Pharmacy and Therapeutics Committee Approvals, December 2011

P&T Date: December 13, 2011

<table>
<tr><td>ADDITIONS TO FORMULARY</td><td>

- Ampicillin/clavulanate (Unasyn®) – Add to formulary for animal bites

</td></tr>
<tr><td>REMOVALS FROM FORMULARY</td><td>

- Levorphanol (Levo-Dromoran®) – Due to infrequent usage
- Rosiglitazone (Avandia®) – Due to restricted access program
- Drotrecogin alfa (Xigris®) – Market withdrawal

</td></tr>
<tr><td>AUTOMATIC SUBSTITUTION</td><td>

<table>
<tr><th>Medication Ordered</th><th>Automatic Substitution</th></tr>
<tr><td>Diphenhydramine (Benadryl®) IV</td><td>Diphenhydramine (Benadryl®) PO, same dose and frequency, during shortage periods. Exception: For emergency use, use as outpatient premedication, and/or
patients not tolerating PO</td></tr>
<tr><td>NeutraPhos K powder 1.5gm</td><td>K-Phos Neutral 1 tablet, same route & frequency</td></tr>
<tr><td>K Phos Original 500mg 2 tablets</td><td>K-Phos Neutral 1 tablet, same route & frequency</td></tr>
<tr><td>Phytonadione inj (Vitamin K®)</td><td>Automatic Substitution during Shortage:
In TPN patients receiving Phytonadione inj., pharmacists will write clarification order without contacting the prescriber and will note that change has been approved by NASC Committee and P&T as follows:
• Patients tolerating oral medication, pharmacists will change phytonadione IV orders to oral (same dose and frequency)
• All other TPN patients, pharmacists will extend SQ dosing interval to q3 weeks unless otherwise specified by the prescriber</td></tr>
</table>

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<tr><td>ANTIBIOTIC USE REVIEW COMMITTEE</td><td>

- C.Diff Treatment Guidelines - The guidelines have been updated to include information regarding the use of IVIG. IVIG is considered a last-line therapy for patients with severe, complicated disease in whom colectomy is not feasible.

B15B. C. difficile treatment recommend

</td></tr>
<tr><td>OTHER TOPICS</td><td>

- **Prasugrel (Effient®) Use in TIA/Stroke Patients**
  - Only specific Board certified Vascular Neurologists can prescribe Prasugrel
  - Criteria: For TIA/Stroke patients who have failed Aspirin/Dipyridamole (Aggrenox®), Cilostazol (Pletal®), and Clopidogrel (Plavix®), defined as having a TIA while on therapy.
  - MD has to consent patient prior to initiation of therapy

- **Dabigatran (Pradaxa®) Safety Analysis**

B6. Dabigatran Safety Update PT 11.

- **Statin Automatic Substitution** - Updated to include pravastatin and fluvastatin auto-substitutions

B7. Statins Table 11.11.doc

- **Progressive Care Units (PCU)**
  - Locations for medication administration - This list has been revised due to product recall and workflow issues. Changes include:
    1. Removal of Drotrecogin (Xigris®) – no longer available
    2. Epoprostenol (Flolan®) and Treprostinil (Remodulin®) IV infusion only allowed for continuation of therapy in 6NE and 5SE
    3. Fentanyl IVP and Midazolam IVP allowed in PCU
    4. IV infusion of Ketamine (Ketalar®) no longer allowed in PCU
    5. Infusion of nitroglycerin and nitroprusside (Nipride®) no longer allowed in the progressive

</td></tr>
</table>

care units

Medication expansion PT 12.11.›

- PCU Admission Order Set – To facilitate the admission of patients into the progressive care units, an admission order set was developed.

B8B. PCU order set 12.05.11.doc

- **Rhabdomyolysis Treatment Algorithm**
  - In an effort to improve the management of trauma patients, the Adult Rhabdomyolysis Algorithm was developed. This algorithm outlines both the treatment and monitoring strategies for trauma patients with rhabdomyolysis.
  - Please note Mannitol 25% inj is currently on shortage. Alternatively, Mannitol 20% inj may be used for rhabdomyolysis.

B9. Rhabdomyolylsis MD guidelines algorith

- **Nesiritide (Natrecor®) Guidelines**
  - In collaboration with the department of CT Surgery and Cardiology, the nesiritide guidelines were updated. The guideline includes criteria for use for 3 different indications (ADHF, Post-Op Cardiac Surgery and Post-VAD Placement) and outlines how to monitor patients on nesiritide.
  - In addition, the use of nesiritide is restricted to Cardiology and Cardio-Thoracic Surgery Attending Physicians. Pharmacists may order BMP twice a day for 24-48 hours for patients on nesiritide if not already ordered by the prescriber.

Nesiritide Guideline 12.12.11.doc

- **Abciximab (Reopro®) Concentration Standardization**
  - Since November 2011, the new standard concentration for abciximab infusions has been **40 mcg/ml**, which is prepared by the nursing staff in the Cath Lab by mixing 10mg (1 vial) in 250ml of D5W for a final standard concentration of 40mcg/ml. The maximum infusion dose remains 10mcg/min x 12 hours. Pharmacists will verify that the pump is infusing at the correct rate following verification of an infusion order.

- **Risk Evaluation & Mitigation Strategies (REMS)**
  - Rosiglitazone and rosiglitazone containing products – Previously implemented in November 2011

B12A. Rosiglitazone REMS PT 11.11.doc

  - Dofetilide (Tikosyn®)
    - ***Can be administered in ICU and PCU only***
    - Fact Sheet

B12B. Tikosyn REMS facts sheet 11.11.do

    - 7466 Tikosyn®) Order Set - revision

B12C. 7466 Tikosyn Order Form 12.05.11

  - Medication Guide – Provided to patient by Nursing

B12F. Tikosyn MedGuide 11.11.pdf

- **Alaris PCA Pump Implementation**
  - 7275, 8337, and 8337-A order sets were revised to reflect new PCA pump terminology. Medication content has not been changed.
  - If the physician writes a PCA order set on the old order sets, the nurse or the pharmacist may transcribe the order to the new order set keeping the PCA medication parameters at the same dose.

- **Alaris Library Revision**

Alaris Drug Library Changes Dec 2011.xl

- **Adenosine Infusion for Fractional Flow Reserve (FFR) Measurement During PCI – Physician Guideline**

B17. Adenosine Infusion for FFR Duri

- **Pain Card – Updated**

Pain Reference Card 2011 11.11.doc

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

Rachel Ngo, PharmD — *Pharmacy Program Coordinator*
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CEDARS-SINAI MEDICAL CENTER

C. DIFFICILE INFECTION (CDI) TREATMENT GUIDELINES

These are general guidelines and may not apply to all patients. Clinical judgment must be utilized in all cases.

ALL PATIENTS:

- Discontinue inciting antimicrobial agents as soon as possible
- Minimize frequency & duration of antimicrobial therapy and the number of antimicrobial agents prescribed
- If possible, avoid use of antiperistaltic agents, as these may obscure symptoms and precipitate toxic megacolon
- Treat first recurrence same as initial unless the patient presents with severe disease
- Vancomycin PO may be used in any of the following populations: contraindication, allergy or intolerance to metronidazole, or the patient is *C. diff* toxin + and not responded to metronidazole after ≥5 days of treatment.

MILD – MODERATE DISEASE:

- **CRITERIA:** Any patient who does not meet Severe Disease Criteria AND has < 2 recurrent episodes of *C. difficile* infection
- **TREATMENT: ADULTS - METRONIDAZOLE 500 MG PO TID X 10 – 14 DAYS**
  PEDIATRICS - METRONIDAZOLE 30 MG/KG/DAY PO DIVIDED QID (MAX 2 GRAMS/DAY)
- **SPECIAL CONSIDERATIONS:**
  - May give metronidazole IV if patient unable to take PO
  - There is no evidence to support use of combination therapy to patients with uncomplicated CDI

SEVERE DISEASE:

- **CRITERIA: ≥3 of the following characteristics (minor criteria):**
  - Age >65 years old (immunosenescence)[2,4-6]
  - Temp >38.3°C (100.9°F)[1-3]
  - Immunosuppressed (HIV with CD4<200, transplant on immunosuppression agents, chronic steroid use (equivalent to ≥20 mg prednisone per day) or immunomodulators (eg. TNF-α agents)[5,7,12]
  - Albumin <2.5 g/dL[1,2,13]
  - Bandemia ≥20%[8,24]
  - Abdominal distension on physical examination[8,18,26]
  - Intrinsic gastrointestinal disease (eg. short gut, IBD)[25]
  - **OR any 1 of the following characteristics (major criteria):**
    - Peak WBC > 15K[1-3,8]
    - Neutropenic (defined as ANC<1000)[22-24]
    - Peak SCr (>1.5 x baseline)[2,5,6,8,12]
    - Endoscopic evidence of pseudomembranes[1,2,3,8]
    - Evidence of bowel wall thickening, ileus, or toxic megacolon on imaging studies[1-,3,8]
    - ICU admission due to CDI OR patient requires vasopressor support[1,2,7,8,12]
- **TREATMENT: ADULTS - VANCOMYCIN 125 MG PO QID X 10 – 14 DAYS**
  PEDIATRICS – VANCOMYCIN 40 MG/KG/DAY PO DIVIDED QID (MAX 125 MG QID)
- **SPECIAL CONSIDERATIONS FOR COMPLICATED DISEASE:**
  - If patient presents with complicated disease (hypotension and/or shock, ileus, pseudomembranes, or toxic megacolon[3,8,12]): **Vancomycin 500 mg PO/NG QID + Metronidazole 500 mg IV TID**[7]
  - If complete ileus present: **add vancomycin retention enema**
    - Vancomycin 500 mg in 100 mL NS per rectum QID. Retain for ≥1 hour
  - Consider colectomy if megacolon, colonic perforation, acute abdomen, or rising lactate and WBC
    - Serum lactate > 5mmol/L and WBC>50K is associated with increased postoperative mortality[7,8,15]

RECURRENT DISEASE:

- **CRITERIA: ≥ 2 RECURRENT EPISODES OF *C. DIFFICILE* INFECTION** (Positive PCR with clinical evidence of disease required)
- **TREATMENT: Vancomycin tapered regimen and/or pulse regimen**
  - Adults:125 mg QID x 10-14 days, 125 mg BID x 1 wk, 125 mg daily x 1 wk,125 mg Q 2-3 days x 2-8 wks
  - Pediatrics: 40 mg/kg/day divided QID (max 125 mg QID) x 10-14 days, then decrease frequency to BID x 1 wk, then daily x 1 wk, then give dose every 2-3 days x 2-8 wks
- **SPECIAL CONSIDERATIONS:**
  - No evidence that rifampin or cholestyramine will decrease risk of recurrence
  - Due to limited data and/or increased risk of resistance, rifaximin, nitazoxanide not recommended.
  - IVIG may be considered as a last-line therapy for patients with severe, complicated disease in whom colectomy is not feasible. IDRX discussion and approval required. Recommended dose is 400 mg/kg x 1 dose[15,27].

