dr Let • **Carbamazepine (Tegretol®) – dangerous or fatal skin reactions**  Appendix C - CBZ Dear Dr Letter.pdf

• **2008 ANTIFUNGAL TREATMENT RECOMMENDATIONS – (REVISIONS TRACKED)**	CSMC antifungal treatment 2008
• **2008 EMPIRIC TREATMENT RECOMMENDATIONS FOR COMMON PEDIATRIC INFECTIONS**	2008 Pediatric Empiric Antibiotics
• **MEDICATION SAFETY COLLABORATIVE**	• **CSMC Proposed Plan for Management of Medications with Black Box Warnings** Black Box Warning Plan Revised 09 08

Requests for full monographs or questions regarding this listing may be addressed to the Drug Information Center at **(310) 423-3784**

Angela Hirai Yang, PharmD — *Pharmacy Program Coordinator*
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CEDARS-SINAI MEDICAL CENTER®

DEPARTMENT OF PHARMACY SERVICES

TO DOCTOR		ID #
FROM CLINICAL PHARMACIST		
PAGER #	EXT.	DATE

Addressograph

This is **a permanent** part of the patient's medical record.

ABACAVIR (ZIAGEN®) FATAL HYPERSENSITIVITY REACTIONS (HSR)

Dear Doctor

Your patient was prescribed abacavir (or an abacavir containing product.).

The abacavir HSR is a multi-organ syndrome characterized by 2 or more clinical signs & symptoms that can include fever, rash, gastrointestinal symptoms, respiratory symptoms and constitutional symptoms. Serious and sometimes fatal HSR caused by abacavir therapy are significantly more common in patients with a particular human leukocyte antigen (HLA) allele, HLA-B* 5701.

The FDA has recommended **all patients** should be screened for the HLA-B* 5701 allele *before starting* or *restarting treatment* with abacavir or abacavir-containing medications.

The genetic test for the HLA-B* 5701 allele is available at CSMC. The test result is available within one week or less. Please order a HLA-B*5701 test if your patient has not been previously tested and is starting or restarting therapy with abacavir.

This letter has also been faxed to your office at _____

Thank You

Clinical Pharmacist:_____Pager # _____Ext: _____

For more information:

http://www.fda.gov/medwatch/safety/2008/safety08.htm#Abacavir

Sept 23, 2008

CEDARS-SINAI MEDICAL CENTER®

DEPARTMENT OF PHARMACY SERVICES

TO DOCTOR		ID #
FROM CLINICAL PHARMACIST		
PAGER #	EXT.	DATE

Addressograph

This is **a permanent** part of the patient's medical record.

CARBAMAZEPINE (TEGRETOL®) – DANGEROUS OR FATAL SKIN REACTIONS

Dear Doctor _____:

Your patient was prescribed carbamazepine

Carbamazepine can cause dangerous or even fatal skin reactions, such as Stevens Johnson syndrome & toxic epidermal necrolysis. It is significantly more common in patients with a particular human leukocyte antigen (HLA) allele, HLA-B* 1502. This allele occurs almost exclusively in patients with ancestry across broad areas of Asia, including South Asian Indians.

The FDA recommends HLA –B* 1502 screening for **patients with Asian ancestry** before starting treatment with carbamazepine. Patients who have been taking carbamazepine for more than a few months without developing skin reactions are at low risk of these events ever developing from carbamazepine.

The genetic test for the HLA-B* 1502 allele is available at CSMC. The test result is available within one week or less. Please order a HLA-B* 1502 if your patient has not been previously tested.

This letter has also been faxed to your office at _____

Thank You

Clinical Pharmacist:_____Pager # _____Ext: _____

For more information:

http://www.fda.gov/cder/drug/InfoSheets/HCP/carbamazepineHCP.htm

Sept 23, 2008

CSMC TREATMENT RECOMMENDATIONS FOR FUNGAL INFECTIONS

Approved by: The Antibiotic Use Review Committee, The Pharmacy and Therapeutics Committee

