

**Meeting Minutes**  
**January 5, 2026**

Medical Staff:

- |  |  |   |   |
|--|--|---|---|
| <input checked="" type="checkbox"/> Ryan Millerr, DO P&T Chair | <input type="checkbox"/> William Britton, MD | <input type="checkbox"/> Christopher LaFond, MD         | <input checked="" type="checkbox"/> Emily Dryer, DO |
| <input checked="" type="checkbox"/> Todd Adams, DO             | <input type="checkbox"/> Kelly Clark, MD     | <input type="checkbox"/> Jordyn Emery, PGY2 FP Resident | <input type="checkbox"/> Haley Kopkua, MD           |
| <input type="checkbox"/> Jordyn Emery, PGY3                    |  |   |   |

Hospital Staff:

- |   |   |  |  |
|---|---|--|--|
| <input type="checkbox"/> Butch Bowlby, RPh, MSA             | <input type="checkbox"/> Aimee Cloud, PharmD BCOP       | <input checked="" type="checkbox"/> Wendy Hunt, RN                 | <input type="checkbox"/> Alisa Siebenmorgan, PGY1      |
| <input checked="" type="checkbox"/> Cathi Cornelius, PharmD | <input type="checkbox"/> Jeff Durkin, RPh               | <input checked="" type="checkbox"/> DeAnne Mosher, RN              | <input type="checkbox"/> Kaitlyn Sutliff, PGY1         |
| <input checked="" type="checkbox"/> Emily Warner, PharmD    | <input checked="" type="checkbox"/> Brad Beaman, PharmD | <input type="checkbox"/> Samantha Smith, RN                        | <input type="checkbox"/> Cayman Dulz, PGY1             |
| <input checked="" type="checkbox"/> Heather Tolfree, PharmD | <input checked="" type="checkbox"/> Nick Torney, PharmD | <input type="checkbox"/> Heidi Swensson, Sr Clinical Informaticist | <input checked="" type="checkbox"/> Chris Geetings, RN |
| <input type="checkbox"/> Trevor Warner, PharmD              |   |  |  |

Guests: Dina Kennedy, PharmD and Lacey Knoop, RN

AGENDA ITEM	DISCUSSION	ACTION / CONCLUSION / RECOMMENDATION	RESPONSIBLE PARTY
Call to Order			
A. Welcome: Additions/ Corrections to Agenda	Dr Miller called the meeting to order at 1216. There were not additions or correction to be made to the agenda.		R Miller
B. MMC P&T Minutes	Members were asked to approve the MMC P&T Committee meeting minutes from December 2025 ( <a href="#">link</a> )	Motion by H Tolfree second support from B Beaman, all attendees in support	R Miller
C. Ancillary Meeting Minutes	1. MMC P&T Subcommittee December 11th, 2025 ( <a href="#">link</a> ) 2. MHC System P&T Meeting Minutes: December 2025 ( <a href="#">link</a> )	Informational	R Miller
<b>Consent Agenda Items</b>			
D1. IV Administration Guideline	Modified wording re: tele competent vs trained RN; change acetylcysteine to approved for all levels of care	For Information only – Approved at System P&T – See MHC System P&T December Minutes ( <a href="#">link</a> )	H Tolfree
D2. Hypoglycemia Protocol for Pediatric Patients	Updates to table for clarity, removed oral glucose options not stocked at MHC		
D3. Naloxone Nasal Spray Discharge Prescription Standing Order	Routine review, no changes		
D4. Pharmaceutical Representatives	Slight modifications to approved areas of access, prohibition of P&T influence, loss of access privileges and registration requirements		
D5. Parenteral Potassium Policy	Updated administration guidelines for potassium chloride and phosphate. - Key changes: <ul style="list-style-type: none"> <li>Peripheral concentration max: 7 mmol/100 mL (previously 15 mmol).</li> <li>Standard dilution: 250 mL saline for peripheral administration.</li> <li>Monitoring and infusion rate clarified for central vs peripheral route and tele vs non-tele (max 7.5 mmol/hr if not on tele).</li> </ul>		
D6. Post Thrombolytic Care	New PowerPlan/nursing care guide implemented to address gap in post-thrombolytic management		
D7. Medication Administration	Clarified guidance on duplicate medications for same indication, route selection, and PRN administration based on patient preference. Adjusted time-critical medication list (removed pramipexole and ropinirole).		
D8. Pneumonia PowerPlan	Consolidated ED and inpatient plans. Added IV-to-PO conversion options for antibiotics; influenza antiviral guidance included. Blood cultures unchecked by default.		
D9. Renal Dosing Policy	Updated dosing for Bactrim (especially for Stenotrophomonas infections) per latest IDSA guidance		
<b>New/Old Business</b>			

AGENDA ITEM	DISCUSSION	ACTION / CONCLUSION / RECOMMENDATION	RESPONSIBLE PARTY
E. Corxel Study ( <a href="#">attached</a> )	D Kennedy, D Mosher and L Knoop presented the new Phase 2/3, multicenter, randomized, double-blind, placebo-controlled, parallel-group study to evaluate the efficacy and safety of JX10 in adult participants with acute ischemic stroke with late presentation. JX10 is a thrombolytic agent that induces conformational changes in plasminogen causing fibrin-targeted clot dissolution, potentially lowering hemorrhagic risk due to anti-inflammatory (she inhibition) and antioxidant effects. The drug will be administered as a single IV infusion. Dr Ramiro Castro-Apolo will be the principal investigator. This study has been approved by MHC IRB.	Informational	D Kennedy
F. Aerosolized Prostacycline Protocol ( <a href="#">attached</a> )	Updates to locations approved to administer	Motion by H Tolfree second support from T Warner, all attendees in support	H Tolfree
G. Autotransfusion ( <a href="#">attached</a> )	Update policy to clarify who may administer. Also removed preparation of medication section as pharmacy will now be assisting with this prep.	Motion by T Warner second support from B Beaman, all attendees in support	T Warner
H. Osmotic Therapy Subphase ( <a href="#">attached</a> )	New addition to the Critical Care PowerPlan presented by T Warner. R Miller suggested adding clarification note to indicate this subphase is not for TBI. The TBI powerplan should be used in those cases.	Motion by R Miller to approve with title clarification second support from H Tolfree, all attendees in support	T Warner
I. Cardiac Cath and PCI PowerPlan ( <a href="#">attached</a> )	Added pharmacy to dose heparin orderable, soon Pharmacy will be dosing heparin across the system in a standard fashion. This new orderable will facility this enhancement.	Motion by H Tolfree second support from B Beaman, all attendees in support	H Tolfree
<b>Formulary Changes</b>			
J. Revefenacin ( <a href="#">attached</a> )	Long-acting muscarinic antagonist for COPD; once-daily nebulized therapy. <ul style="list-style-type: none"> <li>Recommend addition to formulary with 6-month financial impact review.</li> </ul>	Motion by B Beaman second support H Tolfree, all attendees in support	B Beaman
<b>Marketplace Status</b>			
K. Drugs Shortages ( <a href="#">attached</a> )	Educational Purposes only; no actions necessary		B Beaman
L. Drug Recalls	Nothing to Report		B Beaman
<b>Periodic Reports</b>			
M. Medication Safety/ Adverse Reaction/ Error Reduction/ ISMP Reports ( <a href="#">attached</a> )		Educational purposes only; no actions necessary	E Warner
Next Meeting	The next meeting is scheduled for 2/02/2026 via Microsoft Teams and in person in Dining Room 2.		

Adjournment at 1245

# **ORION (Corxel) Study Summary: Evaluation of JX10 for Acute Ischemic Stroke (AIS) with Late Presentation**

Principal Investigator: Ramiro Castro-Apolo, MD

Research Nurse: DeAnn Mosher, RN

Pharmacy Research Liaison: Dina Kennedy, PharmD

## **Study Overview:**

**Study Title:** Phase 2/3, multicenter, randomized, double-blind, placebo-controlled, parallel-group study to evaluate the efficacy and safety of JX10 in adult participants with acute ischemic stroke with late presentation

## **Rationale:**

Most AIS patients present beyond the 4.5hr window for current thrombolytic therapy. Existing lytics (alteplase/tenecteplase) rely on systemic plasminogen activation, leading to higher rates of intracranial bleeding and limited clot-specific activity. This is an opportunity for treatment 4.5 to 24 hrs from "last known well" (LKW).

## **Study Drug:**

JX10 is a thrombolytic agent that induces conformational changes in plasminogen causing fibrin-targeted clot dissolution, potentially lowering hemorrhagic risk due to anti-inflammatory (she inhibition) and antioxidant effects.

## **Objectives & Endpoints:**

- Primary Efficacy:
  - o mRS score 0-1 at Day 90 (no/minimal disability)
- Secondary Efficacy:
  - o Ordinal mRS, mRS 0-2
  - o Reperfusion/recanalization at 24 hrs
  - o NIHSS improvement at Day 7 or hospital discharge
  - o Endovascular thrombectomy (EVT) specific angiographic reperfusion
- Safety Endpoints:
  - o Symptomatic intracranial hemorrhage (ICH) within 36 hours
  - o Any ICH (24 hrs, 14 days), major bleeding, cerebral edema
  - o AEs, SAEs, 30-day and 90-day mortality

## **Overall Design:**

Two-Part Adaptive Study:

- Part 1: (Dose-Finding):
  - o 1 mg/kg JX10 vs 3 mg/kg JX10 vs placebo (1:1:1)
  - o Independent Data Monitoring Committee (IDMC) conducts interim analysis based on safety, PK, and mRS outcomes and selects optimal dose (n= 240 participants across all centers)
- Part 2: (Confirmatory)
  - o Optimal JX10 dose vs placebo (1:1) with roughly ~500 participants across centers with same primary endpoint

## **Drug Administration:**

- Single IV dose infusion (10% bolus over 1 min; 90% infusion over 30 min) via Smart Pump
- Does not delay EVT (patients can undergo EVT  $\geq$  1 hour after infusion starts).

