CEDARS-SINAI MEDICAL CENTER

Pharmacy and Therapeutics Committee Approvals
August 2016

Agenda Item	P&T Committee Decision
Drugs for Formulary Consideration	**Riociguat (Adempas®)** – restricted to patients on therapy prior to admission Indications: treatment of adults with persistent/recurrent chronic thromboembolic pulmonary hypertension (CTEPH) after surgical treatment or inoperable CTEPH and pulmonary arterial hypertension (PAH) Usual dose: 1 mg orally 3 times daily Precautions: embryo-fetal toxicity (see REMS below), hypotension, bleeding Monitoring: monitor for hypotension, bleeding, and pulmonary edema **Riociguat Risk Evaluation & Mitigation Strategy (REMS) Procedure** This medication is associated with a REMS process due to teratogenicity. In order to comply with this process: 1. Add the following order questions to CS-Link for female patients – Is this for continuation of therapy? Subsequent questions will address enrollment in Adempas® REMS program. – Is the patient pregnant? For female patients between 12-55 years of age. If no, last date negative pregnancy test must be documented in the comments section 2. Add a link to the CSMC REMS procedure document and medication guide 3. Allow pharmacist to order a pregnancy test if unable to confirm the patient's pregnancy status. For continuation of therapy, when patient enrollment status cannot be confirmed after hours: 1. Allow patients to use own medication (if available) OR 2. Dispense enough medication until the next business day when enrollment status can be confirmed when the benefits of continuing therapy outweigh the risks **Gallium-68 dotatate (Netspot®) –** added to imaging formulary Gallium 68 dotatate is a radiopharmaceutical approved by the FDA in June 2016. It is indicated for use with positron emission tomography (PET) for localization of somatostatin receptor positive neuroendocrine tumors in adult and pediatric patients. Gallium 68 dotatate offers several advantages over the current product which is In-111 (Octreoscan®) including lower radiation exposure, improved imaging and the convenience of 1 scan (1 hour post injection vs imaging at 24 and 72 hours post injection for In-111). **Gadolinium Based Contrast Agents for MRI** The imaging department evaluated the safety and use of gadolinium based contrast agents (GBCA's) in light of a recent FDA warning regarding brain deposition of gadolinium. – The use of linear gadolinium agents (Optimark® and Omniscan®) will be restricted to situations where other (non-linear) agents are contraindicated and the benefits outweigh the risks. – Non-linear gadolinium agents such as Gadovist® and Multihance® are recommended as first line imaging agents. **Additional Items** – Phentolamine – product was not available previously. Add to formulary. – Leuprolide acetate for depot injection (Lupron® Depot – Ped) – add to outpatient formulary for treatment of precocious puberty – Doxorubicin lyophilized 50mg vials Shortage – FDA allows temporary importation of product from India. Allow use during shortage period.
Antimicrobial Stewardship	**Dalbavancin (Dalvance®) and Oritavancin (Orbactiv®)** – not added to formulary Dalbavancin & oritavancin were FDA approved for the treatment of acute bacterial skin and skin structure infections (aBSSSI) caused by susceptible gram-positive bacteria. – Dalbavancin (Dalvance®) – Usual dose: 1500mg IV x1 over 30 minutes – Precautions: serious hypersensitivity reactions have been reported; rapid infusion can cause reactions similar to Red Man Syndrome Monitoring: no Boxed warnings or REMS required – Oritavancin (Orbactiv®) – Usual dose: 1200mg IV infusion x1 over 3 hours – Precautions: increased bleeding risk with warfarin- artificially prolongs PT/INR for 24 hr and aPTT for 48 hrs – Monitoring: no Boxed warnings or REMS required