These recommendations are not intended to supercede clinical judgement

INDICATION	FLUCONAZOLE[1] (FZ)	VORICONAZOLE [1,2,3] (VCZ)	CASPOFUNGIN[4,5]	AMPHOTERICIN B[2] (AMB)	ABLC[2]	OTHER CONSIDERATIONS
NEUTROPENIC FEVER-EMPIRIC Persistent fever of unknown origin despite 4-7 days of broad spectrum antibacterial therapy	CONSIDER IF **LOW RISK** FOR ASPERGILLOSIS ▪ no sinusitis ▪ no lung infection ▪ no CNS infection ▪ no recent use of FZ **Dose:** **400mg daily**	CONSIDER FOR VERY **HIGH RISK** FOR INVASIVE ASPERGILLOSIS (IA) (BASED ON CHEST XRAY OR H/O IA) **Dose:** **Loading:** **6 mg/kg IV/PO Q12H x 2** **Maintenance:** **4 mg/kg IV/PO Q12H**	PREFERRED AGENT **Dose:** **70mg X1 then 50mg daily**	PREFERRED FOR PATIENTS WITH CHRONIC DIALYSIS **Dose:** **0.6 mg/kg/day**	PREFERRED FOR PATIENTS WITH HIGH RISK FOR RESISTANT MOLDS **Dose:** **3-5mg/kg/day** **(5 mg/kg: suspected Aspergillus or other molds)**	**CONSIDER OTHER CAUSES OF FEVER**: ▪ antibiotic resistance ▪ secondary or occult infection ▪ inadequate antibacterial ▪ dose or penetration ▪ drug fever **AMPHOTERICIN B PRODUCTS:** **DILIGENT POTASSIUM REPLACEMENT REQUIRED** **(CONSULT PHARMACIST)**
NON-NEUTROPENIC HOST-EMPIRIC (cultures pending) THERAPY SHOULD MAINLY BE LIMITED TO PATIENTS WITH **ALL** BELOW: ▪ Colonized with yeast (at ≥2 sites) ▪ Trial of antibiotics (broad spectrum) ▪ Full culture work up ▪ High Risk* for fungal infection (TPN, central line, ICU stay >7 days, GI surgery, GI trauma or perforation) ▪ If Liver Transplant: patient: added risk if re-transplantation, or re-operation	PREFERRED IF: ▪ azole resistance **NOT** suspected* (see considerations) ▪ hemodynamically stable **Dose:** **400mg-800mg daily**	NOT RECOMMENDED no advantage over fluconazole	PREFERRED WITH **ANY** BELOW: ▪ suspected azole resistance* ▪ persistent infection while on FZ ▪ hemodynamically unstable **Dose:** **70mg X1 then 50mg daily**	CONSIDER FOR CHRONIC DIALYSIS AND ▪ azole resistance ▪ persistent infx on FZ ▪ hemodynamically unstable **Dose:** **0.7 mg/kg/day**	CONSIDER IF DEEP INFECTION SUSPECTED AND • Suspected azole resistance OR • Hemodynamically unstable OR • Failure of FZ or Caspofungin **Dose:** **3-5mg/kg/day**	***AZOLE RESISTANCE RISK INCREASED:** ▪ recent history of *C. glabrata* or *C. krusei* ▪ recent use of FZ (within 30 days) **CONSIDER OTHER CAUSES OF FEVER**: ▪ antibiotic resistance ▪ secondary or occult infection ▪ inadequate antibacterial dose or penetration ▪ drug fever Patients without risk factors of TPN, GI surgery, GI trauma or perforation are unlikely to benefit from fluconazole therapy

[1] Use intravenous formulation ONLY if NPO

[2] Dose based on total body weight. For voriconazole, total body weight greater than 130kg not studied

[3] Avoid intravenous Voriconazole if CrCl <50 ml/min unless benefit outweighs risk (such as documented invasive aspergillosis and NPO)

[4] Liver failure (Child-Pugh >7) use Caspofungin 70 mg load dose, then 35 mg daily

[5] No Clinical Correlation with reported MIC values

CSMC TREATMENT RECOMMENDATIONS FOR FUNGAL INFECTIONS

Approved by: The Antibiotic Use Review Committee, The Pharmacy and Therapeutics Committee