PROBIOTICS: Use of probiotics (*lactobacillus*, *S boulardii*) is not recommended to prevent primary *C. difficile* infection and there is a potential risk of bloodstream infections[10,15]

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C. DIFFICILE LITERATURE REVIEW

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Dabigatran (Pradaxa) Safety Update

Pharmacy and Therapeutics Committee
December 6, 2011

1. August 2011 – Japanese Ministry of Health Labor and Welfare
   a) **81 cases** of serious bleeding complications
   b) Used in approximately 64,000 people in Japan since January 2011
      i. Potential cause of death in 5 people
         - 1 with kidney failure and 4 > 80 years of age

2. October 2011 – Australia Therapeutic Goods Administration
   a) December 2009 – prevention of VTE following orthopedic surgery; April 2011 – prevention of stroke in patients with atrial fibrillation
   b) Adverse events since 2009 – **297**
      - Serious Adverse Events – **196 including GI bleeding and ICH**
      - Events in patient ≥ 75 years of age – **166 including 108 serious events**
   c) Risk Factors Publicized
      - Age ≥ 75 years
      - Moderate renal failure (creatinine clearance 30 - 50 mL/min)
      - Use with aspirin, clopidogrel, NSAIDS, warfarin

3. November 2011 – FDA Required Labeling Changes
   a) Patients with CrCl 30-50ml/min receiving dronedarone or ketoconazole: reduce dose to 75mg BID
   b) Check CrCl prior to initiation and yearly in patient with CrCl <50ml/min or >75 years of age
   c) Check CrCl in clinical situations affecting kidney function

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STATIN INTERACTIONS

MEDICATION ORDERED	AUTOMATIC SUBSTITUTION*		
		PATIENTS RECEIVING: ***CLARITHROMYCIN, ERYTHROMYCIN, TELITHROMYCIN, DANAZOL ITRACONAZOLE, KETOCONAZOLE, POSACONAZOLE***	***HIV PATIENTS OR PATIENTS RECEIVING:*** ***AMIODARONE, CYCLOSPORINE, TACROLIMUS FIBRATES (GEMFIPROZIL, FENOFIBRATE), DILTIAZEM, VERAPAMIL, AMLODIPINE, RANOLAZINE***
Simvastatin 10mg	Dispense as ordered	Pravastatin 20mg	Pravastatin 20mg Pravastatin 10mg (Pts on Cyclosporine or Tacrolimus)
Simvastatin 20mg	Dispense as ordered	Pravastatin 40mg	Pravastatin 40mg Pravastatin 20mg (Pts on Cyclosporine or Tacrolimus)
Simvastatin 40mg	Dispense as ordered	Pravastatin 80mg Pravastatin 40mg (Pts on Clarithromycin)	Pravastatin 80mg Pravastatin 20mg (Pts on Cyclosporine or Tacrolimus)
Simvastatin 60	Dispense as ordered	Rosuvastatin 5mg	Rosuvastatin 5mg
Simvastatin 80mg	Rosuvastatin 10mg	Rosuvastatin 10mg	Rosuvastatin 10mg Rosuvastatin 5mg (Pts on Cyclosporine or Tacrolimus)
Pravastatin 10mg	Pravastatin 10mg	Pravastatin 10mg	Pravastatin 10mg
Pravastatin 20mg	Pravastatin 20mg	Pravastatin 20mg	Pravastatin 20mg
Pravastatin 40mg	Pravastatin 40mg	Pravastatin 40mg	Pravastatin 40mg Pravastatin 20mg (Pts on Cyclosporine or Tacrolimus)
Pravastatin 80mg	Pravastatin 80mg	Pravastatin 80mg Pravastatin 40mg (Pts on Clarithromycin)	Pravastatin 80mg Pravastatin 20mg (Pts on Cyclosporine or Tacrolimus)
Fluvastatin 20mg	Pravastatin 10mg	Pravastatin 10mg	Pravastatin 10mg
Fluvastatin 40mg	Pravastatin 20mg	Pravastatin 20mg	Pravastatin 20mg
Fluvastatin 80mg per day	Pravastatin 40mg	Pravastatin 40mg	Pravastatin 40mg Pravastatin 20mg (Pts on Cyclosporine or Tacrolimus)
Atorvastatin 10mg	Pravastatin 40mg	Pravastatin 40mg	Pravastatin 40mg Pravastatin 20mg (pt on Cyclosporine or Tacrolimus)
Atorvastatin 20mg	Pravastatin 80mg	Pravastatin 80mg	Pravastatin 80mg Pravastatin 20mg (pt on Cyclosporine or Tacrolimus)
Atorvastatin 40mg, 60mg	Rosuvastatin 10mg	Rosuvastatin 10mg	Rosuvastatin 10mg Rosuvastatin 5mg (Pts on Cyclosporine or Tacrolimus)

Atorvastatin 80mg	Dispense as ordered	Monitor pt closely for potential myotoxicity & consider decreasing atorvastatin dose	Monitor pt closely for potential myotoxicity & consider decreasing atorvastatin dose
Lovastatin 10mg	Pravastatin 10mg	Pravastatin 10mg	Pravastatin 10mg
Lovastatin 20mg	Pravastatin 20mg	Pravastatin 20mg	Pravastatin 20mg
Lovastatin 40mg	Pravastatin 40mg	Pravastatin 40mg	Pravastatin 40mg Pravastatin 20mg (pt on Cyclosporine or Tacrolimus)
Lovastatin 80mg	Pravastatin 80mg	Pravastatin 80mg	Pravastatin 80mg Pravastatin 20mg (pt on Cyclosporine or Tacrolimus)
Rosuvastatin 5-10 mg	Dispense as ordered	Dispense as ordered	Rosuvastatin 5mg (Pts on Cyclosporine or Tacrolimus)
Rosuvastatin >10 mg	Dispense as ordered	Dispense as ordered	Rosuvastatin 5mg (Pts on Cyclosporine or Tacrolimus) Rosuvastatin 10mg (HIV Patients or Pts on Fibrates)

Costs/tablet: Simvastatin = $0.06 – $0.12; Pravastatin = $0.35 - $1.62; Atorvastatin = $2.24 - $3.36; Rosuvastatin = $0.66

* When administering pravastatin with protease inhibitors, fibrates or cyclosporine, there is a potential drug interaction. It is less, however, when compared to atorvastatin, simvastatin & lovastatin.

Medications Administration Based on Level of Patient Monitoring

	Critical Care Areas*	Progressive Care	Med-Surg Tele
Nursing Units	4SCCT 5SCCT 6SCCT 7SCCT 8SCCT ED	3SCCT 5North 6North 6SE	**Med:** 4NW (monitored), 4South, 5South, 6SW, 7SE **Surg:** 7North, 8North, 8South
Nurse:Patient Ratio		1:3	Med/surg/Tele: 1:4 4SW BMT: 1:1
Routine Frequency of Vital Sign Monitoring	every 1 hour	every 2-4 hour	**Med:** every 8 hour **Surg:** every 4h x first 24h; if on PCA, every 2h x 24h then every 4h
Type of Monitoring	bedside hardwire monitors	bedside hardwire monitors	remote monitoring
Nursing Credentials	ACLS/BLS	ACLS/BLS	BLS
Abciximab (Reopro®)	IV infusion	IV infusion (for continuation of therapy initiated in the cath lab)	NA
Adenosine (Adenocard®)	IV Push	IV Push	NA
Amiodarone (Cordarone)	IVPB (loading dose) IV Infusion	IVPB (loading dose) IV infusion	NA
Amrinone (Inocor®)	IV Push IV Infusion	NA	NA
Atracurium Besylate (Tracrium®)	IV Push IV Infusion	NA	NA
Atropine Sulfate	IV Push	IV Push	IV Push
Bretylium (Bretylol®)	IVPB IV Infusion	NA	NA
Calcium Chloride	IV Push IVPB	NA	NA
Calcium Gluconate	IV Push IVPB	IVPB	IVPB
Chlorothiazide Sodium (Diuril Sodium®)	IV Push IVPB	IVPB	IVPB
Cisatracurium (Nimbex®)	IV Push IV Infusion	NA	NA