## **Inclusion Criteria:**

- Age 18-90, NIHSS  $\geq$  5
- LVO on CTA/MRA or perfusion deficit, salvageable penumbra
- Treatment window: 4.5-6 hours (no perfusion) or 4.5-24 hrs with perfusion mismatch
- Pre-stroke mRS  $<2$  (or  $<1$  if age 86-90)

## **Exclusion Criteria:**

- Any ICH, coagulopathy, INR  $> 1.7$ , platelets  $<100K$ , CrCl  $<60$  mL/min/1.73m<sup>2</sup>, Severe hepatic impairment, recent major surgery/trauma or thrombolytic use, oral anticoagulants within 48 hrs, pregnancy/breastfeeding

## **Key Operational & Pharmacy Considerations:**

- Receipt and storage similar to all other IMP
- Preparation/handling similar to alteplase/tenecteplase and unblinded for pharmacy personnel ONLY to be done in Basement Pharmacy
- Close neurologic and BP monitoring first 24 hours (aligns with existing post-thrombolytic protocols)

## **Request for P&T Approval:**

- Use, storage, and preparation of IMP JX10
- Implementation of Corxel JX10 Study

## DISPENSING GUIDELINES

<b>Clinical Trial #:</b> JX10002	<b>Protocol Version/date:</b> v.2 (10/21/24)	<b>Rx Manual Version/date:</b> v.2 (3/28/25)
<b>PI:</b> Ramiro Castro-Apolo, MD		<b>Study Coordinator:</b> DeAnn Mosher
<b>Protocol:</b> A phase 2/3, multicenter, double-blind, placebo-controlled, randomized, parallel-group study to evaluate the efficacy and safety of JX10 in acute ischemic stroke with late presentation. (ORION STUDY)		
<b>Sponsor Name:</b> CORXEL		<b>Authorized Prescribers:</b> Neurology Providers

### JX10 -- 100 mg (Vial)

~ All doses to be prepared in Inpatient Basement Pharmacy ~

<b>Hazard Class</b>	This Investigational Medication Product (IMP) has been categorized as <b>NON-hazardous</b> .
<b>Supply</b>	<b>JX10:</b> Sterile lyophilized powder for injection 100 mg single-use vial <b>Placebo:</b> Lyophilized powder for injection Placebo single-use vial Appearance: white to light yellow powder Supplied in kits, each containing one vial of JX10 or placebo with a unique vial identification number
<b>Storage</b>	Inpatient Basement Pharmacy (Fridge #6- "Factor Fridge") -- Refrigeration (2°C to 8°C). Protect from light.

### DETERMINE TREATMENT ASSIGNMENT, DOSING, & ADMINISTRATION: (UNBLINDED)

<b>Randomization:</b> <i>Conducted by XX via Interactive Response Technology (IRT), which will assign each subject a specific vial kit number following registration. The IRT treatment assignment and kit number confirmation will be automatically emailed to the Pharmacist. Upon receipt, the Pharmacist <b>must print and file the documentation in the "Orion Study" Binder</b> (located in Basement Pharmacy) and use it for order entry and verification within MedManager.</i>
<b>Dosing:</b> The study drug dose and volume will be determined based on the subject's weight (rounded to the nearest 0.1 kg). Upon entry of the subject's weight by the Pharmacist, the IRT system will automatically calculate the number of vials required. <ul style="list-style-type: none"> <li>• Weight, dose, and volume should be rounded to the nearest 0.1 decimal place</li> <li>• See Attachment H: Drug and 0.9% NaCl Volumes for 1mg/kg JX10/Placebo</li> <li>• See Attachment I: Drug and 0.9% NaCl Volumes for 3mg/kg JX10/Placebo                     <ul style="list-style-type: none"> <li>◦ Maximum dose of 100 mg (JX10 1mg/kg) and 300 mg (JX10 3mg/kg)</li> </ul> </li> <li>• Pharmacist to use "Dose Calculation and Preparation Worksheet (Attachment F) during or immediately following dose preparation and place in the "ORION Study" Binder located in Basement Pharmacy</li> </ul> <p><b>JX10 1 mg/kg vs. JX10 3 mg/kg vs. Matching Placebo:</b> Administered as a single IV infusion over 31 minutes (IV bolus of 10% of the total dose over 1 min, followed by a continuous infusion of remaining 90% over 30 min)</p> <ul style="list-style-type: none"> <li>• Infusion via smart pump through a dedicated peripheral IV line</li> </ul>

**Commented [DK1]:** Per Pharmacy Manual (Pg 9): Trained unblinded site personnel will initially access IRT to register a subject. Treatment assignments for subjects will be determined and assignment will be provided by IRT and specific vial kit numbers will be assigned to the subject. The IRT treatment assignment and kit number confirmation emailed to the unblinded pharmacist must be printed and filed in the Pharmacy Binder."

Need to clarification on determining a reproducible and consistent process involving numerous pharmacists?

**Commented [DK2]:** Per Pharmacy Manual (Pg 9): "Study drug dose and volume will be calculated based on subject's weight. The # of vials needed to meet dose requirements will be calculated by the IRT system when site personnel enter the subject's weight into the system."

Seems like subject registration into IRT will have to be completed by the pharmacist to obtain dose, volume, and kit number assignments?

### PREPARE AND DISPENSE (follow Institutional Policies/Procedures for compounding sterile products)

<b>Ancillary Prep Supplies</b>	<p>Items for IMP reconstitution:</p> <ul style="list-style-type: none"> <li>• Sterile Water for Injection (SWFI)</li> <li>• Luer lock injection syringe (size will vary depending on dose)</li> <li>• Sterile needle</li> </ul> <p>100 mL 0.9% Sodium Chloride infusion bag or Empty sterile IV bag (100 mL capacity) Standard IV infusion set with pump or flow regulator <b>**DO NOT USE AN IN-LINE FILTER**</b></p>
<b>Pre-Dilution Instructions</b>	<ul style="list-style-type: none"> <li>• Confirm each kit number(s) of IMP vials match unique identification number(s) on label                     <ul style="list-style-type: none"> <li>◦ Can have up to five unique kit identification numbers for each study patient (if applicable)</li> </ul> </li> </ul>
<b>Diluent Bag</b>	Obtain prefilled 0.9% Sodium Chloride 100 mL infusion bag:

**Commented [DK3]:** Need to add to smart pump library (email Emily Warner)  
Total Volume= 80mL, with 8mL (10%) set at infusion rate at 480mL/hr (8mL/min) & 72mL (90%) set at infusion rate at 144mL/hr (2.4 mL/min)

**Commented [DK4]:** Per Eric Warren- we do carry PO bags (consisting of PP and PE) AND EVA bags in the pharmacy Per Eric Warren- this will be a NON-standard bag and we will need to ensure that labeling calls out exactly what is required to prep.

**Commented [DK5]:** Or- could use an empty sterile 100 mL IV bag and add 0.9% NaCl  
At most the study drug dose will be 5mL for 1mg/kg or 15mL for 3mg/kg dosing. So might be easier to go with prefilled 100mL NS bag and remove to get to a TV of 80mL.

<b>Reconstitution</b>	<ul style="list-style-type: none"> <li>Gently Reconstitute contents of each IMP vial with 5 mL of SWFI vial and manual mix via a swirling mechanism until powder dissolves (~ 5 minutes) <ul style="list-style-type: none"> <li>Final IMP concentration after reconstitution = <b>20 mg/mL</b></li> <li>Reconstituted solution should be used within 1 hour of preparation to prepare IV bag</li> </ul> </li> <li>Withdraw calculated volume (mL) of reconstituted IMP solution, then set aside</li> </ul>		
<b>Final Product Preparation</b>	<ul style="list-style-type: none"> <li>Withdraw and discard from the 0.9% Sodium Chloride infusion bag the following amount:  <i>Discarded amount = 20 mL + 10 mL (bag overfill volume) + IMP volume calculated above</i>  <b>*****Final Total Volume = 80 mL to be administered for ALL preparations*****</b> </li> <li>Slowly transfer reconstituted IMP solution into the prepared final 0.9% Sodium Chloride infusion bag</li> </ul>		
<b>Mix</b>	Gently invert bag 5-10 times to mix. <b>Do NOT shake.</b>		
<b>Stability from time of vial puncture:</b>		<b>Sterile Compounding Area – Room Temp</b>	<b>Sterile Compounding Area - Refrigeration</b>
	<b>Hang By</b>	<b>3 hours</b>	<b>N/A</b>
	<b>Expiration</b>	<b>4 hours</b> <small>**including 31 minutes for IV infusion</small>	<b>N/A</b>
<b>SAVE vials and boxes: All IMP (used, partially used, unused vials, unused IV infusion bags) must be retained at study site for IMP accountability</b>			
<b>Auxiliary Labels and/or Special Instructions:</b>		<b>**Flush line after administration**</b>	
<b>Do NOT Tube. Hand deliver to patient location as a STAT for the 1st dose and to the floor at scheduled times.</b>			
<b>COMPLETE INVESTIGATIONAL PRODUCT ACCOUNTABILITY DOCUMENTATION</b>			
<b>**To be completed by Inpatient Pharmacy</b>			
<b>**Following Documents kept in Fridge #6 “Factor Fridge” alongside study drug located in Basement Pharmacy</b>			
<ul style="list-style-type: none"> <li>Master Site Investigational Product Accountability Log (Attachment C)</li> <li>Dose Calculation and Preparation Worksheet (Attachment F)</li> </ul>			
<b>**Extra blank forms found in back of “ORION Study” Binder located in ED and Inpatient Basement Pharmacy</b>			

**Commented [DK6]:** Per RX Manual- Foaming may occur during mixing, and because of this, the final volume to be collected per vial is ~ 4.5-4.7mL, but the IRT vial assignment calculations assume 4 mL is recoverable which allows for IMP overfill.

**Commented [DK7]:** Per RX Manual (Pg 13): All partially used study meds/kits may be destroyed on-site according to institutional policy.

Given that this is blinded to everyone w/exception of Pharmacy- how do you want to handle IMP accountability? Do you want all vials saved and only destroyed once either Aleah or myself verify we have all of the records completed? If so, Aleah, should we have purchasers (Tony or Eric) hold on to all the used vials?



