Guidelines for Use of Palivizumab (Synagis) for RSV Prophylaxis  
2016-2017 Season 

Authors:  Caren Liviskie, PharmD, BCPPS; Christopher McPherson, PharmD; Brandy Zeller, PharmD, BCPPS 

A. Eligibility Criteria for prophylaxis of high-risk infants and young children:

1. Premature Infants (Born at ≤28 6/7 weeks gestation) in the first year of life

2. Infants with Chronic Lung Disease (CLD)/Bronchopulmonary Dysplasia (BPD) who are:
   i. <12 months of age AND <32 weeks gestation AND required oxygen supplementation for at least the first 28 days of life
   ii. <24 months of age AND have required medical therapy for CLD/BPD within 6 months of start of RSV season (On or after 5/1/2016)
      1. Medical therapy defined as ANY ONE of the following:
         a. Supplemental oxygen
         b. Chronic corticosteroids
         c. Diuretics

3. Infants with Congenital Heart Disease (CHD) who are <12 months of age with hemodynamically significant disease, defined as ANY ONE of the following:
   i. Receiving medication to control congestive heart failure
   ii. Has moderate to severe pulmonary hypertension
   iii. Has cyanotic heart lesion
   iv. The following group of infants should NOT receive prophylaxis:
      1. Infants with hemodynamically insignificant heart disease
      2. Infants with heart lesions adequately corrected by surgery, unless requiring medication for congestive heart failure
      3. Infants with mild cardiomyopathy who are NOT receiving medical therapy for the condition
      4. Children with CHD in the second year of life

4. Other Considerations
   i. Infants with congenital abnormalities of the airway (including congenital diaphragmatic hernia) or neuromuscular condition that compromises handling of respiratory secretions in the first year of life
   ii. Severely immunocompromised children (ex. Severe combined immunodeficiency or advanced immunodeficiency syndrome)
   iii. Lung transplant recipients less than 2 years of age
   iv. Patients receiving extracorporeal membrane oxygenation (ECMO) management or cardiopulmonary bypass that qualify for palivizumab should be considered for an additional dose of 15 mg/kg after bypass or ECMO course
B. **Process of Palivizumab Administration**
   1. If the indication is consistent with the above guidelines, palivizumab will be administered within 48-72 hours of the patient’s anticipated discharge on either Mondays or Thursdays
      i. Make sure to discuss plan for follow up outpatient doses with discharge planner/care coordination/outpatient provider
   2. Period of prophylaxis will begin on November 1st and end on March 31st
   3. Consent is not required

C. **Breakthrough RSV infection:** If an infant or child receiving palivizumab prophylaxis experiences a breakthrough RSV infection, monthly prophylaxis should be **discontinued** due to the low incidence of a second hospitalization due to RSV in the same season.

D. Infants who are admitted to the hospital during the RSV season (not for an RSV infection) and who have already been started on palivizumab prophylaxis should continue the scheduled monthly prophylaxis.
   1. Consider waiting until after discharge if scheduled dose only off by a few days

E. If an **RSV outbreak** is documented in the NICU, accepted guidelines indicate that primary emphasis should be placed on proper infection control practices, especially hand hygiene. No data exist to support palivizumab use in controlling outbreaks of health-care associated disease, and palivizumab use is **NOT** recommended for this purpose.

F. Palivizumab is **NOT** effective and is not FDA approved for the treatment of RSV disease.

G. Palivizumab does **NOT** interfere with response to vaccines.

H. **Contraindications**
   1. Palivizumab should not be used in patients with a history of severe allergic reaction to a previous palivizumab dose or other components of the product.

I. **Adverse Events**
   1. Fever, irritability, and injection site reaction are the most commonly reported adverse events.

J. Administration of palivizumab to any patient in the hospital outside of the above eligibility guideline criteria must be discussed with the Antimicrobial Stewardship Team.

**Drug Shortages and Reminders**

---DHE (dihydroergotamine) continues to be in short supply and SLCH’s current supply expires at the end of November 2016. As of December 1st, 2016, SLCH does not expect to receive any DHE shipment until the earliest, the end of December. Until this shortage resolves, prescribers in both the Neurology department and the EU will have to continue to utilize other migraine treatment options. Some of these options include: toradol and compazine, valproic acid IV and magnesium IV, until this shortage resolves. All policies and procedures must be applied if necessary when using high risk medications. Please contact the Neurology or pharmacy department for any other questions, concerns or treatment options.

---As a reminder, all narcotics whether IV or PO that are compounded in syringes, will be prepared and capped with red tamper resistant caps. A red cap is a means to provide secure/reliable tamper resistant protection for SLCH’s compounded/pre-packed narcotics.

---Procainamide injection is in VERY short supply nationwide. SLCH currently has no supply (with estimated product release of 4th quarter 2017). With no product availability, procainamide vials are no longer in the OR CT carts. Please let the heart center pharmacists or EP team know if any questions arise regarding the shortage or potential alternatives (as applicable). SLCH will keep the key stakeholders updated as new information and additional information becomes available.

---Outpatient Pharmacy: Hours of operation 9am-6 pm Monday through Friday. Please remember to send down discharge and re-label prescriptions as soon as possible when written. If possible, communicate the approximate discharge time for the pharmacy to prioritize. The families or caregivers should pick up the prescriptions within the above hours of operation even though a patient may be discharged after hours or on the weekend.
SLCH Anticoagulation Policy

Purpose: To ensure the safe use of anticoagulation therapy in hospitalized patients.