Medications Administration Based on Level of Patient Monitoring

	Critical Care Areas*	Progressive Care	Med-Surg Tele
Nursing Units	4SCCT 5SCCT 6SCCT 7SCCT 8SCCT ED	3SCCT 5North 6North 6SE	**Med:** 4NW (monitored), 4South, 5South, 6SW, 7SE **Surg:** 7North, 8North, 8South
Diazepam (Valium®)	IV Push	NA	NA
Digoxin (Lanoxin®)	IV Push	IV Push	IV Push
Digoxin Immune Fab (Ovine) (Digibind®)	IV Push, IVPB IV Infusion	IV Push, IVPB IV Infusion	NA
Diltiazem (Cardizem®)	IV Push IV Infusion	IV Infusion (No titration)	NA
Dobutamine HCl (Dobutrex®)	IV Infusion	IV Infusion (Pre-Transplant, Advanced CHF, No titration infusion)	NA
Dopamine Hydrochloride (Intropin®)	IV Infusion	6SE: IV Infusion (Pre-Transplant, Advanced CHF. No titration at dose NTE 10 mcg/kg/min)	4SW for BMT patients only: IV Infusion (No titration at dose NTE 5 mcg/kg/min)
Doxapram HCl (Dopram®)	IV Push IV Infusion	NA	NA
~~Drotrecogin (Xigris®)~~	~~IV infusion~~	~~NA~~	~~NA~~
Enalaprilat (Vasotec I.V.®)	IV Push IVPB	IVPB	NA
Ephedrine Sulfate (Ephedrine®)	Slow IV Push	NA	NA
Epinephrine HCl	IV Infusion	NA	NA
Epoprostenol (Flolan®)	IV Infusion	**6NE:** IV Infusion (for continuation of therapy. No titration)	~~**5SE:**~~ IV Infusion (for continuation of therapy. No titration)
Eptifibatide (Integrilin®)	IV infusion	IV infusion (for continuation of therapy initiated in the cath lab)	NA
Esmolol (Brevibloc®)	IVPB IV Infusion	NA	NA
Ethacrynate Sodium (Edecrin®)	IVPB	IVPB	IVPB

Medications Administration Based on Level of Patient Monitoring

	Critical Care Areas*	Progressive Care	Med-Surg Tele
Nursing Units	4SCCT 5SCCT 6SCCT 7SCCT 8SCCT ED	3SCCT 5North 6North 6SE	**Med:** 4NW (monitored), 4South, 5South, 6SW, 7SE **Surg:** 7North, 8North, 8South
Fentanyl (Sublimaze®)	IV Push IV Infusion	~~IVP PCA, PCEA~~ IV infusion	PCA, PCEA IV infusion
Flumazenil (Romazicon®)	IV Push	IV Push	IV Push
Furosemide (Lasix®)	IV Push, IVPB IV Infusion	IV Push, IVPB IV Infusion	IV Push, IVPB IV Infusion
Haloperidol Lactate (Haldol®)	IV Push IVPB	IV Push IVPB	NA
Hydralazine Hydrochloride (Apresoline®)	IV Push IVPB	IVPB	IVPB
Ibutilide (Corvert®)	IV Infusion	IV Infusion	NA
Insulin, Regular	IV Push IV Infusion	IV Push IV Infusion	IV Push 7SE: IV Push, IV Infusion
Isoproterenol (Isuprel®)	IV Push IV Infusion	NA	NA
Ketamine (Ketalar®)	IV Infusion LOW DOSE IN PCA	~~IV Infusion~~ LOW DOSE IN PCA	LOW DOSE IN PCA
Labetalol (Normodyne®, Trandate®)	IV Push IV Infusion	IV Push IV Infusion	NA
Lidocaine (Xylocaine®)	IV Push, IVPB IV Infusion	IV Push, IVPB IV Infusion	NA
Lorazepam (Ativan®)	IV Push IV Infusion	IV Push	IV Push
Magnesium sulfate, I.V. Administration of (Non-Obstetric Use)	IVPB IV Infusion	IVPB	IVPB
Mannitol Injection, (Mannitol®)	IV Infusion	IV Infusion	IV Infusion
Meperidine HCl (Demerol®)	IV Push, IV Infusion	IV Push	IV Push
Metoprolol	IV Push IVPB	IVPB	IVPB

Medications Administration Based on Level of Patient Monitoring

	Critical Care Areas*	Progressive Care	Med-Surg Tele
Nursing Units	4SCCT 5SCCT 6SCCT 7SCCT 8SCCT ED	3SCCT 5North 6North 6SE	**Med:** 4NW (monitored), 4South, 5South, 6SW, 7SE **Surg:** 7North, 8North, 8South
Midazolam (Versed®)	IV Push, IVPB IV Infusion	**IV Push**	NA
Milrinone (Primacor®)	IV Infusion	6SE: IV Infusion (Pre-Transplant, Advanced CHF, No titration infusion)	IV Infusion (Pre-Transplant, Advanced CHF. Patients stabilized on a fixed drip rate of milrinone x 72 hour. No titration infusion)
Norepinephrine (Levarterenol, Levophed®)	IV Infusion	NA	NA
Nicardipine (Cardene®)	IV Infusion	NA	NA
Nitroglycerin	IV Infusion	~~IV Infusion. No titration~~	NA
Nitroprusside (Nipride®)	IV Infusion	~~6SE: IV Infusion (Pre-Transplant, Advanced CHF, No titration infusion)~~	NA
Pancurionium Bromide (Pavulon®)	IV Push IV Infusion	NA	NA
Pentobarbital (Nembutal®)	IVPB IV Infusion	NA	NA
Phenobarbital Sodium (Luminal®)	IV Push IVPB	IVPB (6SE only)	IVPB (4SW only)
Phentolamine (Regitine®)	IVPB	IVPB	NA
Phenylephrine (Neo-Synephrine®)	IV Infusion	NA	NA
Phytonadione (Vitamin K) (Aqua Mephyton®)	IV Push (Emerg only) IVPB	IVPB	IVPB
Potassium Chloride	IVPB up to 20 mEq/hr	IVPB up to 20 mEq/hr	IVPB at 10 mEq/hr 4S: IVPB up to 15mEq/hr

Medications Administration Based on Level of Patient Monitoring

	Critical Care Areas*	Progressive Care	Med-Surg Tele
Nursing Units	4SCCT 5SCCT 6SCCT 7SCCT 8SCCT ED	3SCCT 5North 6North 6SE	**Med:** 4NW (monitored), 4South, 5South, 6SW, 7SE **Surg:** 7North, 8North, 8South
Procainamide HCL (Pronestyl®)	IVPB IV Infusion	IVPB IV infusion	NA
Propofol (Diprivan®)	IV Infusion	NA	NA
Propranolol (Inderal®)	IV Push	NA	NA
Rocuronium bromide (Zemuron®)	IV Push IV Infusion	NA	NA
Sodium Chloride, 3%	IV Bolus (ICP only) IV Infusion	IV Infusion (NTE 100 ml/hr)	IV Infusion (NTE 100 ml/hr)
Sodium Chloride 23.4%	IVPB	NA	NA
Succinylcholine Chloride (Anectine®, Quelicin®)	IV Push	NA	NA
Tirofiban (Aggrastat®)	IV infusion	IV infusion (for continuation of therapy initiated in the cath lab or initiation of Plavix bridging protocol)	NA
Treprostinil (Remodulin®)	SQ, IV Infusion	6NE: SQ, IV Infusion (for continuation of therapy. No titration)	5SE: SQ, IV Infusion (for continuation of therapy. No titration)
Vasopressin (Pitressin®)	IV Infusion	NA	NA
Vecuronium Bromide Norcuron®)	IV Push IV Infusion	NA	NA
Verapamil	IV Push IV infusion	NA	NA

NTE = not to exceed

* Critical Care Areas = ED, ICU, PACU, OR, L&D

Exclusion: all medications needed for emergent situations (e.g. Code Blues, RRT) may be administered; all medication can be administered for patients managed under the Palliative Care/Dying Patient Protocol

CEDARS-SINAI MEDICAL CENTER

Critical Care Services

ADMISSION ORDERS
PROGRESSIVE CARE UNIT

PATIENT I.D.

TIME:_____ **DATE:**_____

1. **Admit as:** ● Inpatient Level of Care: Progressive Care
2. **Primary Admitting Attending**:_____ID#:_____
3. **Admitting Diagnosis:** _____
4. **Condition:** □ Serious □ Fair/Stable
5. **Allergies:** □ No Known Allergies
   - □ Allergies to :_____
     - Reaction: □ anaphylaxis □ edema □ hives □ pruritus □ rash □ unknown □ other: _____
     - Severity: □ Severe □ Moderate □ Mild
   - □ Intolerances to: _____
6. **Isolation:** □ None □ Contact □ Contact Plus □ Airborne □ Droplet Precautions
7. **Code Status:** □ Full Resuscitation □ DNAR (no intubation, no CPR) □ Limited Resuscitation:_____
8. **Nursing:** □ Daily Weight □ Foley Catheter □ Strict I & O □ Pulse Oximetry

   Continuous Cardiac Monitoring

   Vital signs: every 2 hours unless otherwise specified: _____

   Notify MD if: □ SBP > _____< _____ DBP > _____< _____

   □ HR > _____< _____ □ Temp > _____ □ O_2 Sat < _____

   □ RR > _____< _____ □ Urine Output < _____over _____hrs

   Neuro Checks: □ every hour up to 8 hours □ every 2 hours □ every 4 hours

   For changes notify:_____

   Vascular Checks: □ every hour up to 8 hours then every 2 hours □ every 2 hours □ every4 hours

   For changes notify:_____
9. **Activity:** □ Bed rest □ As tolerated □ Bedside Commode □ Other: _____
10. **Precautions:** □ Aspiration □ Seizure □ Fall □ C-Spine
11. **Nutrition:** □ NPO □ Tube feeding: Type :_____Rate: _____

    □ Diet:_____ □ TPN (Use Form #: 4401-03)

❑ **TELEPHONE ORDER**					**R.N.**	**DATE**	**TIME**
PHYSICIAN I.D. NUMBER ☐☐☐☐☐					**M.D.**	**DATE**	**TIME**
SIGNATURE OF TRANSCRIBER	**INIT**	**TITLE**	**DATE**	**TIME**	**SIGNATURE OF NURSE (NOTED)** **R.N.**	**DATE**	**TIME**

CEDARS-SINAI MEDICAL CENTER

Critical Care Services

ADMISSION ORDERS
PROGRESSIVE CARE UNIT

PATIENT I.D.