These recommendations are not intended to supercede clinical judgement

INDICATION	FLUCONAZOLE[1] (FZ)	VORICONAZOLE [1,2,3] (VCZ)	CASPOFUNGIN[4,5]	AMPHOTERICIN B[2] (AMB)	ABLC[2]	OTHER CONSIDERATIONS
SYSTEMIC CANDIDIASIS-A (RARELY AZOLE RESISTANT) *C. albicans* (or PNA FISH+) *C. tropicalis* *C. parapsilosis*	PREFERRED FOR MOST INFECTIONS **Dose:** **400 mg daily**	NOT RECOMMENDED no advantage over fluconazole	NO ADVANTAGE OVER FLUCONAZOLE	CONSIDER FOR DEEP ORGAN INFECTION **AND** ON CHRONIC DIALYSIS **Dose:** **0.7 mg/kg/day**	CONSIDER FOR DEEP ORGAN INFECTION **Dose:** **3-5mg/kg/day**	**THE MICROBIOLOGY LABORATORY ROUTINELY PERFORMS SUSCEPTIBILITY TESTING ON BLOODSTREAM ISOLATES** CATHETER OR "HARDWARE" RELATED INFECTIONS: REMOVE IF FEASIBLE
SYSTEMIC CANDIDIASIS-B (AZOLE RESISTANCE PREVALENT) *C. glabrata* *C. krusei* (rare at CSMC)	PREFERRED IF SUSCEPTIBILITY **CONFIRMED** **Dose:** **400 – 800 mg daily**	NOT RECOMMENDED: NO ADVANTAGE OVER FLUCONAZLE 800MG	PREFERRED AGENT FOR AZOLE RESISTANT STRAINS **Dose:** **70 mg X1 then 50 mg daily**	PREFERRED FOR PATIENTS ON CHRONIC DIALYSIS AND FZ RESISTANT **Dose:** **0.7 - 1 mg/kg/day**	CONSIDER FOR DEEP ORGAN INFECTION **Dose:** **5 mg/kg/day**	THE MICROBIOLOGY LABORATORY ROUTINELY PERFORMS SUSCEPTIBILITY TESTING ON BLOODSTREAM ISOLATES CATHETER OR "HARDWARE" RELATED INFECTIONS: REMOVE IF FEASIBLE
ESOPHAGITIS	PREFERRED AGENT **Dose:** **100 – 400 mg daily**	NOT RECOMMENDED	PREFERRED FOR AZOLE RESISTANCE **Dose:** **70 mg X1 then 50 mg daily**	CONSIDER FOR AZOLE RESISTANCE **AND LIKELY TO TOLERATE*** **Dose:** **0.5-0.7 mg/kg/day**	NOT PREFERRED	▪ AVOID ITRACONAZOLE (NONFORMULARY) * TOLERANCE TO AMB IS LIKELY IF: ▪ ClCr > 50ml/min, ▪ Not on other nephrotoxins ▪ No multi-organ failure
URINARY TRACT INFECTION (bladder only)	PREFERRED AGENT **Dose:** **100 mg daily**	NO ROLE POOR PENETRATION	NO ROLE POOR PENETRATION (4%)	CONSIDER BLADDER IRRIGATION FOR CASES OF FLUCONAZOLE RESISTANCE **Dose:** 50 mg in 1 liter sterile water for irrigation as continuous bladder irrigation through 3-way Foley catheter daily x 5	NO ROLE	

[1] Use intravenous formulation ONLY if NPO

[2] Dose based on total body weight. For voriconazole, total body weight greater than 130kg not studied

[3] Avoid intravenous Voriconazole if CrCl <50 ml/min unless benefit outweighs risk (such as documented invasive aspergillosis and NPO)

[4] Liver failure (Child-Pugh >7) use Caspofungin 70 mg load dose, then 35 mg daily

[5] No Clinical Correlation with reported MIC values

CSMC TREATMENT RECOMMENDATIONS FOR FUNGAL INFECTIONS

Approved by: The Antibiotic Use Review Committee, The Pharmacy and Therapeutics Committee