	MCS Antibiotic Selection for Surgical Prophylaxis Protocol In collaboration with the mechanical cardiac support (MCS) team and the Division of Infectious Diseases, surgical prophylaxis guidelines for MCS patients were developed. Please refer to the document for details: http://sharepoint/clinical/PharmacyKnowRepo/clinop/Clinical%20Library/Infectious%20Diseases/MCS%20Antibiotic%ection%20for%20Surgical%20Prophylaxis.pdf **Removal of Pneumococcal Vaccination Nursing Screening – Implementation Date TBD** Current Advisory Committee on Immunization Practices (ACIP) recommendations for the use of pneumococcal conjugate vaccine (PCV13, Prevnar13®) and pneumococcal polysaccharide vaccine (PPSV23, Pneumovax®) specify the timing, age, and comorbidities that determine the correct administration of the 2 types of pneumococcal vaccines. The challenges associated with the current inpatient vaccination screening tool include: 1. Complexity of screening for the appropriate pneumococcal vaccine 2. The risk of diminished antibody response to PCV13 in the setting of concurrent inactivated influenza vaccine in adults 3. Potential for duplicate vaccination 4. Reliance on patient's recollection of timing and specifics of vaccines received 5. Look-alike, sound-alike errors 6. Lack of a TJC or CMMS mandate for inpatient screening Based on these guidelines and the above challenges, the following recommendations were approved: 1. Remove current CSMC pneumococcal vaccination nursing screening tool 2. PCV13 and PPSV23 will be dispensed based on physician orders 3. Build a pneumococcal vaccine CS-Link Panel to assist with product selection based on national guidelines **Ophthalmic Antibiotics for Endophthalmitis Prophylaxis in Cataract Surgery – Implementation Date TBD** Based on available literature and input from the Divisions of Infections Disease and Ophthalmology, the following guidelines were approved: 1. Routine use of antibiotic irrigation solutions is not indicated, given lack of literature-supported benefit over non-antibiotic-containing irrigation solutions. If irrigation use is warranted, use balanced salt solution only 2. In high risk patients, intracameral antibiotic injection can be considered. Cefuroxime 1mg/0.1mL will be the preferred agent within the Cedars-Sinai Health System for intracameral injection due to its wide use, demonstrated efficacy, and safety profile. **Antimicrobial Stewardship QC Updates** FY17 goals for Antimicrobial Stewardship: 1. Improve the optimal (effective) use of antibiotic therapy by 30% through the following strategies: a. Improve efficiency of the BPA through best practices and scale the BPA to additional units. b. Implement updated Rapid Diagnostic Test language and increase awareness through marketing and education. 2. Reduce unnecessary urine studies by 30% in targeted areas. a. Identify and implement strategies to improve urine testing and interpretation per evidence based guidelines. **2015 Antibiogram – Revision** The following was added: MRSA susceptibility to clindamycin is 82% (n=17) for patients aged <18 years. **IM Vaccines in Anticoagulated Patients** IM vaccine injections can be safely administered in anticoagulated patients. The following administration instructions will be added to all therapeutic anticoagulants (heparin infusion, LMWH >30mg BID and 40mg daily/BID, warfarin, apixaban, rivaroxaban, dabigatran, argatroban): – 'RN Please Note: OK to give intramuscular VACCINES as ordered'. **Order Sets with Urine Studies – Implementation Date TBD** UA and/or urine culture will be removed from selected order sets in attempt to reduce unnecessary treatment of asymptomatic bacteriuria.
Other Updates	**Low Dose Ketamine Infusion (0.05 – 0.5 mg/kg/hr) for Treatment of Refractory Chronic Pain Policy** Low dose ketamine infusions have been approved for the treatment of refractory chronic pain. These infusions can only be administered in the PACUs or ICUs. For treatment of refractory chronic pain, the ketamine infusion dosage range is 0.05-0.5mg/kg/hour with a maximum rate of 50mg/hour. **Disease Research Group (DRG) Guidelines Update** As part of the DRG guidelines update for gastrointestinal malignancies, multiple myeloma, breast cancer and urologic cancers, the following medications were recommended for formulary addition: 1. Liposomal irinotecan (Onivyde®) 2. Daratumumab (Darzalex®) 3. Nivolumab (Opdivo®) 4. Atezolizumab (Tecentriq®)

Pediatric Pharmacy & Therapeutics Committee

NICU Parenteral Nutrition Guidelines and Addition of Heparin to Stock TPN
The NICU parenteral nutrition guidelines were updated based on a review of recent publications and recommendations from neonatal physicians and dieticians, pediatric gastroenterology, surgery, nephrology and neonatal pharmacists. Additionally, 125 units of heparin will be added during pharmacy IV preparation to stock (vanilla) TPN to improve lipid absorption.

IVIG for Hemolytic Disease of the Newborn
The 2004 American Academy of Pediatrics Guidelines for treatment of hyperbilirubinemia state that IVIG has been shown to reduce the need for exchange transfusions in Rh and ABO hemolytic disease. The recommended dose is 0.5–1.0 g/kg over 2 h with a repeat dose after 12 hours as needed. Based on the available literature, it was approved that IVIG 1g/kg (with a repeat dose of 0.5 g/kg in 12 hours if total serum bilirubin continues to rise) be used for the treatment of hemolytic diseases of the newborn.

Standardized Definition of "Female of Reproductive Potential"
REMS requirements do not always provide a definition of Female of Reproductive Potential (FRP) based on an age range which can potentially cause issues in identifying affected patients. The CSMC definition of "females between the ages of 12-55 years" for FRP will be applied to REMS medications unless an age range is specified in the REMS requirements.

Boxed Warning Updates: NSAIDs, iloperidone, Involamet®, lomitapide, mipomersen, ezogabine, Kadcyla®
There were changes to the above drugs' BBW language, but none resulted in changes to current practice.