12. **NGT/OGT:** □ Place NGT □ Place OGT □ Portable CXR Reason: Tube position confirmation
    □ Low continuous suction □ Gravity □ Clamped
13. **Chest Tube:** □ Low suction @_____cm H_2O □ Water seal □ Heimlich valve
14. **Respiratory:**
    - □ Respiratory Therapy Order Set (Use Form #: 9718)
    - □ Mechanical Ventilation/BIPAP/CPAP (Use Form# 10218)
15. **Elevate Head of Bed 30 degrees** unless otherwise stated or contraindicated.
    - □ Other angle: _____
    - □ Reverse Trendelenberg
    - □ Contraindications: DO NOT ELEVATE HOB, REASON:
      - □ Thoraco-lumbar injury/surgery
      - □ Shock worsened by elevation of the head
      - □ Protective measures for prevention of decubitus ulcers
      - □ HOB elevation precludes comfortable positioning
      - □ BP decreases significantly with HOB elevation
      - □ Other: _____
16. **Venous Thromboembolism (VTE) Prophylaxis**: (Form # 9279)
17. **Peptic Ulcer Disease (PUD) Prophylaxis** (Indicated for ventilated or high risk patients ie. patients on high dose steroids)

    Choose either Ranitidine (Zantac®) or Sucralfate (Carafate®)

    ❑ Ranitidine (Zantac®) □ 50 mg IVP every 8 hour (Pharmacist may adjust dose for renal function),

    OR

    □ 150 mg PO every 12 hours (Pharmacist may adjust dose for renal function)

    ❑ Sucralfate (Carafate®) 1 gm PO QID

    ❑ Other: _____

❑ **TELEPHONE ORDER**					**R.N.**	**DATE**	**TIME**
PHYSICIAN I.D. NUMBER ☐☐☐☐☐					**M.D.**	**DATE**	**TIME**
SIGNATURE OF TRANSCRIBER	**INIT**	**TITLE**	**DATE**	**TIME**	**SIGNATURE OF NURSE (NOTED)** **R.N.**	**DATE**	**TIME**

CEDARS-SINAI MEDICAL CENTER

Critical Care Services

ADMISSION ORDERS
PROGRESSIVE CARE UNIT

PATIENT I.D.

18. **Medications:** All drips are in D_5W unless otherwise specified: □ Normal Saline
Titration is NOT allowed in PCU
- □ Concentrate all medications maximally
- □ Dopamine 800 mg/250mL: _____mcg/kg/min
- □ Dobutamine 500 mg/250mL: _____mcg/kg/min
- □ Amiodarone - Loading Dose: 150 mg IVPB x 1 over 15 minutes, followed by 1mg/minute x 6 hours, then 0.5 mg/minute continuous infusion
- □ Amiodarone_____mg IVPB daily
- □ Diltiazem: _____mg/hr IV
- □ Milrinone 20mg/100mL (6SE only): _____mcg/kg/min
- □ Tirofiban (Aggrastat): 12.5mg/250mL _____mcg/kg/min

19. **Admission Lab Work and Diagnostic Studies:**
- □ CBC: □ STAT □ in AM □ Every _____hrs
- □ Hgb/Hct: □ STAT □ in AM □ Every _____hrs
- □ BMP: □ STAT □ in AM □ Every _____hrs
- □ Potassium/Magnesium/Creatinine:
- □ STAT □ in AM □ Every _____hrs
- □ Magnesium/Phos: □ STAT □ in AM □ Every _____ hrs
- □ PT/PTT: □ STAT □ in AM □ Every _____ hrs
- □ Troponin: □ STAT □ Every 8 hours
- □ Lactic Acid: □ STAT □ in AM □ Other
- □ Type and Cross ____ units Packed Red Blood Cells

Micro: Culture & Sensitivity:
- □ Sputum □ U/A, Urine □ Blood, x 2
- □ Fungal blood culture □ Stool C-Diff □ Sputum C&S to rule Out MDRO
- □ Nasal Swab C&S to rule out MRSA □ Rectal Swab to rule Out VRE

ABG: □ STAT □ in AM □ Every ____ hrs

12-Lead EKG: □ STAT □ in AM □ Every ____ hrs

X-RAY: □ Portable Chest STAT (Reason): _____

Other Labs: _____ □ STAT □ in AM □ Every _____ hrs

_____ □ STAT □ in AM □ Every _____ hrs

_____ □ STAT □ in AM □ Every _____ hrs

❑ **TELEPHONE ORDER**					**R.N.**	**DATE**	**TIME**
PHYSICIAN I.D. NUMBER ☐☐☐☐☐					**M.D.**	**DATE**	**TIME**
SIGNATURE OF TRANSCRIBER	**INIT**	**TITLE**	**DATE**	**TIME**	**SIGNATURE OF NURSE (NOTED)** **R.N.**	**DATE**	**TIME**

CEDARS-SINAI MEDICAL CENTER

Critical Care Services

ADMISSION ORDERS
PROGRESSIVE CARE UNIT

PATIENT I.D.

20. IV Fluids: _____at _____ml/hour

21. Blood Products: Transfuse patient with ____ units PRBC ____ units FFP _____ units Platelets

Pre-medicate with □ Acetaminophen 650 mg PO/PR x 1 – give PR only if patient can't tolerate PO
□ Diphenhydramine 25 mg PO/IV x 1 – give IV only if patient can't tolerate PO

□ CBC ____ hours post- transfusion

22. Pain Management:

Mild pain (pain score: 1-3)	Moderate Pain (pain score: 4-6)	Severe pain (pain score: 7-10)

Use if patient is unable to take oral pain medication: **Parenteral Medication**

Administer: □ Morphine □ Dilaudid □ _____

_____ mg □ SC □ IV every _____ hours PRN Mild Pain
_____ mg □ SC □ IV every _____ hours PRN Moderate Pain
_____ mg □ SC □ IV every _____ hours PRN Severe Pain

Use if patient is able to take oral pain medications: **Oral Medications**

□ Acetaminophen 650 mg PO every 6 hours PRN Mild Pain
□ Norco (Hydrocodone 5 mg + Acetaminophen 325 mg) 1 TAB PO every 4 hrs PRN Moderate Pain
□ Norco (Hydrocodone 10 mg + Acetaminophen 325 mg) 1 TAB PO every 4 hrs PRN Severe Pain
□ _____PO every _____hrs PRN _____ pain

No greater than 3 grams Acetaminophen/day from all sources.

23. Other Medications:
- □ Ondansetron 4 mg IVP every 8 hrs PRN nausea/vomiting
- □ Docusate 100 mg PO BID: hold for loose bowel movement
- □ Bisacodyl 10 mg PR daily PRN for constipation
- □ Magnesium Hydroxide 30 ml PO PRN constipation
- □ Zolpidem 5 mg PO HS PRN insomnia, may repeat x 1.
- □ Acetaminophen 650 mg PO/PR/NGT every 6 hrs PRN fever greater than 38°C. Give PR only if patient can't tolerate PO

24. □ CIWA Protocol (Use Form #: 8933)

25. Additional Orders: _____

_____

_____

❑ TELEPHONE ORDER					R.N.	DATE	TIME
PHYSICIAN I.D. NUMBER □□□□□					M.D.	DATE	TIME
SIGNATURE OF TRANSCRIBER	INIT	TITLE	DATE	TIME	SIGNATURE OF NURSE (NOTED) R.N.	DATE	TIME

CEDARS-SINAI MEDICAL CENTER

Adult Trauma Service: Rhabdomyolysis Algorithm

This is a guideline only and not to be substituted for individual clinical judgment.
Trauma service to consider nephrology consultation in select cases.

1. OBTAIN INITIAL SERUM CK

>10,000 U/L?

- No → Obtain CK q8h on high risk patients until 3 consecutive values decline
- Yes →
  1. Ensure that adequate resuscitation has taken place and hypovolemia has been corrected. *If true, enter the following orders:*
  2. Bolus with mannitol 25% 0.5gm/kg over 20 minutes
  3. Bolus with 1,000 mL 1/2NS+ 75 mEq sodium bicarbonate over 30-60 minutes
  4. Begin mannitol 20% infusion at 0.1gm/kg/hr
  5. Begin D51/4NS+100 mEq sodium bicarbonate at 2-5 mL/kg/hr
  6. Check serum osmolality and ABG q8h

IMPORTANT CONSIDERATIONS

- High risk patients include those with multiple long bone fractures, crush injuries, vascular compromise, or hypotension
- To avoid fluid overload, consider hemodynamic monitoring, especially in patients with heart disease
- Obtain serum osmolality q8h while on mannitol (max 200g/24h & cumulative dose of 800g) and hold if serum osmolality > 320 mosm/kg or osmolal gap (measured-calculated serum osmolality) > 55mOsm/kg
  *Osmolality=2xNa+Glucose/18+BUN/2.8
- If urine pH does not rise above 6 after 12 hours of treatment, consider discontinuing alkalization and continue hydration with NS or LR

WARNING

- Oliguria in patients with rhabdomyolysis requires conversion to a brisk urine output within 1-2 hours to avoid volume overload and need for dialysis
- If persistent oliguria is present (< 400 mL/24h), mannitol and bicarbonate are discouraged.

2. MONITOR URINE OUTPUT HOURLY

>2-3 mL/kg/hr?

- No → **Bolus with mannitol 25% 0.5 gm/kg** Consider increasing mannitol drip rate after multiple boluses if adequate intravenous volume is present → 2. MONITOR URINE OUTPUT HOURLY
- Yes → **Maintain mannitol & sodium bicarbonate infusions & *Proceed to #3***
- *Reduce mannitol and crystalloid infusions by 50% if urine output maintained at >3 mL/kg/hr x 2 hours*

continue

3. MONITOR URINE pH Q4H

- <6 → **Bolus with 50mEq sodium bicarbonate** → **Recheck urine pH after 2 hours** → **If pH still <6 DO NOT BOLUS with sodium bicarbonate yet** → **Check ABG**
- 6-7 → **Continue ABG q8h while on sodium bicarbonate infusion – *Proceed to #4***
- >7 → **STOP sodium bicarbonate infusion and use maintenance crystalloid infusions as needed**

Check ABG

Serum pH >7.5?