Origination 2/18/2022  
Last Approved N/A  
Effective N/A  
Last Revised N/A  
Next Review N/A

Owner Duane Croel:  
Clinical Coord -  
Resp Care  
Operations  
Area/  
Department Respiratory Care  
Applicability MMC

## Aerosolized Prostacyclin Protocol

### Purpose

To provide a plan for Inhaled Epoprostenol (iEPO) Administration.

### Background

- A. Pulmonary hypertension is a serious complication following cardiothoracic surgery. There are many factors that may attribute to the development of postoperative pulmonary hypertension which includes pre-existing pulmonary hypertension, heart or lung transplantation, prolonged time on cardiopulmonary bypass, or valve procedures. Pulmonary vasodilators may be used for treatment of pre and postoperative pulmonary hypertension.
- B. Acute respiratory distress syndrome is characterized by diffuse alveolar damage, leaky alveolar capillaries, and protein rich pulmonary edema. Traditional treatment strategies include addressing the underlying cause, conservative fluid management, lung protective ventilation strategies, and supportive care. A subset of patients develop severe refractory hypoxemia, in this patient population rescue therapies have shown to improve oxygenation.
- C. Traditionally inhaled nitric oxide (iNO) was the first agent shown to be a selective pulmonary artery vasodilator that has been shown to improve oxygenation; however nitric oxide has several associated toxicities such as methemoglobinemia, rebound pulmonary hypertension, and hemodynamic deterioration. An alternative agent, inhaled epoprostenol (iEPO), has proven to achieve similar results as inhaled nitric oxide for the management of pulmonary hypertension following cardiac surgery and refractory hypoxemia due to acute respiratory distress syndrome.
- D. Epoprostenol, a synthetic analog of prostacyclin, activates the prostaglandin receptor leading to an increase in the intracellular cyclic adenosine monophosphate (cAMP) through activation of adenylate cyclase in smooth muscle cells. The increase in cAMP results in relaxation of the smooth muscle cells. Epoprostenol's major pharmacological action is direct vasodilation of

pulmonary and systemic arterial vascular beds, and when delivered via inhalation, epoprostenol causes pulmonary vasodilation. By decreasing pulmonary vascular resistance, epoprostenol may improve cardiac output that is exacerbated by pulmonary vasoconstriction. The pulmonary vasodilation leads to improvements in ventilation perfusion mismatch and oxygenation without systemic hemodynamic effects.

## Protocol

### Indications

- A. Mechanically ventilated post cardio-thoracic surgical patients with acute postoperative pulmonary hypertension, refractory hypoxemia, or right sided heart failure.
- B. Mechanically ventilated patients in the intensive care unit (ICU) with refractory hypoxia due to acute respiratory distress syndrome.
- C. **Restrictions:**
  - 1. Adult patients located in A2, A3, ICU
  - 2. Cardiac Surgery may also initiate Operating Room.
- D. **Absolute Contraindications:**
  - 1. Known allergy or sensitivity to epoprostenol
  - 2. Active pulmonary hemorrhage

### Relative Contraindications

- A. Pregnancy
- B. Thrombocytopenia (platelets less than 50,000/uL)
- C. Patients less than 18 years of age

### Initiation of iEPO

- A. Cardiac surgery patients or mechanically ventilated patients in the ICU will be initiated on iEPO per order of a cardiothoracic surgeon or a pulmonary and critical care physician. iEPO will be managed by a respiratory therapist (RT).
  - 1. The providers will enter the order: "**Epoprostenol Inhalation-Initiation**"
  - 2. Once inhaled epoprostenol is ordered to start and verified by pharmacy, it will be administered by RT
    - a. Due to lack of compatibility data with other aerosolized medications, all other scheduled and as needed (PRN) nebulized medications should be discontinued by the primary team

### Administration by RT

- A. If RT received a provider order to start inhaled epoprostenol, RT will obtain syringes from

**pharmacy. RT will notify central pharmacy that iEPO is to be started and request that pharmacy may prepare 2 iEPO syringes for the patient for the next 24 hours.**

1. RT will prepare ventilator circuit and Aerogen nebulizer set.
2. iEPO will be the only medication attached to the syringe pump. No other intravenous (IV) or syringe modules are to be used on the pump being utilized for administration of iEPO.
3. Label pump and distal end of tubing "Epoprostenol for Inhalation"
4. Set-up Pump and transfer epoprostenol to 60-ml Aerogen syringe. NOTE: total volume for drug is 50 ml.
5. Double-check and document the epoprostenol route, calculations, and pump settings.
6. Initiate therapy and assess for desired clinical response.
  - a. If there is no clinical response at maximum dose after 2 hours, notify the providers to wean off therapy
  - b. Treatment may be continued if the desired clinical response is observed after 2 hours of treatment
7. Aerosol delivery into the ventilator circuit must be confirmed visually. Verify that the epoprostenol is running, a drip may be visualized approximately every 30 seconds. Due to the precise nature of the Aerogen medication nebulizer, it is not unusual for the nebulizer to appear as though it has run dry between drops of medication. This does not affect the dosing.

## Monitoring Parameters

- A. **Documentation of initiation, titration of dose, and wean MUST be noted in the patients MAR**
- B. Vital signs and hemodynamic parameters:
  1. (Blood pressure, heart rate, Oxygen saturation, CVP, CO, CI, PAP, SVR)
- C. Ventilator parameters will be continuously monitored and documented by RT upon setup and at 30 minutes post-initiation and then hourly
- D. If no dose change after first 4 hour and Vital signs are stable RT may change to every 2 Vent and nebulizer checks.
- E. Once weaning has begun, monitoring and documentation will be every 30 minutes until weaned off
- F. Monitor for symptoms of epoprostenol toxicity: jaw pain, headache, flushing, nausea, vomiting, diarrhea, abdominal pain, signs of bleeding, bronchoconstriction or hypotension

## References

- De Wet CJ, Affleck DG, Jacobsohn E, et al, "Inhaled Prostacyclin is Safe, Effective, and Affordable in Patients with Pulmonary Hypertension, Right Heart Dysfunction, and Refractory Hypoxemia After Cardiothoracic Surgery," J Thorac Cardiovasc Surg, 2004, 127(4):1058-67

- McGinn, K., & Reichert, M. (2016). A Comparison of Inhaled Nitric Oxide Versus Inhaled Epoprostenol for Acute Pulmonary Hypertension Following Cardiac Surgery. *Annals of Pharmacotherapy*, 50(1), 22–26. <https://doi.org/10.1177/1060028015608865>
- Eichelbrönnner O, Reinelt H, Wiedeck H, et al. Aerosolized prostacyclin and inhaled nitric oxide in septic shock: different effects on splanchnic oxygenation? *Intensive Care Med* 1996;22:880
- Subramanian K, Yared JP. Management of pulmonary hypertension in the operating room. *Semin Cardiothoracic Vasc Anesth* 2007; 11:119-36
- Haraldson A, Kieler-Jensen . Inhaled prostacyclin and platelet function after cardiac surgery and cardiopulmonary bypass. *Intensive Care Med*. 2000;26:188-94
- Ammar MA, Bauer SR, Bass SN, Sasidhar M, Mullin R, Lam SW. Noninferiority of inhaled epoprostenol to inhaled nitric oxide for the treatment of ards. *Ann Pharmacother*. 2015;49(10):1105-1112.
- Arumpanayil A. Inhaled epoprostenol to support the severely hypoxemic patient with acute respiratory distress syndrome. *Dimens Crit Care Nurs*. 2013;32(5):229-236.

## Approval Signatures

Step Description	Approver	Date
P&T Committee	Heather Tolfree: Mgr Pharmacy - CPS	Pending
Medical Director	Shiloh Tackett: Physician	12/4/2025
Cardiothoracic Surgery Director	Edward Bergeron: PHYSICIAN	9/10/2025
Document Owner	Duane Croel: Clinical Coord - Resp Care Operations	9/10/2025

## Applicability

Munson Medical Center

## Standards

No standards are associated with this document



Origination	7/12/2017	Owner	Sandra Cranson: Coord Nursing Quality
Last Approved	N/A	Area/ Department	Surgical Services - Operating Room
Effective	Upon Approval	Applicability	MMC
Last Revised	11/26/2025	Tags	Procedure
Next Review	3 years after approval		

## Autotransfusion

### Purpose

To provide a process for intraoperative autotransfusion in which shed blood is collected and returned to the patient.

### Procedure

- A. The set-up and monitoring of an autotransfusion occurs by the perfusionist, registered nurse (RN), or **an autotransfusion technician employed by Specialty Care** a **trained staff member**.
- B. Autotransfusion may be utilized for any surgical case where there may be an expected blood loss from the patient of one or more units of homologous blood products or at the request of the attending physician/surgeon.
- C. Autotransfusion may also be utilized outside the perioperative setting in emergent situations, as directed by the physician.
- D. Contraindications for use of the autotransfusion device are as defined by the manufacturer.
- E. **Contraindications including but not limited to:**
  - 1. **Microfibrillar products:** Avitene, Helitene, Oxycel, Gelfoam power, Instat, MCH
  - 2. **Sponge/fabric materials:** Surgicel, Surgicel Nu-Knit, Gelfoam sponge, Helistat, Hemopad, Superstat, HemoFoam
  - 3. **Topical liquids:** Thrombin-JMI, Thrombostat, Thrombogen
  - 4. **Methyl Methacrylate:** Hardened, liquid, powdered
  - 5. Alcohol

6. Antibiotics: Bacitracin, Neomycin, Polymyxin
7. Betadine
8. Hypertonic solution: 3% NaCl, 7.5% NaCl, dextrose solution
9. Hypotonic solution: Sterile water, glycine
10. Lactated Ringers (in presence of Citrate anticoagulant)
11. Amniotic fluid
12. Tumor Cells

**F. Recommended Action:**

1. Avoid aspiration in the presence of the above items.
2. \*Antibiotics increase wash by 500 mL of saline.
3. If items aspirated, irrigate with copious irrigation 0.9% sodium chloride.
4. For tumor cells, avoid aspiration at tumor site except at the discretion of the physician.