These recommendations are not intended to supercede clinical judgement

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INVASIVE ASPERGILLOSIS	NO ROLE	PREFERRED AGENT **Dose:** **Loading:** **6 mg/kg IV / PO Q12H x 2** **Maintenance:** **4 mg/kg IV/PO Q12H**	MAY CONSIDER IF VCZ IS NOT AN OPTION (NOT TOLERATING OR CONTRAINDICATED) **Dose:** **70 mg X1 then 50 mg daily**	NOT RECOMMENDED	PREFERRED IF VCZ IS NOT AN OPTION (NOT TOLERATING OR CONTRAINDICATED) **Dose:** **5 mg/kg/day**	COMBINATION ANTIFUNGAL THERAPY **HAS** NO ESTABLISHED CONSENSUS REGARDING USE
CRYPTOCOCCAL MENINGITIS	AFTER INITIAL AMPHO B INDUCTION THERAPY, PREFERRED AZOLE **Dose:** **400 - 800 mg daily**	UNCLEAR ROLE AT THIS TIME DUE TO LACK OF CLINICAL DATA	NO ROLE	PREFERRED AGENT WITH OR WITHOUT 5FC FOR INDUCTION THERAPY **Dose:** **AmB:0.7-1 mg/kg/day** **5FC: 100 mg/kg/day**	CONSIDER IN PATIENT WITH CLCR< 35ML/MIN OR UNLIKELY TO TOLERATE AMB* **Dose:** **5 mg/kg/day**	* TOLERANCE TO AMB IS LIKELY IF: ▪ ClCr > 50ml/min, ▪ Not on other nephrotoxins ▪ No multi-organ failure
COCCIDIOIDOMYCOSIS	Preferred Agent **Dose:** **400 - 800 mg daily**	UNCLEAR ROLE AT THIS TIME DUE TO LACK OF CLINICAL DATA	NO ROLE	PREFERRED ONLY FOR DIFFUSE PNEUMONIA, OTHERWISE USE FLUCONAZOLE **Dose:** **0.7 – 1 mg/kg/day**	CONSIDER IN PATIENT WITH CLCR< 35ML/MIN OR UNLIKELY TO TOLERATE AMB* **Dose:** **5 mg/kg/day**	REFRACTORY MENINGITIS: CONSIDER INTRATHECAL AMB (CSMC GUIDELINE AVAILABLE, LINK TO BE ADDED) * TOLERANCE TO AMB IS LIKELY: ▪ ClCr > 50ml/min, ▪ Not on other nephrotoxins No multi-organ failure
HISTOPLASMOSIS	NO ROLE	NOT RECOMMENDED	NO ROLE	ALTERNATIVE IF AT LOW RISK FOR NEPHROTOXICITY **Dose:** **0.7-1 mg/kg/day**	PREFERRED AGENT **Dose:** **5 mg/kg/day**	ITRACONAZOLE MAY BE USED IN THE MEDICAL CENTER FOR HISTOPLASMOSIS, USUALLY AFTER AMPHO B INDUCTION THERAPY DISSEMINATED DISEASE:: CONTACT FACULTY OR AUR PHARMACIST

[1] Use intravenous formulation ONLY if NPO

[2] Dose based on total body weight. For voriconazole, total body weight greater than 130kg not studied

[3] Avoid intravenous Voriconazole if CrCl <50 ml/min unless benefit outweighs risk (such as documented invasive aspergillosis and NPO)

[4] Liver failure (Child-Pugh >7) use Caspofungin 70 mg load dose, then 35 mg daily

[5] No Clinical Correlation with reported MIC values

CSMC TREATMENT RECOMMENDATIONS FOR FUNGAL INFECTIONS

Approved by: The Antibiotic Use Review Committee, The Pharmacy and Therapeutics Committee

These recommendations are not intended to supercede clinical judgement

INDICATION	FLUCONAZOLE[1] (FZ)	VORICONAZOLE [1,2,3] (VCZ)	CASPOFUNGIN[4,5]	AMPHOTERICIN B[2] (AMB)	ABLC[2]	OTHER CONSIDERATIONS
ZYGOMYCETES (RHIZOPUS, ABSIDIA, MUCOR, RHIZOMUCOR)	**NO ROLE**	NO ROLE	NO ROLE	ALTERNATIVE IF AT LOW RISK FOR NEPHROTOXICITY **Dose:** **1-1.5 mg/kg/day**	PREFERRED AGENT **DOSE:** **5 mg/kg/day**	POSACONAZOLE MAY HAVE A ROLE FOR CERTAIN PATIETNS BUT DATA ARE LIMITED AND SUSCEPTIBILITY BREAKPOINTS ARE NOT ESTABLISHED: CONTACT AUR PHARMACIST OR ID FACULTY IF CEREBRAL INVOLVEMENT, CONTACT AUR PHARMACIST OR ID FACULTY