Policy Statements
A. The Anticoagulation Safety Team, which includes members from the Medical Staff, Nursing Staff, and Pharmacy Staff, will develop and implement all protocols for dosing and monitoring anticoagulation therapies.
B. The Pharmaceutics, Diagnostics, & Therapeutics Committee will review and have final approval on anticoagulation protocols and the anticoagulation safety program.
C. Designated order sets within computerized provider order entry (CPOE) will be used for initiating and adjusting doses of warfarin, unfractionated heparin, and low molecular weight heparin for therapeutic anticoagulation. These order sets will include dosing parameters, and information regarding the required baseline and ongoing laboratory monitoring. Relevant laboratory values will be pulled into the order set as appropriate based on the anticoagulant ordered.
D. The pharmacist will verify all dosing calculations, per the order set, prior to dispensing warfarin, unfractionated heparin, and low molecular weight heparin for therapeutic anticoagulation.
E. The nurse will verify all dosing calculations and required laboratory parameters per the order set prior to administering warfarin, unfractionated heparin, and low molecular weight heparin for therapeutic anticoagulation.

Procedure
A. Warfarin
1. Prescribing and Monitoring
   a. For new starts, a baseline INR must be obtained within 7 days prior to warfarin initiation.
   b. For patients receiving continuation of existing therapy, documentation of a current INR obtained within the last 7 days is required.
2. Dispensing
   a. A pharmacist will screen the orders for possible drug interactions with warfarin.
   b. Exact patient doses are dispensed in single use or unit-dose packages to patient care units.
3. Administration
   a. The standard administration time for patients receiving warfarin is 8 p.m. unless the documented home medication time differs from the standard and is deemed necessary.
4. Reversal
   a. An order set for warfarin reversal exists within CPOE and will be utilized when warfarin reversal is deemed necessary.

B. Unfractionated Heparin
1. Prescribing and Monitoring
   a. A baseline aPTT, and CBC, within 48 hours of heparin initiation, are required for all patients.
   b. The aPTT will be checked every 4 - 6 hours until therapeutic aPTT is achieved per the order set and then the aPTT will be checked every 24 hours thereafter. Routine CBCs should be considered to monitor for decreased hemoglobin/hematocrit and platelets. Specific order sets/information are available for patients with Ventricular Assist Devices, ECMO and post cardiac catheterization.
2. Dispensing
   a. Continuous infusions of heparin will be entered into the pharmacy system as demand items.
   b. A standardized, commercially available, heparin concentration of 100 units / mL will be used to prepare continuous infusions. A standard volume of 50 mL will be drawn into a syringe. A 250 mL bag will be prepared for large patients with higher infusion rates. The medication will be labeled appropriately and a green heparin auxiliary sticker will be placed on the label to alert staff.
   c. The final product will be hand delivered to the unit or sent as a secured carrier via the pneumatic tube system.
3. Administration
   a. Continuous heparin infusions are administered via programmable pumps utilizing safety software.
   b. An independent double check is required for continuous heparin infusions. Refer to the Medications: Independent Double Check policy.
C. Low Molecular Weight Heparin

1. Prescribing and Monitoring
   a. A baseline CBC, within 48 hours of low molecular weight heparin administration, is required or all patients.
   b. The antiXa level will be checked within the first 48 hours of therapy and with dosage changes until a therapeutic level is achieved per the pre-printed order set.
   c. After a therapeutic level is achieved, a monthly CBC and antiXa level are recommended.
   d. It is not necessary to monitor the antiXa level in adult-size patients receiving a normal adult dose.

2. Dispensing
   Individualized, patient specific doses will be prepared, labeled, and dispensed utilizing the commercially available concentration of 100 mg / mL. If the dose is <10mg, then a concentration of 20mg/ml will be utilized.

3. Administration
   Doses are administered subcutaneously.

D. Education

1. The Pharmacy Department will work in collaboration with Dietary Services and when ordered provide warfarin - food interaction review and education.
2. Pharmacists provide patient / family education on warfarin, including written information that addresses follow-up monitoring, compliance, possible drug-food and drug-drug interactions, and adverse drug reactions.
3. At least annually, pharmacists, nurses, and clinical dieticians will receive education on the safe use of anticoagulants via the Learning Management System.
4. At least annually, physicians will receive education / updates on the safe use of anticoagulants via newsletters.

E. Process Improvement

1. The Safe Medication Practices Subcommittee reviews reported events and near misses related to anticoagulants on an ongoing basis to identify and implement improvement strategies. Every six months, the Subcommittee will provide a report to the Anticoagulation Safety Team and the Pharmacy, Diagnostics, & Therapeutics Committee as part of the hospital-wide adverse drug event program.
2. Periodic evaluation of order set compliance and efficacy of dosing / monitoring strategies will be completed.
3. Pharmacy Expert System (PES) reports will be evaluated. The PES anticoagulation alerts include:
   a. INR > 5 and no vitamin K
   b. Warfarin drug interaction with high or low INR
   c. Warfarin therapy and no INR
   d. Anticoagulation / epidural contraindication
   e. Renal dosage adjustments for low molecular weight heparin.