## Quality Control (QC)

- A. Instrument function, preventive maintenance and repairs are documented and reviewed by the Bio-Med department.
- B. All QCs/checks will be performed, documented, and reports generated and reviewed with **OR operating room (OR) management by the Specialty Care Services Group clinical technicians.**
- C. **Specialty Care** policy/procedure/guidelines manual will be available through the Education Coordinator **along with current credentials.**

## ~~Case Notification: Hospital Clinical Services Group Personnel~~

- ~~A. The Operating Room (OR) scheduler will contact Specialty Care Services Group dispatch center regarding scheduled autotransfusion cases.~~
- ~~B. To access the clinical technicians in an unscheduled emergent/urgent case or in situations where the desire to perform autotransfusion on a scheduled case is decided at the time of surgery, the personnel will contact Specialty Care Services Group Dispatch Center. This phone number will also be available on the "On-Call Assignment Phone List". The OR circulating RN may direct the nursing house supervisor to contact Specialty Care Services Group Central Dispatch to notify the clinical technician when they are needed for a case that would require autotransfusion.~~
- ~~C. If an autotransfusion case is canceled, modified, or rescheduled, contact Specialty Care dispatch center as soon as possible.~~

## Procedure Specific Information

- ~~A. The following procedures for "Preparation of the Anticoagulant" and "Collect First Technique"~~

outline responsibilities that the circulating RN may need to perform in an emergency situation. This will only be necessary if collection of blood is required before the Specialty Care Services Group clinical technician arrives for an on-call or unscheduled urgent/emergent procedure. Pharmacy preps heparin bags.

- B. Primarily, anticoagulant is ~~now~~ prepared by Pharmacy and has directives to support this.
- C. Also regarding anticoagulant, it is important to know if patient has heparin/poline allergy, if so, use ACD-A (premixed IL bags in pharmacy).

## **Collect First Technique**

A. **Introduction:** Collect First Technique refers to the set-up of the blood collection system prior to the autotransfusion device being present in the OR or set-up for operation.

B. **Responsible Personnel:** Perioperative RN

C. **Equipment and Supplies:** Specialty Care stocks each machine with every use except for anticoagulant.

1. Aspiration and Anticoagulant Assembly (A&A) line
2. Anticoagulant – Heparin 30,000 units
3. 1,000 cc bag of 0.9% Sodium Chloride
4. Collection reservoir (Logistics item)
5. Hospital suction tubing
6. Medication label

D. **Procedure Steps & Key Points:**

1. Gather equipment and supplies.
  - a. Plug white vacuum hose to appropriate receptacle in column.
2. Setup of Collection Reservoir:
  - a. Mix the anticoagulant.
    - i. 30,000 units of Heparin in 1,000 cc 0.9% NACL
  - b. Complete and attach medication label to the anticoagulant solution.
  - c. Hang the anticoagulant solution on the intravenous (IV) pole.
  - d. Open the A&A package and pass the A&A line to the sterile field.
  - e. The ST passes the step-down connector to the RN.
  - f. Attach reservoir holder to IV pole.
  - g. Place the collection reservoir in the reservoir holder.
  - h. Slide the clamp closed on the reservoir base.
  - i. Attach suction tubing to vacuum regulator on the machine.
    - i. **Critical Point:** Do Not turn suction on until ready to prime the A&A line.

- ~~j. Attach the other end of the suction tubing to the vacuum port of the collection reservoir. (Remove yellow cap).~~
- ~~k. Receive the A&A line from the sterile field.~~
- ~~l. Attach the clear capped end of the A&A line to one of the three blue capped inlet ports on the collection reservoir.~~
- ~~m. Close the roller clamp on the A&A line and spike the anticoagulant bag.~~
- ~~n. Turn on the suction source and regulate the vacuum to 150 mm Hg.~~
- ~~o. Prime the A&A line and collection reservoir. The sterile file will pass off A&A line after patient draped.~~
  - ~~i. To prime the tubing and collection reservoir, open the roller clamp and allow a maximum of 200 ml of solution to infuse through tubing and into reservoir.~~
- ~~p. Adjust the drip rate to 30 to 60 drops per minute.~~
  - ~~i. Drip rate may be regulated depending on rate of blood loss, amount of surgical debris, or platelet count/usage.~~

## Platelet Poor Plasma (PPP) and Platelet Rich Plasma (PRP)

- A. PRP therapy is the process of withdrawing whole blood to produce PRP and PPP. Blood is obtained from a venipuncture site and is centrifuged. The separated components are returned to the patient at the surgical site. The goal of PRP is to enhance handling characteristics of bone grafts and be an autologous source of growth factors in the clotting cascade. The PPP is used as a hemostatic agent.

### Personnel

- A. **RN:** Delivers medication to surgical field.
- B. **Scrub Person:** Set up disposable products on sterile field.
- C. ~~Clinical Technician:~~ **Trained Surgical Staff.** Processes the blood using the machine.
- D. Contraindications for use of PRP and PPP device are as defined by the manufacturer.

### QC

### Quality Control

- A. Instrument function, preventative maintenance and repairs are documented and reviewed by the Bio-Med department.

### ~~Case Notification: Specialty Care Services Group Personnel~~

- ~~A. The OR scheduler will contact Specialty Care Dispatch Center regarding scheduled symphony~~

cases.

- B. In the event of emergent/urgent cases, the personnel will contact Specialty Care Services Group Central Dispatch that personnel are needed for a symphony case.
- C. If a case is canceled, modified, or rescheduled, personnel will contact Specialty Care as soon as possible.

## Preparation of Medications

### A. Procedure Steps & Key Points:

1. Clinical technician will obtain thrombin 10,000 units and calcium chloride 10 meq from the Pyxis.
  - a. After verifying medications
2. The circulating nurse dispenses the medications onto the sterile field into the clear cup using sterile technique.
3. The clinical technician places the whole blood obtained from Anesthesia by venipuncture into the centrifuge.
4. The separated components are presented to the sterile field by the clinical technician.
5. The scrubbed personnel prepare the components on the sterile field for delivery to the patient.

Clinical support provided by Specialty Care staff.

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## Approval Signatures

Step Description	Approver	Date
P&T Committee	Heather Tolfree: Mgr Pharmacy - CPS	Pending
Dir Nursing Surgical Services	Amy Verburg: Dir Surgical Services	12/2/2025
Document Owner	Sandra Cranson: Coord Nursing Quality	12/1/2025

## Applicability

Munson Medical Center

## Standards

No standards are associated with this document

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## H. Osmotic Therapy

**Unique Plan Description: Osmotic Therapy**

**Plan Selection Display: Osmotic Therapy**

**PlanType: Subphase (Hidden, can only be used from Critical Care PowerPlan)**

**Available at: MMC**

### Osmotic Therapy

#### Laboratory

- Basic Metabolic Panel  
*Blood, Collect Timed Study, T;N, q6hr, for 14 day(s), Nurse collect  
Comments: Nurse to call lab to notify need for STAT result*
- Osmolality  
*Blood, Collect Timed Study, T;N, q6hr, for 14 day(s), Nurse collect  
Comments: Nurse to call lab to notify need for STAT result*

#### Medications

- Hypertonic 3% Saline IVPB  
*200 mL, IVPB, Inject (IV Only), q6hr, PRN See comment, Infuse Over: 30 minute(s) (DEF)\*  
Comments: PRN sustained ICP greater than or equal to 20. Hold if serum osmolality is greater than or equal to 320 or Na+ greater than or equal to 155, contact physician to validate if administration is appropriate.*
- 300 mL, IVPB, Inject (IV Only), q6hr, PRN See comment, Infuse Over: 30 minute(s)  
Comments: PRN sustained ICP greater than or equal to 20. Hold if serum osmolality is greater than or equal to 320 or Na+ greater than or equal to 155, contact physician to validate if administration is appropriate.*
- 400 mL, IVPB, Inject (IV Only), q6hr, PRN See comment, Infuse Over: 30 minute(s)  
Comments: PRN sustained ICP greater than or equal to 20. Hold if serum osmolality is greater than or equal to 320 or Na+ greater than or equal to 155, contact physician to validate if administration is appropriate.*
- 500 mL, IVPB, Inject (IV Only), q6hr, PRN See comment, Infuse Over: 60 minute(s)  
Comments: PRN sustained ICP greater than or equal to 20. Hold if serum osmolality is greater than or equal to 320 or Na+ greater than or equal to 155, contact physician to validate if administration is appropriate.*
- Mannitol 20% IVPB  
*1 gm/kg, IVPB, IVPB, q6hr, PRN See comment, Infuse Over: 1 hour(s)  
Comments: If ICP sustained greater than or equal to 20. Hold if serum osmolality is greater than or equal to 320 or Na+ greater than or equal to 155. Contact physician to validate if administration is appropriate. BMP & Serum Osmolality q 6 hrs while Mannitol in use*
- Sodium Chloride 23.4% **\*\*CONCENTRATED\*\*** for osmotic therapy  
*30 mL, IVPush, Inject (IV Only), q6hr, PRN See comment, 10 minute(s) (DEF)\*  
Comments: PRN for Sodium Goal. Central Line required. Give over 10 minutes*
- 60 mL, IVPush, Inject (IV Only), q6hr, PRN See comment, 10 minute(s)  
Comments: PRN for Sodium Goal. Central line required. Give over 10 minutes*

#### System Auto-Generated

- Last Plan Review Date

Critical Care, Critical Care, Osmotic Therapy (Planned Pending)		
Laboratory		
<input checked="" type="checkbox"/>	Basic Metabolic Panel	Blood, Collect Timed Study, T;N, q6hr, for 14 day(s), Nurse collect Nurse to call lab to notify need for STAT result
<input checked="" type="checkbox"/>	Osmolality	Blood, Collect Timed Study, T;N, q6hr, for 14 day(s), Nurse collect Nurse to call lab to notify need for STAT result
Medications		
<input type="checkbox"/>	Sodium Chloride 3% intravenous solution (Hypertonic 3% Saline IVPB)	200 mL, IVPB, Inject (IV Only), q6hr, PRN See comment, Infuse Over: 30 minute(s) PRN sustained ICP greater than or equal to 20. Hold if serum osmolality is greater than or equal to 320 or Na+ greater than or equal to 155, contact physician to validate if administration is appropriate.
<input type="checkbox"/>	mannitol (Mannitol 20% IVPB)	1 gm/kg, IVPB, IVPB, q6hr, PRN See comment, Infuse Over: 1 hour(s) If ICP sustained greater than or equal to 20. Hold if serum osmolality is greater than or equal to 320 or Na+ greater than or equal to 155, contact physician to validate if administration is appropriate.
<input type="checkbox"/>	sodium chloride (Sodium Chloride 23.4% <b>**CONCENTRATED**</b> for osmotic therapy)	Sodium goal 211, 30 mL, IVPush, Inject (IV Only), q6hr, PRN See comment, 10 minute(s) PRN for Sodium Goal. Central line required. Give over 10 minutes.