- No → **50 mEq sodium bicarbonate bolus** → Check ABG
- Yes →
  1. **STOP sodium bicarbonate infusion and consider acetazolamide 500 mg IV**
     DO NOT use acetazolamide if patient is allergic to sulfa drugs
  2. **OK to Continue Mannitol as needed**

4. CONTINUE TO CHECK SERIAL CK LEVELS Q8H

- > 10,000 U/L → **CONTINUE TREATMENT**
- < 10,000 U/L X 2 → **STOP TREATMENT**

References:
Brown CVR, et al. *J Trauma*. 2004;56:1191-1196
Eneas JF, et al. *Arch Intern Med*. 1979;139(7):801-805
Malinoski, et al. *Crit Care Clin*. 2004;20(1):171-192
Zager RA. *Lab Invest*. 1969;60(5):619-629
Zager RA, et al. *J Am Soc Nephrol*. 1991;2(4):848-855

Darren Malinoski, MD 02/2008
Revised 11/2011

CEDARS-SINAI MEDICAL CENTER

Department of Pharmacy Services

Nesiritide (Natrecor®) Guidelines

Criteria for Use: Restricted to Cardiology and Cardio-Thoracic Surgery Attending Physicians

	Criteria for Use	Exclusion Criteria	Monitoring Parameter/Goals	Reassessment for Continuation of Therapy
ADHF	1. High Pulmonary Artery Pressure (>60mmHg or trans pulmonary gradient pressure >15mmHg) in catheterized patients) 2. In non-catheterized patients: dyspnea at rest, pulmonary congestion on chest X-ray, increased jugular venous pressure on physical exam 3. If criteria 1 or 2 is met, patient must either be: a. Diuretic resistant (unresponsive to 240mg/day of intravenous furosemide or equivalent and not meeting urine output goal of ≥ 1 liter/day; consider adding metolazone 5mg daily or BID) ***or*** b. Refractory to a trial of oral vasodilators (hydralazine**, isosorbide dinitrate), nitroglycerin or nitroprusside (concurrent therapy with nesiritide may cause significant hypotension)	1.SBP <90 mmHg 2.MAP <60 mmHg *Caution in patients with CI < 2.2ml/min/m^2	1. Fluid status: net negative of 1 liter per day for 24 to 48h 2. Hemodynamics status (*catheterized patients*) pulmonary artery pressure of <60mmHg, transpulmonary gradient pressure of <15mmHg	Discontinue therapy at 48h if patient has: 1. Not achieved euvolemic fluid status ***or*** 2. PAP >60mmHg and transpulmonary gradient pressure >15mmHg **Do not re-initiate therapy* Continue therapy at 48 hours if patient has: 1. Achieved euvolemic fluid status ***or*** 2. PAP <60mmHg,transpulmonary gradient pressure <15mmHg * *Reassess fluid status and hemodynamic status every 48h thereafter* Pharmacists: Calculating Transpulmonary Gradient Pressure (TGP): TGP = PA mean – PCW
Post-Op Cardiac Surgery	1. Diuretic resistant (80mg/hour infusion of furosemide or equivalent for 4-6 hours and not meeting urine output goal of ≥1ml/kg/hr) ***or*** 2. 1st post-op Scr > 2mg/dL		1. SCr BID x 24-48 hours – ***Pharmacist to order if not already ordered*** 2. UOP ≥ 1ml/kg/hr for 24-48h or SCr < 2 mg/dL for 24-48h after initiation of therapy	Discontinue therapy at 4 to 6 hours if UOP goal of less than 1ml/kg/hr is met * *Do not re-initiate therapy* Discontinue therapy at 48h if: 1. UOP ≥ 1ml/kg/hr ***or*** 2. SCr <2 mg/dL **Consider restarting therapy if urine output significantly decreases or if SCr rises above 2mg/dL after withdrawing therapy*
Post-VAD Place-ment	1. Diuretic resistant (80mg/hour of furosemide or equivalent for 4-6 hours and not meeting urine output goal of ≥ 1ml/kg/hr) ***or*** 2. Arrythmias secondary to inotropes (i.e., milrinone) ***or*** 3. 1st post-VAD placement Scr > 2mg/dL		1. SCr BID x 24-48 hours – ***Pharmacist to order if not already ordered*** 2. CI ≥ 2.2ml/min/m^2 3. PAP ≤ 45-50mmHg 4. UOP ≥ 1ml/kg/hr for 24-48h or SCr <2 mg/dL for 24-48h after initiation of therapy	Discontinue therapy at 48h if UOP <1ml/kg/hr, PAP≥ 45-50mmHg, or if SCr >2mg/dL * *Do not re-initiate therapy* Discontinue therapy at 48h if: 1. UOP ≥ 1ml/kg/hr ***or*** 2. SCr <2 mg/dL ***or*** 3. PAP≤ 45-50mmHg **Consider restarting therapy if urine output decreases significantly or if SCr, PAP increases by 25% or more after withdrawing therapy*

**Hydralazine dose range (10-100mg PO TID), isosorbide dinitrate dose range (10-40mg PO TID), nitroglycerin infusion range (5-300 mcg/min), nitroprusside infusion range (0.3-10mcg/kg/min) or maximum tolerated dose of these agents.

References

1. Beaver et al. Effectiveness of nesiritide on dialysis or all-cause mortality in patients undergoing cardiothoracic surgery. Clinical Cardiology 2006 (29) 18-24.
2. Effect of nesiritide in patients with acute decompensated heart failure (ASCEND-HF). New England Journal of Medicine 2011; 365: 32-43.
3. Ejaz et al. Prophylactic nesiritide does not prevent dialysis or all-cause mortality in patients undergoing high-risk cardiac surgery. J Thoracic Cardiovascular Surgery 2009. 138 (4) 959-964.
4. NAPA investigators: Effects of perioperative nesiritide in patients with left ventricular dysfunction undergoing cardiac surgery: The NAPA trial. J Am Coll Cardio 2007. 49(6); 716-728

PHARMACIST CHECKLIST

Patient Information

Date: _____ Name: _____ DOB: _____ Diagnosis: _____

Reason for Admission: _____

Nesiritide Dose: Initial: _____ mcg/kg/min Current: _____ mcg/kg/min

ADHF	☐ PAP >60mmHg ☐ Trans pulmonary gradient pressure >15mmHg ☐ Symptomatic: dyspnea, pulmonary congestion on chest X-ray or physical exam **In the setting of above:** ☐ Diuretic resistance (unresponsive to 240mg/day of furosemide or equivalent and not meeting urine output goal of ≥ 1 liter/day; consider adding metolazone 5mg daily or BID) o UOP/24 hours: _____ ml o Metolazone _____ mg ☐ daily ☐ BID added on _____ (date) ☐ Maximum Dose Administered o Hydralazine _____ mg IV every ____ hrs. o Nitroglycerine _____ mcg/min o Nitroprusside _____ mcg/kg/min o Other: _____.
Post-Op Cardiac Surgery	☐ Diuretic resistance (unresponsive to 240mg/day of furosemide or equivalent and not meeting urine output goal of ≥ 1 liter/day; consider adding metolazone 5mg daily or BID) o UOP/24 hours: _____ ml o Metolazone _____ mg ☐ daily ☐ BID added on _____ (date) ☐ SCr >2mg/dL and rising
Post VAD Placement	☐ Diuretic resistance (unresponsive to 240mg/day of furosemide or equivalent and not meeting urine output goal of ≥ 1 liter/day; consider adding metolazone 5mg daily or BID) o UOP/24 hours: _____ ml o Metolazone _____ mg ☐ daily ☐ BID added on _____ (date) ☐ SCr >2mg/dL and rising ☐ Arrythmias secondary to inotropes

Parameters Immediately Prior to Infusion:

SBP: _____ mmHg Baseline SCr: _____ mg/dL Latest SCr: _____ mg/dL (date: _____) Latest BNP: _____ mg/dL (date: _____)

Medication Regimen at Time of Nesiritide Initiation

Medication	Date Initiated	Dose	Route	Frequency

Notes:

_____

_____

_____

CEDARS-SINAI MEDICAL CENTER

Rosiglitazone (Avandia®), Rosiglitazone/Metformin (Avandamet®), Rosiglitazone/Glimepiride (Avandaryl®) Procedure

ROSIGLITAZONE (AVANDIA®) AND ROSIGLITAZONE CONTAINING PRODUCTS

- Rosiglitazone is a thiazolidinedione antidiabetic agent indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.
- Rosiglitazone should be used only in patients with type 2 diabetes who are:
  - already taking rosiglitazone or
  - unable to control their blood sugar on other diabetes medicines, and after talking with their doctor have decided not to take pioglitazone
- Cardiac Failure: Rosiglitazone can cause fluid retention, which may exacerbate or lead to heart failure.
  - Patients should be observed for signs and symptoms of heart failure. If heart failure develops, discontinuation or dose reduction of rosiglitazone must be considered.
  - Initiation of rosiglitazone in patients with established NYHA Class III or IV heart failure is contraindicated, and it is not recommended in patients with symptomatic heart failure.
- Risk of Myocardial Infarction: A meta-analysis of 52 clinical trials (mean duration 6 months; 16,995 total patients), most of which compared rosiglitazone to placebo, showed rosiglitazone to be associated with a statistically significant increased risk of myocardial infarction.
- Because of the potential increased risk of myocardial infarction, the FDA requires that the manufacturer of rosiglitazone have a REMS (Risk Evaluation and Mitigation Strategy) program in place. The need for REMS is determined by the FDA to ensure that benefits outweigh risks at the time of drug approval and when new safety information is available via clinical trials, ADE reports, post- marketing surveillance.
  - The manufacturer requires that the Patient and Physician enroll in the Avandia-Rosiglitazone Medicines Access Program and are able to comply with the program requirements.