2007 CSMC fungal blood isolates with susceptibility results (N=64):

C. albicans: 32 isolates

C. glabrata: 21 isolates (52% dose dependent susceptible or 19% fully susceptible to FZ; 71% susceptible to voriconazole)

C. parapsilosis: 11 isolates

References available on request

Revised 7/08

[1] Use intravenous formulation ONLY if NPO

[2] Dose based on total body weight. For voriconazole, total body weight greater than 130kg not studied

[3] Avoid intravenous Voriconazole if CrCl <50 ml/min unless benefit outweighs risk (such as documented invasive aspergillosis and NPO)

[4] Liver failure (Child-Pugh >7) use Caspofungin 70 mg load dose, then 35 mg daily

[5] No Clinical Correlation with reported MIC values

2008 EMPIRIC TREATMENT RECOMMENDATIONS FOR COMMON PEDIATRIC INFECTIONS

APPROVED BY : PEDIATRIC INFECTIOUS DISEASES, ANTIBIOTIC USE REVIEW COMMITTEE, PEDIATRIC P&T

BASED ON GUIDELIENS FROM THE INFECTIOUS DISEASES SOCITEY OF AMERICA AND THE CSMC 2007 ANTIBIOGRAM

Antibiotic resistance is increasing in the Medical Center and is a direct result of wide-spread, and prolonged use of broad-spectrum antibiotics. We strongly discourage use of these agents except when resistant pathogens are highly suspected and limited to the shortest acceptable duration.

INFECTION SITE	SUSPECTED PATHOGENS	RECOMMENDED INTRAVENOUS DRUGS	SPECIAL CONSIDERATIONS	ORAL TRANSITION[1]
LUNG (Community acquired)	*S. pneumoniae* *H. influenzae* *M. catarrhalis* *S. aureus* Atypical (>5 years)	Cefotaxime ± macrolide	*If suspect parapneumonic process (abscess, empyema):* cefotaxime + clindamycin ± macrolide Suspect MRSA: add vancomycin (trough 15-20) +/- clindamycin	Cefuroxime ± macrolide **OR** amox/clav ± macrolide
LUNG (Hospital acquired)	Enterobacteriaceae Resistant GNB *S. aureus* *H. influenzae* *S. pneumoniae*	Cefepime + tobramycin, or Piperacillin/tazobactam[3] + tobramycin	*Critically ill*[2] : imipenem[3]+ Amikacin+ Vancomycin Suspect MRSA: add vancomycin (maintain trough 15-20)	Not recommended
URINARY TRACT & PYELONEPHRITIS (Community acquired) >3 months	Enterobacteriaceae Enterococcus	Cefotaxime and ampicillin	*Consider oral transition after 2-3 days of IV therapy*	TMP/SMX, **OR** Cephalexin
ABDOMEN (Community acquired)	Enterobacteriaceae *B. fragilis* Enterococci	Cefotetan + metronidazole	**BILIARY TRACT INVOLVEMENT**: add ampicillin	Amox/clav, **OR** cephalexin + metronidazole
ABDOMEN (Hospital acquired)	Enterobacteriaceae Resistant GNB Enterococci *B. fragilis*	Piperacillin/tazobactam[3] + tobramycin	*Critically ill*[2]*:* imipenem[3] + tobramycin Suspect *C. difficile:* metronidazole NEC : Amp/Tobra/Flagyl or for patients experiencing antibiotic failure use piperacillin/tazo and tobramycin	Not recommended
FEVER WITH NEUTROPENIA (see pathway for complete algorithim)	Enterobacteriaceae Resistant GNB Staphylococci	Piperacillin/tazobactam[3] + tobramycin[4]	*Critically ill*[2]*:* imipenem[3] + amikacin + vancomycin *Erythema and tenderness at line exit site:* add vanco PCN allergy: Cefepime + tobramycin	Not indicated
RULE OUT SEPSIS Age < 1 month	GBS E. coli Listeria	Ampicillin + gentamicin	*Suspect HSV*:consider acyclovir	Not recommended
RULE OUT SEPSIS Age ≥ 1 month	GBS *S. pneumo* *E. coli* Listeria	Cefotaxime 1-3 months: add ampicillin for listeria coverage	*Sickle cell disease:* - Cefotaxime - Critically ill: Add Vancomycin Meningitic doses until CSF obtained	Not recommended
SKIN (Community-acquired)	Streptococci (GpA) *S. aureus* (consider MRSA)	Oxacillin or cefazolin + clindamycin +Vancomycin for severe infections	*Suspect GABHS*[4] : pcn + clindamycin *Human/Animal bite*: Cefuroxime + clindamycin *PCN allergic*: TMP/SMX or clindamycin	MSSA or GAS: Dicloxacillin **OR** cephalexin MRSA: Clindamycin OR TMP/SMX
SKIN (Peri-orbital)	*Streptococci* *H. flu* *S. aureus*	Cefuroxime or Oxacillin + clindamycin	*Orbital involvement:* cefotaxime + clindamycin Suspect MRSA: add Vancomycin	Amox/clav **OR** Cephalexin **OR** Clindamycin
BONE & JOINT INFECTIONS	*S. aureus* *S. pyogenes*	Oxacillin or cefazolin + clindamycin	*Foot puncture: requires debridment and anti-pseudomonal coverage* (cefepime or pip/tazo)	Cephalexin, **OR** Dicloxacillin, **OR** clindamycin
MENINGITIS (Community acquired) Age ≤3 mo	*GBS* *E. coli* *Listeria* *S. pneumo*	Cefotaxime + ampicillin ± vancomycin (if bacterial highly suspected)	*Aseptic meningitis (<2 months):* consider HSV and empirically treat with acyclovir	Not recommended
MENINGITIS (Community acquired) Age > 3mo	*S. pneumoniae* *N. meningitidis* *H. influenzae*	Cefotaxime + vancomycin (if bacterial highly suspected) (trough 15-20)	*Immunocompromised:* - Consider Listeria, add ampicillin	Not recommended
MENINGITIS (Neurosurgery or head trauma or VP shunt)	*S. aureus/ S. epi* Enterobacteriaceae Resistant GNR *S. pneumoniae*	Cefepime + Vancomycin (trough 15-20) **Use maximal doses**	Externalization of shunt or hardware usually necessary for sterilization. *Critically ill*[2]: Meropenem + Vancomycin (trough 15-20) **Use maximal doses**	Not recommended