Details for sodium chloride (Sodium Chloride 23.4% \*\*CONCENTRATED\*\* for osmotic therapy)

Details Order Comments Offset Details Diagnoses



<b>*Sodium goal:</b> <input type="text"/>	<b>*Dose (Volume Dose):</b> <input type="text" value="30"/>
<b>*Dose Unit (Volume Dose Unit):</b> <input type="text" value="mL"/>	<b>*Route of Administration:</b> <input type="text" value="IVPush"/>
Drug Form: <input type="text" value="Inject (IV Only)"/>	<b>*Frequency:</b> <input type="text" value="q6hr"/>
PRN: <input checked="" type="radio"/> Yes <input type="radio"/> No	<b>*PRN Reason:</b> <input type="text" value="See comment"/>
Requested Start Date/Time: <input type="text" value="**/**/****"/> <input type="text" value=""/> EST	Pharmacy Order Priority: <input type="text" value="Routine"/>
Duration: <input type="text" value="10"/>	Duration Unit: <input type="text" value="minute(s)"/>
Additional Information/Instructions: <input type="text"/>	Dispense From Location: <input type="text"/>

# I. Cardiac Catheterization and PCI

**Unique Plan Description: Cardiac Catheterization and PCI - M**

**Plan Selection Display: Cardiac Catheterization and PCI**

**PlanType: Medical**

**Version: 7**

**Begin Effective Date: 1/25/2025 1/25/2025 2:52**

**End Effective Date: Current**

**Available at: MMC**

## Pre-Catheterization Orders

### Non Categorized

- Consent for
  - Cardiac Catheterization and/or PCI, Print additional armband and give to nurse to ensure bilateral armband is in place. (DEF)\**
  - Coronary Intervention, Print additional armband and give to nurse to ensure bilateral armband is in place.*
  - Renal Angiogram with possible stent*
  - Right Heart Catheterization, Print additional armband and give to nurse to ensure bilateral armband is in place.*
  - Cardiac Cath and/or PCI with Right Heart Catheterization, Print additional armband and give to nurse to ensure bilateral armband is in place.*
  - Coronary Catheterization Only, print additional armband and give to nurse to ensure bilateral armband is in place.*
  - Peripheral Angiogram and/or PTA*
  - Arch Aortogram with 4 vessel run off*
  - Carotid Angiogram*
  - Upper Extremity Angiogram*
  - Upper Extremity Angiogram with PTA*
  - Lower Extremity Angiogram*
  - Lower Extremity Angiogram with PTA*
  - Mesenteric Angiogram with or without PTA*
  - Abdominal Aortogram with or without Run Off*
  - Abdominal Aortogram with or without PTA*
- Planned Access Site
  - Planned Access Site: Femoral - Right (DEF)\**
  - Planned Access Site: Femoral - Left*
  - Planned Access Site: Radial - Right, A6 staff to perform the modified Allen's test prior to procedure. Start IV in opposite arm of planned radial access or move existing IV out of the target zone.*
  - Planned Access Site: Radial - Left, A6 staff to perform the modified Allen's test prior to procedure.*
  - Planned Access Site: Brachial - Right, A6 staff to perform modified Allen's test prior to procedure. Start IV in opposite arm of planned radial access or move existing IV out of the target zone.*
  - Planned Access Site: Brachial - Left, A6 staff to perform the modified Allen's test prior to procedure.*
  - Planned Access Site: Popliteal - Right*
  - Planned Access Site: Popliteal - Left*
  - Planned Access Site: Internal Jugular - Right*
  - Planned Access Site: Internal Jugular - Left*
- Cath Lab / EP Procedures Protocol
  - T;N*
  - Comments: \*\*\*\*If patient is female and between menarche and menopause, complete a pregnancy test per protocol. See attached reference text.\*\*\**

### Patient Care

- Nursing - Pre-Cath PREP Instructions
  - \*\*\*\*See Reference Text\*\*\*\**
- Convert IV to Int Lock - when taking oral fluids well
- Pain Management Tips - Reference Text

### Activity

- Bladder Scanner Protocol
  - Follow Bladder Scanner Protocol*

**Diet/Nutrition**

- NPO - Cath Lab Protocol  
*T;N, NPO*
- NPO after Midnight  
*T+1;0001, NPO*
- NPO  
*T+1;0600, NPO Except Meds with Sips of Water (DEF)\**  
*Comments: No trays ordered from dietary department starting at 0600, but patient may have clear liquid breakfast with nurse provided clear liquids from unit pantry until 0830. After 0830 patient to be NPO except meds with sips of water*  
*NPO Except Meds with Sips of Water*

**Laboratory**

- Nurse to Order Lab Test in Future Task  
*qShift (8hr), Nurse to order: CBC, BUN, Creatinine, PT, PTT, and Potassium on day of procedure*

**AM LABS**

- CBC w/o Diff  
*Blood, Collect Am Draw, ONCE*
- BUN  
*Blood, Collect Am Draw, ONCE*
- PT  
*Blood, Collect Am Draw, ONCE*
- PTT  
*Blood, Collect Am Draw, ONCE*
- Potassium Level  
*Blood, Collect Am Draw, ONCE*
- Creatinine  
*Blood, Collect Am Draw, ONCE*

**Cardiology**

- EKG PRN (nsg)  
*PRN in CCL*
- Electrocardiogram - M  
*STAT, Once if not done within the last month*

**Continuous Infusions**

Note to provider: Review potential nephrotoxic drugs: NSAIDS (excluding aspirin), diuretics, ACE inhibitors, Metformin, Vancomycin, aminoglycoside antibiotics, anti-rejection medications.(NOTE)\*

Note to provider: If pre-selected IV infusion below are un-checked, Provider must select individual preferred hydration plan.(NOTE)\*

- Sodium Chloride 0.9% IV SOLN  
*1,000 mL, IV, Give 1.5 mL/kg/hr x 2 hours then KVO*  
*Comments: For PREHYDRATION: Infusion to be completed prior to start of catheterization, convert to KVO after infusion complete.*
- Sodium Chloride 0.9% IV SOLN  
*1,000 mL, IV, 100 mL/hr x \_\_\_\_\_ hours*  
*Comments: This line is to have no medications in it or piggybacked to it. If cath procedure time unknown start fluids at midnight.*

**Medications**

- Hold Metformin  
*Hold Metformin - see comments, Note, Note, BIDWM, 48 hour(s)*  
*Comments: Hold Metformin day of procedure and for at least 48 hours post-procedure if patient is to receive contrast and patient is on Metformin. Nurse - If patient is scheduled to receive or receives contrast during a procedure and Metformin is scheduled to be administered before and/or within 48 hours post-procedure, please contact a pharmacist to have the Metformin order discontinued and re-entered with an appropriate start date/time.*

For patients on oral anticoagulants dabigatran (Pradaxa), rivaroxaban (Xarelto), or apixaban (Eliquis) the following are recommendations to stop the medication prior to high risk bleeding procedures If patient is on dabigatran (Pradaxa) prior to cath it had been stopped for - 3 days in patients with CrCl greater than 50ml/min - 4 days in patients with CrCl 30-50mL/min - 6 days in patients with CrCl less than 30 mL/min If patient is on rivaroxaban (Xarelto) prior to cath it has been stopped for - 2 days in patients with CrCl greater than 50 mL/min -

3 days in patients with CrCl less than 50 mL/min If patient is on apixaban (Eliquis) prior to cath it has been stopped for - 3 days in patients with CrCl great than 50 mL/min - 4 days in patients with CrCl less than 50 mL/min(NOTE)\*

- Cardiac - Nursing Anticoagulation Prior to Procedure  
*D/C Heparin Drip, Enoxaparin, or Fondaparinux, Note, Note, q4hSTD, NOW (DEF)\**  
*Comments: Pre-Procedure Cardiac Cath/PCI - directions to nurse for patient on Heparin Infusion:1. Nurse to stop Heparin Infusion when patient transfers to CCL2. D/C Heparin Powerplan3. D/C this note. (For patients on subcutaneous heparin for DVT prophylaxis-continue subcutaneous heparin pre procedure)- For patients on low molecular weight heparin (enoxaparin or dalteparin) or fondaparinux stop drug 24 hours prior to procedure - INSTRUCTIONS: Once procedure date and time are determined, nurse to modify stop time to stop drug 24 hours prior to procedure. THEN D/C this note*  
*Continue Current Heparin Drip to CCL, Note, Note, q4hSTD, NOW*  
*Comments: Pre-Procedure Cardiac Cath/PCI - directions to nurse:1. Continue Current Heparin Drip to CCL2. Once patient leaves floor D/C Heparin Powerplan3. D/C this note*

#### Anxiolytic

- Valium TAB  
*5 mg, Oral, Tab, ON CALL, 72 hour(s) (DEF)\**  
*Comments: Give 1-2 hours prior to procedure*  
*2.5 mg, Oral, Tab, ON CALL, 72 hour(s)*  
*Comments: Give 1-2 hours prior to procedure*  
*10 mg, Oral, Tab, ON CALL, 72 hour(s)*  
*Comments: Give 1-2 hours prior to procedure*

#### Contrast Allergy

- Contrast Allergy.(SUB)\*

#### Post-Catheterization Orders

##### Non Categorized

- Code Status  
 Nurse Facilitated Discharge - OPE - POST CATH PCI PVI(SUB)\*  
 Post Femoral Cath - M(SUB)\*  
 Post Radial Cath - M(SUB)\*  
 Post Brachial Cath - M(SUB)\*  
 Post Venous Cath - M(SUB)\*  
 Post Tibial Cath - M(SUB)\*  
 Pacemaker Transvenous(SUB)\*  
 MACRA Quality Measure Patient Encounter