PROCEDURE:

1. Rosiglitazone is non-formulary. No new starts of rosiglitazone will be permitted in the hospital.
2. **Continuation of therapy –** If a patient was on rosiglitazone prior to admission and is ordered to continue therapy during admission in the hospital:
   a. Confirm that patient is enrolled in Avandia-Rosiglitazone Medicines Access Program* by calling 1-800-282-6342
      *Note: Hours of operation of Avandia-Rosiglitazone Medicines Access Program 8:00 AM to 8:00 PM ET.
   b. Prescriber ordering continuation of therapy of rosiglitazone for patient does not need to be enrolled
   c. Check to see if patient is able to provide own supply.
      i. If yes, please process order as Patient's Own Medication
      ii. If no, please contact DI/AOD in order to obtain patient-specific supply
   d. For all orders processed, please create an iVent to communicate that prescriber and patient (patient only if continuation of therapy) are enrolled in Avandia-Rosiglitazone Medicines Access Program.

CEDARS-SINAI MEDICAL CENTER

DOFETILIDE (TIKOSYN®) FACT SHEET

DOFETILIDE (TIKOSYN®)

- Tikosyn is an antiarrhythmic agent indicated for the conversion to and maintenance of normal sinus rhythm in highly symptomatic patients with atrial fibrillation/atrial flutter.
- Dofetilide should be reserved for these types of patients, because it can cause life threatening ventricular arrhythmias.
- Ventricular Arrhythmia: Dofetilide can cause serious ventricular arrhythmias, primarily Torsade de Pointes (TdP), which is associated with QT interval prolongation.
    - To minimize the risk of induced arrhythmia, patients initiated or re-initiated on dofetilide should be placed for a minimum of 3 days in a facility that can provide calculations of creatinine clearance, continuous electrocardiographic monitoring, and cardiac resuscitation.
    - Patients must also be rehospitalized for 3 days if the dofetilide dose is to be increased. Previous toleration of higher doses does not eliminate the need for rehospitalization.
    - Dofetilide is contraindicated in patients with congenital or acquired long QT syndromes and in patients with severe renal impairment (calculated creatinine clearance <20 mL/min).

RISK EVALUATION AND MITIGATION STRATEGY (REMS)

- Because of the potential increased risk of life threatening ventricular arrhythmias, the FDA requires that the manufacturer of dofetilide have a REMS program in place.
- The need for REMS is determined by the FDA to ensure that benefits outweigh risks at the time of drug approval and when new safety information is available via clinical trials, ADE reports, and post- marketing surveillance.
- Previous to the REMS mandated by the FDA, the manufacturer of dofetilide, Pfizer, had already required that the Prescriber and Pharmacy become certified. Therefore, those already certified need only complete a **one-time recertification by January 2012**.

DOFETILIDE – CSMC PROCEDURE

1. In order to prescribe dofetilide for patients admitted to CSMC, the physician must be certified by having submitted a completed Prescriber Certification Form to Pfizer. The prescriber must be certified for both initiation and continuation of therapy.
2. Initiation, re-initiation, or dose escalation of dofetilide therapy requires a minimum of 3 days inpatient stay.
3. Patients receiving dofetilide must be admitted to a monitored bed capable of continuous electrocardiographic monitoring.
4. Orders for dofetilide must be completed using the Dofetilide order form (#7466).
5. Upon receipt of an order for dofetilide, the pharmacist will contact the prescriber to confirm that he/she has been certified before processing the order.
6. Patients receiving dofetilide will receive a Medication Guide with first dose.
7. Upon discharge:
    - The patient will receive a free 7-day supply of dofetilide from the Inpatient Main Pharmacy
    - Pharmacist will provide patient counseling.
    - The prescriber must provide a separate prescription for the patient's ongoing outpatient supply.

CEDARS-SINAI MEDICAL CENTER
DEPARTMENT OF PHARMACY SERVICES

Dofetilide (Tikosyn®) Order Form

(To be completed by Tikosyn® certified prescriber)

PROOF
This Form Has Not Been Approved to Print

PATIENT I.D.

TIME: _____ DATE: _____

Patient must be admitted to a unit with continuous EKG monitoring prior to initiation of therapy and for a minimum of 3 days.

1. Yes No Each of the following criteria must be met (must be marked "yes")

❑ ❑ All previous antiarrhythmic therapy has been discontinued for at least 3 half-lives:
- Amiodarone (must be discontinued at least three months unless serum level < 0.3 mcg / mL)
- Bretylium (t ½ = 6 - 14 hours)
- Disopyramide (t ½ = 4 - 10 hours)
- Ibutilide (t ½ = 2 - 12 hours)
- Procainamide (PA t ½ = 3 - 8 hours; NAPA t ½ = 5 - 9 hours)
- Quinidine (t ½ = 6 - 8 hours)
- Flecainide (t ½ = 7 - 22 hours)
- Mexiletine (t ½ = 10 - 14 hours)
- Lidocaine (t ½ = 1.5 - 2 hours)
- Tocainide (t ½ = 11 - 23 hours)
- Propafenone (t ½ = 10 - 32 hours)
- Sotalol (t ½ = 12 hours)
- Moricizine (t ½ = 6 - 13 hours)

❑ ❑ Patient does <u>not</u> have orders for the following meds:
(Concurrent use with dofetilide is contraindicated)
- Cimetidine (Tagamet®)
- Hydrochlorothiazide alone or in combinations (Dyazide®)
- Ketoconazole (Nizoral®)
- Megestrol (Megace®)
- Verapamil (Calan®, Isoptin®, Verelan®, Covera-hs®)
- Prochlorperazine (Compazine®)
- Trimethoprim alone or in combination with sulfamethoxazole (Bactrim®, Septra®)

❑ ❑ Patient does <u>not</u> have congenital or acquired long QT interval

❑ ❑ 12-lead ECG to be done prior to each dose of dofetilide

2. ❑ KCL _____ meq PO now (if K^+ < 4 meq / l, replace K^+ prior to initiating dofetilide); recheck K^+ 4 hours after dose and before initiating dofetilide

3. ❑ MagPlus® (133 mg = 10.95 meq Magnesium $^{2+}$) _____ tabs PO now (if Magnesium $^{2+}$ < 2 mg / dl, replace Magnesium $^{2+}$ prior to initiating dofetilide)

4. • Continuous ECG monitoring prior to and during dofetilide for a minimum of 3 days or a minimum of 12 hours after electrical or pharmacological conversion to normal sinus rhythm, whichever is greater
   • Do not start dofetilide if HR < 50.
   • Do not start dofetilide if QTc > 440 msec or QTc > 500 msec in patients with ventricular conduction abnormalities

5. Starting dofetilide dose *(See next page for dosing chart)*

Dofetilide _____ mcg PO every 12 hours

<u>To estimate creatinine clearance (Clcr):</u>

Clcr: **Males:** $\frac{\text{(140-age) x body weight (kg)}}{72 \times \text{Scr (mg / dl)}}$ **Females:** 0.85 X Males

					R.N.		DATE	TIME
PHYSICIAN I.D. NUMBER					SIGNATURE OF PHYSICIAN M.D.		DATE	TIME
SIGNATURE OF TRANSCRIBER	INIT.	TITLE	DATE	TIME	SIGNATURE OF NURSE (NOTED) R.N.		DATE	TIME

CEDARS-SINAI MEDICAL CENTER
DEPARTMENT OF PHARMACY SERVICES

Tikosyn™ (Dofetilide) Order Form

(To be completed by Tikosyn® certified prescriber)

PROOF
This Form Has Not Been Approved to Print

PATIENT I.D.

	Calculated Creatinine Clearance	Dofetilide Dose
Starting dose	> 60 ml / min	500 mcg PO every 12 hours
	40 - 60 ml / min	250 mcg PO every 12 hours
	20 - 39 ml / min	125 mcg PO every 12 hours
	< 20 ml / min	Contraindicated
Second Dose At 2-3 hrs after the first dose, determine the QTc interval. If the QTc has increased by > 15% compared to baseline or if the QTc is > 500 msec (> 550 msec in patients with ventricular conduction abnormalities) the dose should be reduced. Only 1 dose reduction is recommended; if the QTc remains prolonged following the first dose reduction, dofetilide therapy should be discontinued.	**If the starting dose based on calculated CLcr is**	**Then the adjusted dose (for QT prolongation) is**
	500 mcg PO every 12 hours	250 mcg po every 12 hours
	250 mcg PO every 12 hours	125 mcg po every 12 hours
	125 mcg PO every 12 hours	125 mcg po every 24 hours
Doses 3-5	At 2 to 3 hours after each subsequent dose, determine QTc interval. If at any time after the second dose of dofetilide, the QTc is > 500 msec (550 msec in patients with ventricular conduction abnormalities) **discontinue dofetilide**.	

Nursing orders

- Nurse to provide patient with a Medication Guide with the 1st dose.

6. Document all QTc interval measurements in CS-Link (note: QT interval should be used if HR < 60 or > 100 bpm)
7. Check baseline heart rate and QTc interval prior to first dose of dofetilide. Contact the following dofetilide certified prescriber _____, MD with the results at the following phone number: ( ) _____.
8. Contact the above certified prescriber with the result of the QTc interval, as determined by 12-lead ECG prior to every dose of dofetilide
9. Run a 12-lead ECG to measure the QTc interval 2-3 hours after each dose of dofetilide. Contact the physician with the results as noted in order #7. If the QTc interval increases by > 15% compared to baseline value or the absolute value is > 500 msec in patients with ventricular conduction abnormalities), the physician is to hold or reduce the dose of dofetilide
10. Measure the QTc interval 2-3 hours after each dose (doses 2-5) of dofetilide thereafter. **Hold** dofetilide if the QTc interval is > 500 msec (> 550 msec in patients with ventricular conduction abnormalities) at any time after the second or subsequent doses, and notify the prescribing physician
11. **Discharge Process to Assure Continued Medication Supply**
    - Upon discharge, a **7-day** supply will be dispensed from the Inpatient Main Pharmacy free of charge and will be delivered to the patient by the pharmacist.
    - Pharmacist to provide discharge counseling prior to patient discharge.
    - A **separate prescription** for further therapy should be obtained from the certified prescribing physician for the patient's ongoing outpatient supply; this prescription should be given to the patient by the physician. The discharge prescription for ongoing therapy can be filled as follows:
      a) Approved retail pharmacy within the patient's zip code. Call 1-877-845-6796 - Option 2
      b) CVS Caremark Specialty Pharmacy (mail order): Patient can enroll himself / herself by calling 1-800-238-7828; Hours 9am - 1 pm EST. Prescriber should call or fax (1-800-567-8000) in order thereafter.