Medication Management Safety Committee
Best Practice Management of Weights - *informational*
ISMP has released Best Practice recommendations with respect to accurate documentation of patient weight:
1. Weigh each patient as soon as possible on admission and during each appropriate outpatient or emergency department encounter. Avoid the use of stated, estimated or historical weight.
2. Measure and document patient weights in metric units only.

The following efforts are in process:
1. ED changes
   a. Dedicated staff to weigh patient in triage to eliminate use of estimated/stated weight
   b. RN review of entered weights in the ED System once a patient is roomed
2. Heparin infusion ERX revision which provides a Best Practice Alert (BPA) when dose change exceeds 15%
3. Assess if CS-Link can provide both metric and pounds by 'hovering' over weight which would eliminate need for placing conversion charts on the scales
4. Diminish use of written weights by eliminating paper order forms
5. Encourage EPIC to adopt the metric scale exclusively

Direct Oral Anticoagulant (DOAC) Summary - Updated
The summary was revised to include updates regarding heparin-induced thrombocytopenia recommendations, drug interactions, and reversal agents. Please see the summary for details:
http://sharepoint/clinical/PharmacyKnowRepo/clinop/Clinical%20Library/Anticoagulation/DOAC%20Comparison%20Table.pdf

Atrial Fibrillation Protocol Update: vitamin C, vitamin E, and fish oil
This protocol involves the preoperative use of n-3 PUFA 1.8 gm, Vitamin C 1 gm and Vitamin E 400 IU daily for 7 days prior to surgery and continued until discharge with the goal of reducing the incidence of post-operative atrial fibrillation. Due to the promising results to date (April-July 2016), the TOC will be extended through December 2016 to increase the number of patients enrolled, thereby increasing the power and ability to more accurately measure the impact of the therapy.

Total Parenteral Nutrition: Administration Clinical Nursing Policy - Revision
Administration of lipids require a separate 1.2 micron filter and should not be run through the 0.22 micron filter for the TPN. If lipids are to be simultaneously administered, administer lipids piggyback through a 1.2 micron filter at the Y-port most proximal to the patient so that they do not infuse though the 0.22 micron TPN filter.

Policies and Procedures Revisions (please refer to the intranet for the most updated version)
Policies & Procedures
- Chemotherapy Extravasation Treatment Procedure: Medication Management
  http://cshsppmweb/dotNet/documents/?docid=30031&mode=view
- Chemotherapy Ordering and Checking (MM.01.01.03a) Procedure: Medication Management
  http://cshsppmweb/dotNet/documents/?docid=38485&mode=view
- Chemotherapy Administration, Safe Handling Precautions, Accidental Spill Clean-up and Medical Surveillance of Employees Policy: Clinical Manual/General Clinical
  http://cshsppmweb/dotNet/documents/?docid=37084&mode=view
- Total Parenteral Nutrition: Administration Clinical Nursing Policy
  http://cshsppmweb/dotNet/documents/?docid=29557&mode=view

	– Anticoagulation Therapy (Standard), Clinical Procedure http://cshsppmweb/dotNet/documents/?docid=40497&mode=view – Disaster Plan MM.02.01.01.c Procedure: Medication Management http://cshsppmweb/dotNet/documents/?docid=40395&mode=view – Discharge Prescriptions (MM.07.01.01.d) Procedure: Medication Management http://cshsppmweb/dotNet/documents/?docid=31842&mode=view – Staff Expectations Procedure: Pharmacy http://cshsppmweb/dotNet/documents/?docid=40345&mode=view – Monthly Inspection and Coordination (MM.03.01.01.c) Procedure: Medication Management http://cshsppmweb/dotNet/documents/?docid=33363&mode=view – Outpatient Pharmacies: Pricing and Billing Procedure: Pharmacy http://cshsppmweb/dotNet/documents/?docid=39206&mode=view – Technician - Check -Technician Procedure: Pharmacy http://cshsppmweb/dotNet/documents/?docid=38876&mode=view – Dispensing (MM.05.01.11) Procedure: Medication Management http://cshsppmweb/dotNet/documents/?docid=38755&mode=view – Interdepartmental Orders Procedure: Pharmacy http://cshsppmweb/dotNet/documents/?docid=38754&mode=view – Unit Dose Packaging (MM.05.01.11.a) Procedure: Medication Management http://cshsppmweb/dotNet/documents/?docid=15654&mode=view – Immunization EHS Nursing Protocol – GI Motility Program Breath Testing - Lactulose, Lactose, Glucose, Fructose Standardized Procedure Clinical GI Motility Program Policy: Clinical Manual/General Clinical http://cshsppmweb/dotNet/documents/?docid=33239&mode=view **IV Guidelines** http://web.csmc.edu/clinical/clinical-departments/pharmacy/iv-guidelines.aspx – Cangrelor (Kengreal®) IV guideline – Norepinephrine (Levophed®) IV guideline – Posaconazole (Noxafil®) IV guideline