GNB=gram negative bacilli; GBS=group B streptococci; GABHS=Group B beta hemolytic strep

1: Consider early transition to PO using well absorbed antibiotics (after 2-3 days of IV therapy) if the following criteria are met: (1) functioning GI tract, (2) fever < 100.5 for 24 hours, (3) hemodynamic stability, (4) clinical improvement. **2**: Critically ill includes hemodynamic instability nd in the ICU. **3**: For patients with a history of serious penicillin allergy, substitute with aztreonam (nonformulary), ± vancomycin ± metronidazole as indicated. **4**: Consider for erysipelas, toxic shock syndrome, or scarlet fever

CSMC Proposed Plan for Management of Medications with Black Box Warnings – Revised 09/10/08

MEDICATIONS WITH EXISTING BLACK BOX WARNINGS

- 238 medications with formulary status
- 32 medications with formulary/restricted status
- Proposal for Zynx Health Incorporated to conduct evidence-based review of formulary medications with BBW to determine whether evidence supports changes to the formulary. **Zynx decided to not pursue at this time.**
- **MIDAS evaluation (previously presented) demonstrated no ADRs due to medications with Black Box Warnings**

MEDICATIONS WITH NEW BLACK BOX WARNING DESIGNATION

- New FDA black box warnings identified will be evaluated according to evidence-based literature
    - Obtain input from physicians with expertise in the areas where the particular medication is used
    - Recommendations developed through medical staff committee consensus
- Communication to medical staff via established communication channels (e.g. Pulse and Sutures)
- Pharmacy and Therapeutics Committee to evaluate recommendations and determine whether action is warranted based on evidence

PRE-CS-LINK PLAN FOR BLACK BOX WARNINGS

- **Link to Black Box Warnings placed in WebVS below medication list**
- **Proposal to flag medications with Black Box Warnings in WebVS for patients on routine care units (HartMeds)**