☐ TELEPHONE ORDER					R.N.	DATE	TIME
PHYSICIAN I.D. NUMBER	SIGNATURE OF PHYSICIAN				M.D.	DATE	TIME
SIGNATURE OF TRANSCRIBER	INIT.	TITLE	DATE	TIME	SIGNATURE OF NURSE (NOTED) R.N.	DATE	TIME

MEDICATION GUIDE

TIKOSYN® (Tee' ko sin)
(dofetilide) Capsules

Read the Medication Guide before you start taking TIKOSYN and each time you get a refill. This information does not take the place of talking with your doctor about your condition or treatment.

What is the most important information I should know about TIKOSYN?

TIKOSYN can cause serious side effects, including a type of abnormal heartbeat called Torsade de Pointes, which can lead to death.

To establish the right dose of TIKOSYN, treatment with TIKOSYN must be started in a hospital where your heart rate and kidney function will be checked for the first 3 days of treatment. It is important that when you go home, you take the exact dose of TIKOSYN that your doctor prescribed for you.

While you take TIKOSYN, always watch for signs of abnormal heartbeat.

Call your doctor and go to the hospital right away if you:

- feel faint
- become dizzy, or
- have a fast heartbeat

What is TIKOSYN?

TIKOSYN is a prescription medicine that is used to treat an irregular heartbeat (atrial fibrillation or atrial flutter).

It is not known if TIKOSYN is safe and effective in children under 18 years of age.

Who should not take TIKOSYN?

Do not take TIKOSYN if you:

- have an irregular heartbeat called long QT syndrome
- have kidney problems or are on kidney dialysis
- take any of these medicines:
  - cimetidine (TAGAMET, TAGAMET HB)*
  - verapamil (CALAN, CALAN SR, COVERA-HS, ISOPTIN, ISOPTIN SR, VERELAN, VERELAN PM, TARKA)*
  - ketoconazole (NIZORAL, XOLEGEL, EXTINA)*
  - trimethoprim alone (PROLOPRIM, TRIMPEX)* or the combination of trimethoprim and sulfamethoxazole (BACTRIM, SEPTRA SULFATRIM)*
  - prochlorperazine (COMPAZINE, COMPO)*
  - megestrol (MEGACE)*
  - hydrochlorothiazide alone or in combination with other medicines (such as ESIDRIX, EZIDE, HYDRODIURIL, HYDRO-PAR, MICROZIDE, or ORETIC)*

  Ask your doctor if you are not sure if any of your medicines are the kind listed above.
- are allergic to dofetilide in TIKOSYN. See the end of this leaflet for a complete list of ingredients in TIKOSYN.

What should I tell my doctor before taking TIKOSYN?

Before taking TIKOSYN, tell your doctor about all of your medical conditions including if you:

- have heart problems
- have kidney or liver problems
- are pregnant or plan to become pregnant. It is not known if TIKOSYN will harm your unborn baby.
- are breast-feeding or plan to breast-feed. It is not known if TIKOSYN passes into your breast milk. You and your doctor should decide if you will take TIKOSYN or breast-feed. You should not do both.

Especially tell your doctor if you take medicines to treat:

- heart problems
- high blood pressure
- depression or other mental problems
- asthma
- allergies, or hay fever
- skin problems
- infections

Ask your doctor if you are not sure about the medicines you take. Tell your doctor about all prescription and non-prescription medicines, vitamins, dietary supplements, and any natural or herbal remedies. TIKOSYN and other medicines may affect each other, causing serious side effects. If you take TIKOSYN with certain medicines, you will be more likely to have a different type of abnormal heartbeat. See "Who should not take TIKOSYN?"

Know the medicines you take. Keep a list of your medicines and show it to your doctor and pharmacist when you get a new medicine.

How should I take TIKOSYN?

- Take TIKOSYN exactly as your doctor tells you.
- Do not change your TIKOSYN dose unless your doctor tells you to.
- Your doctor will do tests before you start and while you take TIKOSYN.
- Do not stop taking TIKOSYN until your doctor tells you to stop. If you miss a dose, just take the next dose at your regular time. **Do not take 2 doses of TIKOSYN at the same time.**
- TIKOSYN can be taken with or without food.
- If you take too much TIKOSYN, call your doctor or go to the nearest hospital emergency room right away. Take your TIKOSYN capsules with you to show to the doctor.

What are the possible side effects of TIKOSYN?

TIKOSYN can cause serious side effects, including a type of abnormal heartbeat called Torsade de Pointes, which can lead to death. See "What is the most important information I should know about TIKOSYN?"

The most common side effects of TIKOSYN include:

- headache
- chest pain
- dizziness

Call your doctor right away if you have signs of electrolyte imbalance:

- severe diarrhea

- unusual sweating
- vomiting
- not hungry (loss of appetite)
- increased thirst (drinking more than normal)

Tell your doctor if you have any side effects that bother you or do not go away.

These are not all the possible side effects of TIKOSYN. For more information, ask your doctor or pharmacist. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store TIKOSYN?

- Store TIKOSYN between 59° to 86°F (15° to 30°C).
- Keep TIKOSYN away from moisture and humidity.
- Keep TIKOSYN in a tightly closed container.
- Keep TIKOSYN and all medicines out of the reach of children.

General information about TIKOSYN

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use TIKOSYN for a condition for which it was not prescribed. Do not give TIKOSYN to other people, even if they have the same symptoms you have. It may harm them.

This Medication Guide summarizes the most important information about TIKOSYN. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about TIKOSYN that is written for health professionals.

For more about TIKOSYN, go to **www.tikosyn.com** or call **1-877-TIKOSYN (1-877-845-6796)**.

What are the ingredients in TIKOSYN?

Active ingredient: dofetilide

Inactive ingredients:

Capsule fill: microcrystalline cellulose, corn starch, colloidal silicon dioxide, and magnesium stearate

Capsule shell: gelatin, titanium dioxide, and FD&C Yellow 6

Imprinting ink: iron oxide black, shellac, n-butyl alcohol, isopropyl alcohol, propylene glycol, and ammonium hydroxide

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Rx only

Distributed by

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LAB-0405-1.0

Revised February 2011

This Medication Guide has been approved by the U.S. Food and Drug Administration.

Alaris Drug Library Changes Date Current Library Name: **CSMC V3 OCT 2011** New Library Name: **CSMC V4 DEC 2011**

Date	Description	Library Change Recommendations
11/2/2011	**Aggrastat (Tirofiban):** Current parameters in Adult ICU profile. Concentration = 12.5mg/250ml Dosing units: continuous in mcg/kg/min Dosing range: 0.05 - 0.5 mcg/kg/min	Profile: Adult ICU, Telemetry, Procedural Area Add concentration: --mg/--ml Profile: Procedural Area Add medication to the Procedural Area profile using the same dosing units as Adult ICU profile
11/15/2011	**Dopamine:** Current concentrations: 400mg/250ml, 800mg/250ml	Profile: Adult ICU, Adult Telemetry: Add concentration = -- mg/ -- ml
11/20/2011	**Lorazepam:** Previously administered thru Curlin pump; switch to Alaris pump Concentration: 100mg/50ml, -- mg/-- mL Dosing units: mg/h Dosing range: 1-20 mg/h	Profile: Adult ICU Add medication to Adult ICU profile
11/20/2011	**Midazolam:** Current concentrations: 125 mg / 250 mL, -- mg / --- mL	Profile: Adult ICU add concentration = 250mg/250ml
11/15/2011	**Milrinone:** Current parameters in Adult ICU profile. Concentration = 20mg/100ml Dosing units: continuous in mcg/kg/min Dosing range: 0.1 mcg/kg/min - 0.8 mcg/kg/min (soft minimum and soft maximum)	Profile: Adult ICU add concentration = 40 mg/100ml, --mg/--ml Profile: Telemetry add medication to the Telemetry profile using the same dosing units as Adult ICU profile
11/14/2011	**Phenylephrine:** Current concentrations: 50 mg / 250 mL (0.2 mg / mL), -- mg / --- mL	Profile: Adult ICU Add concentration = 100 mg/ 250ml
	Adenosine CATH LAB: Previously administered using 'basic infusion' without limits. Concentration: 90mg/90ml Dosing units: mg/kg Dosing range: 0.7 - 0.84 mg/kg (soft minimum and soft maximum) (Based on infusion of 140 mcg/kg/min over 6 minutes) Duration of infusion: 1 - 9 minutes (soft minimum and soft max)	Profile: Procedural Area Add medication to the Procedural Area profile

Alaris Drug Library Changes Date Current Library Name: **CSMC V3 OCT 2011** New Library Name: **CSMC V4 DEC 2011**

Date	Description	Library Change Recommendations
11/30/2011	**Pentobarbital DRIP:** Current concentrations: 1,500mg/500mL (3mg/mL), 1,500mg/250mL (6mg/mL), 4,000mg/500mL (8mg/mL)	Profile: Adult ICU Add concentration: --mg/--ml
12/2/2011	**Fentanyl:** Current concentrations: 2,500 mcg/250 mL (10 mcg/mL), 5,000 mcg/250 mL (20 mcg/mL)	Profile: Adult ICU, Telemetry Add concentration: --mg/--ml
12/2/2011	**Lidocaine:** Current concentration: 2,000 mg/500 mL (4 mg/mL)	Profile: Adult ICU, Telemetry Add concentration: --mg/--ml
12/2/2011	**Hydromorphone DRIP:** Current concentrations: 50 mg/250 mL (0.2 mg/mL), 250 mg/250 mL (1 mg/mL), --mg/--mL.	Profile: Adult ICU, Telemetry, 3/4 Adult Oncology, Adult Med/Surg

CEDARS-SINAI MEDICAL CENTER

PHYSICIAN GUIDELINE: ADENOSINE INFUSION FOR FRACTIONAL FLOW RESERVE (FFR) MEASUREMENT DURING PCI

BACKGROUND:

Fractional flow reserve (FFR) identifies the significance of a coronary stenosis by identifying a ratio of maximal flow rate in the area of stenosis to normal maximal flow. Adenosine infusion is indicated to aid in measurement of FFR during percutaneous coronary intervention (PCI) by creating hyperemia (coronary vasodilatation) to allow measurement of FFR. PCI is an angiography guided procedure that is performed in the Cath Lab to identify diseased coronary arteries with lesions and to implant the stent(s) based on their angiographic appearance. The FFR measurement allows more selective stenting of the angiographically located lesions by identifying and measuring physiological significance (degree of flow) of the stenosis. [1]

PROCEDURE:

1. A physician order is required for: Adenosine infusion 140 mcg/kg/min intravenously for FFR during PCI procedure
   a. Maximim total dose 0.84mg/kg
2. Pharmacy will prepare adenosine infusion as 90mg/90 ml 0.9%NS
3. Adenosine infusion may ONLY be administered in the cath lab.