##### Continuous Infusions

Note to provider: : If pre-selected IV infusion below are un-checked, Provider must select individual preferred hydration plan.(NOTE)\*

- Sodium Chloride 0.9% IV SOLN  
*1,000 mL, IV, Give 5 mL/kg/hr x 4 hours then int lock (DEF)\**  
*Comments: POST CATH HYDRATION: based on LVEDP less than 13. Convert to intermittent lock when infusion complete*  
*1,000 mL, IV, Give 3 mL/kg/hr x 4 hours then int lock*  
*Comments: POST CATH HYDRATION: based on LVEDP 13-18. Convert to intermittent lock when infusion complete*  
*1,000 mL, IV, Give 1.5 mL/kg/hr x 4 hours then int lock*  
*Comments: POST CATH HYDRATION: based on LVEDP greater than 18. Convert to intermittent lock when infusion complete*
- Sodium Chloride 0.9% IV SOLN  
*1,000 mL, IV, Give 100 mL/hr x 4 hours then int lock (DEF)\**  
*Comments: Convert to intermittent lock when IV finished*  
*1,000 mL, IV, Give 150 mL/hr x 4 hours then int lock*  
*Comments: Convert to intermittent lock when IV finished*  
*1,000 mL, IV, Give 75 mL/hr x 4 hours then int lock*  
*Comments: Convert to intermittent lock when IV finished*
- Intermittent Lock - Peripheral Saline Flush(SUB)\*

#### Medications

- Hold Metformin  
*Hold Metformin - see comments, Note, Note, BIDWM, 48 hour(s)*  
*Comments: Hold Metformin day of procedure and for at least 48 hours post-procedure if patient is to receive contrast and patient is on Metformin. Nurse - If patient is scheduled to receive or receives contrast during a procedure and Metformin is scheduled to be administered before and/or within 48 hours post-procedure, please contact a pharmacist to have the Metformin order discontinued and re-entered with an appropriate start date/time.*

- Continue Integrilin  
*1 Note, Note, Once*  
*Comments: If Integrilin ordered in Cath Lab, continue Integrilin as ordered*

**Antiplatelets**

- aspirin  
*81 mg, Oral, Tab Chew, DailyWM*  
*Comments: Give with food if able.*

**Heparin Dosing**

- Heparin - Pharmacy to Dose  
*Initial Bolus? No*  
*Comments: Restart Post-Cath - See Patient Care Orders for Post Sheath Pull Start Time*
- Post Sheath Pull Heparin Start Time Task  
*T;N+360, 6 hours post-hemostasis (DEF)\**  
*T;N+480, 8 hours post-hemostasis*  
*T;N+240, 4 hours post-hemostasis*  
*T;N+120, 2 hours post-hemostasis*

**Low-Molecular-Weight Heparin**

- Lovenox  
*Indication: Other, 1 mg/kg, Subcut, Syringe, q12hr, Start T+1;N (DEF)\**  
*Comments: Start in 24 hours*  
*Indication: Other, 1 mg/kg, Subcut, Syringe, q12hr, Start T;N+720*  
*Comments: Start in 12 hours*

**Oral Anticoagulants**

- Pharmacy to Dose - Warfarin  
*Medication to Dose: Coumadin*
- PT  
*Blood, Collect Am Draw, T+1;0330, Daily Lab, for 3 day(s)*
- Pradaxa  
*Indication: VTE Prophylaxis, 150 mg, Oral, Cap, BID (DEF)\**  
*Comments: Stop IV Heparin prior to first dose; Stop Subcut Heparin/LMWH and start dabigatran within 2 hours of next scheduled dose*  
*Indication: VTE Prophylaxis, 75 mg, Oral, Cap, BID*  
*Comments: Lower dose for reduced renal function CrCl < 30 mL/min; Stop IV Heparin prior to first dose; Stop Subcut Heparin/LMWH and start dabigatran within 2 hours of next scheduled dose*

**Pain**

- Norco 5 mg-325 mg oral tablet  
*1 to 2 tab, Oral, Tab, q4hr, PRN Mild-Moderate Pain*  
*Comments: Pain score 1-3, administer 1 tab. May repeat this dose ONCE after 60 min if pain score remains 1-3. If last cumulative dose of 2 tabs was most effective, may administer 2 tabs at the next dosing interval. Pain score 4-6, administer 2 tabs. Do not exceed 4 grams acetaminophen in 24 hours.*

**Post-PCI Orders**

**Non Categorized**

- Code Status
- Same Day Discharge from A6(SUB)\*
- Nurse Facilitated Discharge - OPE - POST CATH PCI PVI(SUB)\*
- PCI Femoral(SUB)\*
- PCI Radial(SUB)\*
- PCI Brachial(SUB)\*
- PCI Tibial(SUB)\*

- MACRA Quality Measure Patient Encounter

**Laboratory**

**AM LABS**

- Creatinine  
*Blood, Collect Am Draw, ONCE*
- Hemoglobin  
*Blood, Collect Am Draw, ONCE*

**Continuous Infusions**

Note to provider: : If pre-selected IV infusion below are un-checked, Provider must select individual preferred hydration plan.(NOTE)\*

- Sodium Chloride 0.9% IV SOLN  
*1,000 mL, IV, Give 5 mL/kg/hr x 4 hours then int lock (DEF)\**  
*Comments: POST CATH HYDRATION: based on LVEDP less than 13. Convert to intermittent lock when infusion complete*  
*1,000 mL, IV, Give 3 mL/kg/hr x 4 hours then int lock*  
*Comments: POST CATH HYDRATION: based on LVEDP 13-18. Convert to intermittent lock when infusion complete*  
*1,000 mL, IV, Give 1.5 mL/kg/hr x 4 hours then int lock*  
*Comments: POST CATH HYDRATION: based on LVEDP greater than 18. Convert to intermittent lock when infusion complete*
- Sodium Chloride 0.9% IV SOLN  
*1,000 mL, IV, Give 100 mL/hr x 4 hours then int lock (DEF)\**  
*Comments: Convert to intermittent lock when IV finished*  
*1,000 mL, IV, Give 150 mL/hr x 4 hours then int lock*  
*Comments: KVO. Convert to intermittent lock when IV finished*  
*1,000 mL, IV, Give 75 mL/hr x 4 hours then int lock*  
*Comments: Convert to intermittent lock when IV finished*
- Intermittent Lock - Peripheral Saline Flush(SUB)\*

**Medications**

- Hold Metformin  
*Hold Metformin - see comments, Note, Note, BIDWM, 48 hour(s)*  
*Comments: Hold Metformin day of procedure and for at least 48 hours post-procedure if patient is to receive contrast and patient is on Metformin. Nurse - If patient is scheduled to receive or receives contrast during a procedure and Metformin is scheduled to be administered before and/or within 48 hours post-procedure, please contact a pharmacist to have the Metformin order discontinued and re-entered with an appropriate start date/time.*
- Continue Integrilin  
*1 Note, Note, Once*  
*Comments: If Integrilin ordered in Cath Lab, continue Integrilin as ordered*

**Antiplatelets**

- Note  
*1 Note, Note, Once*  
*Comments: Nurse to ensure patient is on dual antiplatelet therapy with Aspirin AND either Clopidogrel, Prasugrel or ticagrelor post pci. If not contact provider for order. This note may be D/C'd if patient has orders for dual antiplatelet therapy.*
- aspirin  
*81 mg, Oral, Tab Chew, DailyWM*  
*Comments: Start tomorrow. Give with food if able.*
- Plavix  
*75 mg, Oral, Tab, Daily, Start T+1;0500*
- Plavix  
*300 mg, Oral, Tab, Once, STAT*
- Brilinta (ticagrelor)  
*90 mg, Oral, Tab, BID*  
*Comments: Start 12 hours after loading dose. If combined with aspirin, the aspirin dose should be 81 mg po daily.*
- Brilinta (ticagrelor)  
*180 mg, Oral, Tab, Once, STAT*

Comments: Non-formulary; stocked in ED only for loading dose prior to transfer to higher level of care.

Effient (prasugrel) is contraindicated in patients with pathological bleeding, history of TIA or CVA, and age over 75 years. For patient weight 60 kg or less dose should be reduced to 5 mg.(NOTE)\*

Effient

10 mg, Oral, Tab, Daily, \*\*Restricted to Cardiology (DEF)\*

Comments: Reduce dose to 5 mg weight less than 60kg. Not recommended in patients over the age of 75 years

5 mg, Oral, Tab, Daily, \*\*Restricted to Cardiology

Comments: Reduce dose to 5 mg weight less than 60kg. Not recommended in patients over the age of 75 years

### Heparin Dosing

Heparin - Pharmacy to Dose

Initial Bolus? No

Comments: Restart Post-Cath - See Patient Care Orders for Post Sheath Pull Start Time

Post Sheath Pull Heparin Start Time Task

T;N+360, 6 hours post-hemostasis (DEF)\*

T;N+480, 8 hours post-hemostasis

T;N+240, 4 hours post-hemostasis

T;N+120, 2 hours post-hemostasis

### Low-Molecular-Weight Heparin

Lovenox

Indication: Other, 1 mg/kg, Subcut, Syringe, q12hr, Start T+1;N (DEF)\*

Comments: Start in 24 hours

Indication: Other, 1 mg/kg, Subcut, Syringe, q12hr, Start T;N+720

Comments: Start in 12 hours

### Oral Anticoagulants

Pharmacy to Dose - Warfarin

Medication to Dose: Coumadin

PT

Blood, Collect Am Draw, T+1;0330, Daily Lab, for 3 day(s)

Pradaxa

Indication: VTE Prophylaxis, 150 mg, Oral, Cap, BID (DEF)\*

Comments: Stop IV Heparin prior to first dose; Stop Subcut Heparin/LMWH and start dabigatran within 2 hours of next scheduled dose

Indication: VTE Prophylaxis, 75 mg, Oral, Cap, BID

Comments: Lower dose for reduced renal function CrCl less than 30 mL/min; Stop IV Heparin prior to first dose; Stop Subcut Heparin/LMWH and start dabigatran within 2 hours of next scheduled dose

### Pain

morphine IVPush

2 to 4 mg, IVPush, Inject, q2hr, PRN Severe Pain

Comments: Pain score 7-10, administer 2 mg, may repeat this dose ONCE after 15 min if pain score remains 7-10. If last cumulative dose of 4 mg was most effective, may administer 4 mg at the next dosing interval.

Norco 5 mg-325 mg oral tablet

1 to 2 tab, Oral, Tab, q4hr, PRN Mild-Moderate Pain

Comments: Pain score 1-3, administer 1 tab. May repeat this dose ONCE after 60 min if pain score remains 1-3. If last cumulative dose of 2 tabs was most effective, may administer 2 tabs at the next dosing interval. Pain score 4-6, administer 2 tabs. Do not exceed 4 grams acetaminophen in 24 hours.

### System Auto-Generated

Last Plan Review Date

### \*Report Legend:

DEF - This order sentence is the default for the selected order

GOAL - This component is a goal

IND - This component is an indicator

INT - This component is an intervention

IVS - This component is an IV Set  
NOTE - This component is a note  
Rx - This component is a prescription  
SUB - This component is a subphase

## Yupelri (revefenacin) – Monograph Summary

**AHFS Therapeutic Description:** Antimuscarinics/Antispasmodics<sup>1</sup>

**AHFS Therapeutic Class:** 12:08.08<sup>1</sup>

**Pharmacological Class:** Anticholinergic Agent, Long-Acting<sup>2</sup>

**Pharmacology/Mechanism of Action:** long-acting muscarinic antagonist which competitively and reversibly inhibits the action of acetylcholine at type 3 muscarinic (M3) receptors in bronchial smooth muscle causing bronchodilation<sup>2</sup>

- **Clinical**
  - Yupelri (revefenacin) is FDA-approved for maintenance treatment of adults with chronic obstructive pulmonary disease.
  - Yupelri is administered once daily by oral inhalation via jet nebulizer.
  - No dose adjustments are required for renal or hepatic impairment.
  
- **Operations**
  - Yupelri is available as a solution for inhalation in 175 mcg/3 mL single-use vials.
  - Yupelri should be stored at room temperature and protected from direct sunlight/excessive heat.

**IDN/Facility Recommendation: Recommend adding Yupelri to MHC formulary with a review in 6 months to determine financial impact. This review will be presented to Pharmacy Clinical Council for discussion.**

## Yupelri (revefenacin) – Monograph

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**Pharmacology/Mechanism of Action:**

### Clinical Review

	Yupelri <sup>3</sup>
<b>Generic</b>	Revefenacin
<b>Manufacturer</b>	Mylan
<b>Indication</b>	
COPD, maintenance	X
<b>Patient Population</b>	
	Adults
<b>Adult Dosing (age ≥18 years)</b>	<b>COPD, maintenance</b> • 175 mcg once daily
<b>Pediatric Dosing (age &lt;18 years)</b>	• Safety/efficacy not established
<b>Dose Adjustments</b>	<u>Renal</u> : monitor for systemic antimuscarinic effects in patients with severe impairment <u>Hepatic</u> : none
<b>Dosing Frequency</b>	• Once daily
<b>Pharmacokinetics<sup>2,3</sup></b>	
<b>Onset</b>	• Bronchodilation:
<b>Duration</b>	• Bronchodilation:
<b>Protein Binding</b>	• ~71% (parent); ~42% (active metabolite)
<b>Metabolism</b>	• Primarily via hydrolysis of the primary amide to carboxylic acid
<b>Excretion</b>	• Feces (primary); urine (<1%)
<b>Half-life</b>	• 22-70 hours

COPD = chronic obstructive pulmonary disease; X = FDA-approved indication

### Safety Review

	Yupelri <sup>3</sup>
<b>Adverse Reactions</b>	<i>Incidence ≥2% and more often than placebo group</i> • Headache (4%) • Nasopharyngitis (4%) • Back pain (2%) • Upper respiratory tract infection (3%)
<b>Contraindications</b>	• Hypersensitivity to any component of the product
<b>Precautions</b>	• Deterioration of disease and acute episodes • Paradoxical bronchospasm • Worsening of narrow-angle glaucoma • Worsening of urinary retention • Immediate hypersensitivity reactions
<b>Black Box Warnings</b>	None

	Yupelri <sup>3</sup>
REMS <sup>4</sup>	None
Pregnancy	<ul style="list-style-type: none"> <li>• No adequate data; use caution</li> <li>• Animal studies with subcutaneous administration showed no evidence of fetal harm at 209x max human doses</li> </ul>
Lactation	<ul style="list-style-type: none"> <li>• Limited data; use caution</li> <li>• Present in rat milk</li> </ul>
Drug Interactions	<ul style="list-style-type: none"> <li>• Anticholinergics</li> <li>• Transporter-related drug interactions</li> </ul>
Laboratory Monitoring and Interactions	<ul style="list-style-type: none"> <li>• None listed</li> </ul>
Inactive Ingredients	<ul style="list-style-type: none"> <li>• Citric acid</li> <li>• Hydrochloric acid</li> <li>• Sodium chloride</li> <li>• Sodium citrate</li> <li>• Sodium hydroxide</li> <li>• Water for injection</li> </ul>
Hazardous Drug Classification <sup>2, 5-11</sup>	<ul style="list-style-type: none"> <li>• <u>ISMP</u> – none</li> <li>• <u>Look-alike/Sound-alike</u> – revfenacin may be confused with darifenacin, Revlimid</li> <li>• <u>Beers Criteria</u> – none</li> <li>• <u>NIOSH</u> – none</li> </ul>

ISMP = Institute for Safe Medication Practices; NIOSH = National Institute for Occupational Safety and Health; REMS = Risk Evaluation and Mitigation Strategies

### Operations Review

	Yupelri <sup>3</sup>
Dosage Forms/ Packaging	<u>Solution for inhalation, single-use vial</u> <ul style="list-style-type: none"> <li>• 175 mcg/3 mL               <ul style="list-style-type: none"> <li>○ NDC 49502-0806-77 (#7)</li> <li>○ NDC 49502-0806-93 (#30)</li> </ul> </li> </ul>
Preparation and Administration	<u>Preparation</u> <ul style="list-style-type: none"> <li>• Remove unit-dose vial from pouch immediately before use</li> <li>• Open vial and pour solution into nebulizer for administration</li> <li>• Compatibility when mixed with other drugs has not been established</li> </ul> <u>Administration</u> <ul style="list-style-type: none"> <li>• Administer orally via inhalation once daily</li> <li>• Should be administered by the orally inhaled route via a standard jet nebulizer connected to an air compressor</li> </ul>
Stability	<ul style="list-style-type: none"> <li>• No information</li> </ul>
Storage	<ul style="list-style-type: none"> <li>• 20-25°C (68-77°F); excursions permitted 15-30°C (59-86°F)</li> <li>• Protect from direct sunlight and excessive heat</li> <li>• Keep in foil pouch</li> </ul>
Generic Available?	No
HealthTrust Contract?	Yes; see catalog and wholesaler
Cost/Unit (\$ WAC) <sup>12</sup>	<u>Solution for inhalation, single-use vial</u> <ul style="list-style-type: none"> <li>• 175 mcg/3 mL = \$43.37 per vial</li> </ul>
FDA-Approval Date	November 2018

FDA = U.S. Food & Drug Administration; NDC = national drug code; WAC = wholesale acquisition cost

## Clinical Guidelines

Guideline	Recommendation
<b>2023 GOLD Guidelines for COPD<sup>13</sup></b>	<ul style="list-style-type: none"> <li>Pharmacological therapy can reduce COPD symptoms, reduce the frequency and severity of exacerbations, and improve health status and exercise tolerance. Data suggest beneficial effects on rates of lung function decline and mortality.</li> <li>Each pharmacological treatment regimen should be individualized and guided by the severity of symptoms, risk of exacerbations, side-effects, comorbidities, drug availability and cost, and the patient's response, preference, and ability to use various drug delivery devices.</li> <li>Antimuscarinic drugs block the bronchoconstrictor effects of acetylcholine on M3 muscarinic receptors expressed in airway smooth muscle. SAMAs, namely ipratropium and oxitropium, also block the inhibitory neuronal receptor M2, which potentially can cause vagally induced bronchoconstriction. <b>LAMAs</b>, such as tiotropium, aclidinium, glycopyrronium bromide (also known as glycopyrrolate) and umeclidinium have prolonged binding to M3 muscarinic receptors, with faster dissociation from M2 muscarinic receptors, thus prolonging the duration of bronchodilator effect.</li> <li>Among <b>LAMAs</b>, some are administered once a day (tiotropium and umeclidinium), others twice a day (aclidinium), and some are approved for once daily dosing in some countries and twice daily dosing in others (glycopyrrolate). <b>LAMA</b> treatments improve symptoms, including cough and sputum and health status. They also improve the effectiveness of pulmonary rehabilitation and reduce exacerbations and related hospitalizations. Clinical trials have shown a greater effect on exacerbation rates for <b>LAMA</b> treatment (tiotropium) versus LABA treatment.</li> </ul>

COPD = chronic obstructive pulmonary disease; GOLD = Global Initiative for Chronic Obstructive Lung Disease; LABA = long-acting beta-agonists; LAMA = long-acting muscarinic antagonists; SAMA = short-acting muscarinic antagonists

## Clinical Trial Data

**Abbreviations:** AE = adverse event; CI = confidence interval; COPD = chronic obstructive pulmonary disease; FEV1 = forced expiratory volume over 1 second; FVC = forced vital capacity; ICS = inhaled corticosteroid; LABA = long-acting beta-agonists; LSM = least squares mean; OTE = overall treatment effect; PBO = placebo; REV = revefenacin

<b>NCT02459080 &amp; NCT02512510: Study 0126 and 0127<sup>14</sup></b>						
<b>Design:</b> two phase III, randomized, double-blind, placebo-controlled, multiple-dose, parallel-group studies (n=619 in study 0126; n=610 in study 0127)						
<b>Duration:</b> 12 weeks of treatment						
<b>Intervention:</b> concomitant LABA-containing therapy (with or without ICSs) was permitted in ≤40% of the study population to ensure robust assessments of concurrent therapies used by the participants						
<ul style="list-style-type: none"> <li>Revefenacin 88 mcg once daily in the morning via jet nebulizer for 12 weeks (n=212; n=205)</li> <li>Revefenacin 175 mcg once daily in the morning via jet nebulizer for 12 weeks (n=198; n=197)</li> <li>Placebo once daily in the morning via jet nebulizer for 12 weeks (n=209; n=208)</li> </ul>						
<b>Population:</b> adults (age ≥40 years) with documented COPD history, a smoking history of at least 10 pack years, a post-ipratropium FEV1/FVC ratio <0.7 and a post-ipratropium FEV1 <80% of predicted normal but ≥700 mL at Visit 1B [constituting criteria for moderate to very severe COPD]						
<b>Baseline characteristics</b>						
	Study 0126			Study 0127		
	REV 88 (n=212)	REV 175 (n=198)	PBO (n=209)	REV 88 (n=205)	REV 175 (n=197)	PBO (n=208)
Mean age, years	63.7	64.2	64.3	63.1	63.6	63.5
Male	54.2%	47.0%	52.2%	50.2%	51.8%	46.6%
White race	91.5%	90.4%	91.4%	90.7%	86.8%	90.4%

NCT02459080 & NCT02512510: Study 0126 and 0127 <sup>14</sup>						
Current smoker	48.1%	48.5%	49.3%	47.3%	47.7%	45.7%
Concurrent ICS use	40.1%	44.9%	41.1%	38.5%	43.1%	40.9%
Concurrent LABA or ICS/LABA use	35.8%	39.9%	35.4%	37.6%	37.6%	35.1%
Mean post-ipratropium % predicted FEV1	55.9	54.4	55.8	54.1	53.5	53.7
Mean post-ipratropium FEV1 to FVC ratio	0.6	0.5	0.5	0.5	0.5	0.5
Mean baseline FEV1, liters	1.4	1.3	1.4	1.3	1.3	1.3
0 exacerbations in previous year	77.8%	80.8%	83.7%	70.7%	75.1%	71.2%
<b>Primary Outcome:</b> change from baseline in trough FEV1 (defined as the mean of the 23.25- and 23.75-hour spirometry assessments following the 84 <sup>th</sup> dose) on day 85						
<b>Secondary Outcomes:</b>						
<ul style="list-style-type: none"> <li>Overall treatment effect (OTE) on trough FEV1 (defined as the inverse-variance weighted average of all the trough FEV1 assessments across days 15 through 85 [15, 29, 57 and 85])</li> <li>Peak (maximum) FEV1 (0-2 hours post first dose) on day 1</li> <li>Safety</li> </ul>						
<b>Results (Efficacy):</b>						
	Study 0126		Study 0127		Pooled 0126/0127	
	REV 88 (n=212)	REV 175 (n=198)	REV 88 (n=205)	REV 175 (n=197)	REV 88 (n=417)	REV 175 (n=395)
<b>Primary outcome</b>						
Placebo-adjusted LSM change in trough FEV1, mL	<b>79.2</b>	<b>146.3</b>	<b>106.5</b>	<b>147.0</b>	<b>119.8</b>	<b>148.1</b>
Statistical analysis vs PBO	<b>p=0.0003</b>	<b>p&lt;0.0001</b>	<b>p&lt;0.0001</b>	<b>p&lt;0.0001</b>	<b>p&lt;0.001</b>	<b>p&lt;0.001</b>
Statistical analysis between REV doses	--	--	--	--	p=0.088	
<b>Secondary outcomes</b>						
OTE on trough FEV1, mL (values estimated from graph)	<b>105.0</b>	<b>155.0</b>	<b>123.0</b>	<b>125.0</b>	<b>115.3</b>	<b>142.3</b>
Statistical analysis vs PBO	<b>p&lt;0.001</b>	<b>p&lt;0.001</b>	<b>p&lt;0.001</b>	<b>p&lt;0.001</b>	<b>p&lt;0.001</b>	<b>p&lt;0.001</b>
Placebo-adjusted LSM increase in peak FEV1, mL	--	--	--	--	<b>127.3</b>	<b>129.5</b>
Statistical analysis vs PBO	--	--	--	--	<b>p&lt;0.0001</b>	<b>p&lt;0.0001</b>
<b>Bolded values</b> indicate statistical significance						
<ul style="list-style-type: none"> <li>A significant increase in FEV1 occurred within 2 hours of the first treatment with revefenacin in both studies</li> </ul>						
<b>Results (Safety):</b>						
	Study 0126			Study 0127		
	REV 88 (n=212)	REV 175 (n=198)	PBO (n=209)	REV 88 (n=205)	REV 175 (n=197)	PBO (n=208)
Overall AE	51.9%	51.0%	51.7%	56.6%	51.8%	46.9%
Serious AE	4.7%	5.1%	6.7%	5.4%	2.5%	3.3%
Discontinuations due to AE	10.4%	11.6%	15.8%	13.7%	10.2%	12.4%
Death, n	0	0	1	0	1	0
Major cardiovascular events, n	2	1	0	0	0	0
<b>Conclusion:</b> "Revefenacin (88 µg and 175 µg), administered once daily for 12 weeks to patients with moderate to very severe COPD, demonstrated clinically significant improvements in trough FEV1, as well as OTE FEV1, over the entire treatment period. Revefenacin 175 µg demonstrated greater improvements in FEV1 in concomitant LABA patients and in more severe patients than revefenacin 88 µg. Revefenacin has the potential to be the first once-daily, long-acting bronchodilator for use in patients who require or prefer nebulized antimuscarinic therapy."						

## References

1. AHFS DI. Lexicomp. UpToDate, Inc.; 2023. Updated periodically. Accessed March 2023. <http://online.lexi.com>
2. Lexi-Drugs. Lexicomp. UpToDate, Inc.; 2023. Updated periodically. Accessed March 2023. <http://online.lexi.com>
3. Yupelri (revefenacin), solution for inhalation. Package insert. Mylan Specialty L.P.; May 2022.
4. Approved Risk Evaluation and Mitigation Strategies (REMS). U.S. Food & Drug Administration (FDA). Updated periodically. Accessed March 2023. <https://www.accessdata.fda.gov/scripts/cder/remis/index.cfm>
5. High-alert medications in acute care settings. Institute for Safe Medication Practices (ISMP). Updated August 23, 2018. Accessed March 2023. <https://www.ismp.org/recommendations/high-alert-medications-acute-list>
6. High-alert medications in long-term care (LTC) settings. Institute for Safe Medication Practices (ISMP). Updated May 20, 2021. Accessed March 2023. <https://www.ismp.org/recommendations/high-alert-medications-long-term-care-list>
7. High-alert medications in community/ambulatory care settings. Institute for Safe Medication Practices (ISMP). Updated September 30, 2021. Accessed March 2023. <https://www.ismp.org/recommendations/high-alert-medications-community-ambulatory-list>
8. Look-alike drug names with recommended tall man letters. Institute for Safe Medication Practices (ISMP). Updated January 26, 2023. Accessed March 2023. <https://www.ismp.org/recommendations/tall-man-letters-list>
9. List of confused drug names. Institute for Safe Medication Practices (ISMP). Updated February 28, 2019. Accessed March 2023. <https://www.ismp.org/recommendations/confused-drug-names-list>
10. 2019 American Geriatrics Society Beers Criteria® Update Expert Panel. American Geriatrics Society 2019 updated AGS Beers Criteria® for potentially inappropriate medication use in older adults. *J Am Geriatr Soc.* 2019;67(4):674-694. doi:10.1111/jgs.15767
11. NIOSH: hazardous drug exposures in healthcare. Centers for Disease Control and Prevention (CDC). Updated May 4, 2020. Accessed March 2023. <https://www.cdc.gov/niosh/topics/hazdrug/default.html>
12. IBM Micromedex Red Book. Merative Micromedex. Merative; 2023. Updated periodically. Accessed March 2023. <https://www.micromedexsolutions.com/>
13. Global Initiative for Chronic Obstructive Lung Disease. Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease. Version 1.3. February 17, 2023. Accessed March 9, 2023. [https://goldcopd.org/wp-content/uploads/2023/03/GOLD-2023-ver-1.3-17Feb2023\\_WMV.pdf](https://goldcopd.org/wp-content/uploads/2023/03/GOLD-2023-ver-1.3-17Feb2023_WMV.pdf)
14. Ferguson GT, Feldman G, Pudi KK, et al. Improvements in lung function with nebulized revefenacin in the treatment of patients with moderate to very severe COPD: results from two replicate phase III clinical trials. *Chronic Obstr Pulm Dis.* 2019;6(2):154-165. doi:10.15326/jcopdf.6.2.2018.0152

## K. Drug Shortages

December 23rd, 2025

Drug Name	Strength	Dosage Form	Notes	<b>Estimated</b> date of Recovery	Safety Memo
Acyclovir	500mg and 1000mg	Inj		January 2026	
Hydromorphone	0.5mg/0.5mL	Inj	Allocated	Intermittent availability. ETA 01/2026	
Omnipaque	All	Vial	Working with vendor for direct orders		
Triamcinolone	40mg/1mL	Vial	Purchasing through alternative vendors	February 2026	

# Adverse Drug Reactions - November

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## cases reported this month

- Redman syndrome from vancomycin on two patients without info & reported anonymously (284385)
- Sudden respiratory distress/arrest during ceftriaxone administration. Dose almost completed -> anaphylaxis management, then emergent intubation. Recovery timeline indicates unlikely (288955)



## Oversedation Issue:

- Diazepam 5mg IV admin to 90yo F. ~1min later patient unresponsive to voice or sternal rub. MRT and reversal agent (280386)



## Naloxone use for over sedation:

- 72 yr old with oral roxanol and IV dilaudid 0.25-0.5 mg; "begin with 0.25... this was not done. Pt required narcan around midnight on 11/19/25 and responded. (292988)
- 82 yr old w hip fracture; Norco 5/325 x2 doses earlier in day; MRT w several doses of Narcan w no response (bad IV line); w/ different site pt had immediate response. (292989)
- 70yo opioid tolerant taking Norco 10mg/325mg PTA s/p surgery for shunt replacement. Patient was lethargic when arriving to unit. Neurosurgery ordered Narcan and patient responded, (294553)