ADENOSINE DOSE AND INFUSION RATE[2]:

- Adenosine 90 mg/ 90 ml 0.9% NS for intravenous infusion at a rate of **140 mcg/kg/min** via a central vein until appropriate vasodilation is achieved (typically ≤ 1-2 minutes)
  - Concentration 1 mg/ml (90 mg/ 90 ml of 0.9% of NaCl)
- Dosing Chart

Weight (lb)	Weight (kg)	Drip rate (ml/hr)
99	45	378
110	50	420
121	55	462
132	60	504
143	65	546
154	70	588
165	75	630
176	80	672
187	85	714
198	90	756
209	95	798
220	100	840
231	105	882
243	110	924
254	115	966
265	120	1008

CONTRAINDICATIONS[3]

1. 2nd and 3rd AV block (except in patients with fuctioning artificial pacemaker)
2. sick sinus syndrome/ symptomatic bradycardia (except in patients with fuctioning artificial pacemaker)
3. bronchoconstrictive/ bronchospastic lung disease
4. hypersensitivity

ADVERSE EFFECTS[2]

- cardiac: arrhythmias, AV block, MI, HOTN, HTN, chest discomfort
- respiratory: bronchospasm
- dermatologic: flushing
- musculoskeletal: neck pain
- neurologic: dizziness, headache

MONITORING

- For cath lab administration during PCI only.

DRUG INTERACTIONS

- Cabamazepine: increase in degree of heart block
- Dipyridamole: decreases metabolism and increases toxicity of adenosine
- Theophyline: decreases adenosine effectiveness
- Verapamil: increased risk of ventricular fibrillation

REFERENCES

[1] Tonino P.A.L. Fractional Flow Reserve versus Angiography for Guiding Percutanous Coronary Intervention.*N Engl J Med* 2009;360:213-24.

[2] http://www.volcanocorp.com/products/; 800-228-4728

[3] **Adenoscan®** adenosine for intravenous infusion (package insert) http://www.astellas.us/docs/adenoscan.pdf

CEDARS-SINAI MEDICAL CENTER

PAIN

PAIN MANAGEMENT REFERENCE CARD

TABLE 1: DOSE EQUIVALENTS FOR OPIOID ANALGESICS Equianalgesic doses are not recommended starting doses

Drug	Onset (minutes)	Duration (hours)	Elimination $t_{1/2}$ (hours)	Approx. equianalgesic PARENTERAL dose	Approximate equianalgesic ORAL dose	Oral to Parenteral Ratio
Codeine* Codeine/APAP*	10-30 (IM) 30-60 (PO)	4-6	3-4	75mg q 3-4 hr	130mg q 3-4 hr	2:1 – 3:1
Fentanyl (Sublimaze®) (Duragesic®)	immed. (IV) 12-24 hr (patch)	1-2 72 (patch)	1-6	0.1mg q 1-2 hr		NA
Hydrocodone/ APAP*	10-20 (PO)	4-6	3-4		30mg q 3-4 hr	NA
HYDROmorphone	< 5 min (IV) 15-30 (PO)	4-6	2-4	1.5mg q 3-4 hr	7.5mg q 3-4 hr	5:1
Levorphanol	10-60 (PO)	4-8	12-16		4mg q 6-8 hr	2:1
Meperidine	10-15 (IM/SC) <5 (IV)	2-4	3-4	100mg q 3 hr	300mg q 3 hr	2:1 – 3:1
Methadone	10-20 (IV) 30-60 (PO)	4-6 (acute) >8 (chronic)	15-30	10mg q 6-8 hr	20mg q 6-8 hr	2:1 chronic 1:1 acute
Morphine	<5 (IV) 15-60 (PO)	3-6 SR: 12 hr	2-4	10mg q 3-4 hr	30mg q 3-4 hr (ATC dosing) 60mg q 3-4 hr (single/intermittent dosing)	3:1 (chronic) 6:1 (acute)
Oxycodone Oxycodone/APAP	10-15 (PO)	4-6 SR: 12 hr	3-4		30mg q 3-4 hr#	NA

- Initial dose of a new drug given should be 1/2 or 2/3 of the calculated dose because of opioid-specific tolerance

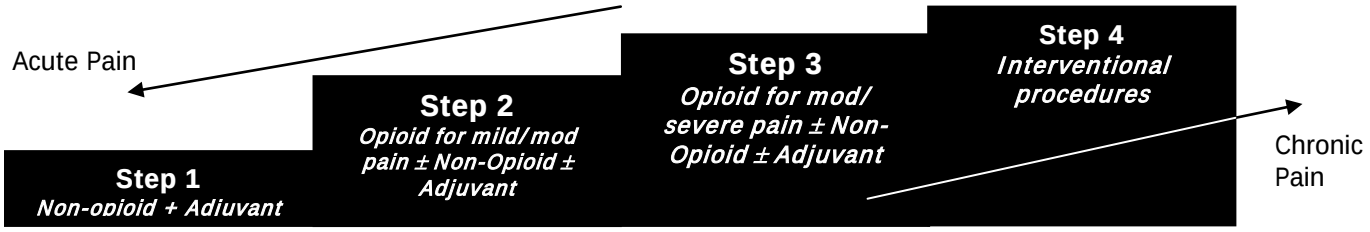
*Pro-drugs that are converted to morphine in the body. Approximately 10% of the population lacks the enzyme.

TABLE 2: FENTANYL PATCH MANUFACTURER DOSE CONVERSION GUIDELINES

- Fentanyl transdermal should be prescribed only for persistent moderate/severe chronic pain in opioid tolerant patients > than 2 yrs on a continuous ATC administration schedule for an extended period of time. Monitor for hypoventilation during the first 24-72 hours of initial treatment

Analgesic	Chronic Daily Dosages (mg/day)			
Morphine (IM/IV)	10-22	23-37	38-52	53-67
Morphine (oral)	60-134	135-224	225-314	315-404
Codeine (oral)	150-447	448-747	748-1047	1048-1347
Oxycodone (oral)	30-67	67.5-112	112.5-157	157.5-202
HYDROmorphone (oral)	8-17	17.1-28	28.1-39	39.1-51
HYDROmorphone (IV)	1.5-3.4	3.5-5.6	5.7-7.9	8-10
Methadone (oral)	20-44	45-74	75-104	105-134
Methadone (IM)	10-22	23-37	38-52	53-67
	⇩	⇩	⇩	⇩
Fentanyl Patch	**25 mcg/h**	**50 mcg/h**	**75 mcg/h**	**100 mcg/h**

NEW ADAPTION OF THE WORLD HEALTH ORGANIZATION ANALGESIC LADDER



Example: acetaminophen, aspirin, or NSAIDs

Example: Norco®, Percocet®, tramadol

Example: oxycodone, morphine, fentanyl patch

Example: nerve block, spine cord stimulator

TABLE 3: COMMON OPIOID ANALGESICS AVAILABLE AT CSMC

Drug	Injection	Oral Tablet	Oral Solution	Suppository
Phenanthrene Derivatives Class				
Codeine*		15mg, 30mg		
Codeine with acetaminophen (APAP)		15mg/300mg APAP (Tylenol#2®) 30mg/300mg APAP (Tylenol #3®) 60mg/300mg APAP (Tylenol #4®)	12mg/120mg per 5mL	
Hydrocodone with acetaminophen (APAP)		5mg/325mg APAP (Norco®) 7.5mg/325mg APAP (Norco® 7.5) 10mg/325mg APAP (Norco® 10)	5mg/334mg per 10mL	
HYDROmorphone* (Dilaudid®)	2mg/mL,4mg/mL	IR 2mg, 4mg, 8mg	1mg/mL	3mg
Levorphanol*		2mg		
Morphine*	2mg/mL, 4mg/mL, 5mg/ml, 10mg/mL	IR: 15mg CR: 15mg, 30mg, 60mg, 100mg	10mg/5mL, 20mg/mL	
Oxycodone*		IR 5mg, 15mg, 30mg SR 10mg, 20mg,40mg, 80mg	5mg/5mL 20mg/mL	
Oxycodone with acetaminophen* (APAP) or aspirin* (ASA)		5mg/325mg APAP (Percocet® 5mg) 7.5mg/325mg APAP (Percocet® 7.5mg) 10mg/325mg APAP (Percocet® 10mg) 4.5mg/325mg aspirin (Percodan®)		
Phenylpiperidine Derivatives Class				
Fentanyl* (Sublimaze®) (Duragesic®)	50mcg/mL	Fentanyl transdermal: 12.5mcg/hr, 25mcg/hr, 50mcg/hr, 75mcg/hr, and 100mcg/hr		
Meperidine* (Demerol®)	50mg/ml, 100mg/mL	50 mg		
Diphenylheptane Derivatives Class				
Methadone* %	10mg/mL	5mg, 10mg	10mg/10mL	
Other				
Tramadol (Ultram®)		IR 50mg		

IR = immediate release; SR = sustained release; ER = extended release; CR = controlled release; ODT = orally disintegrating tablet
*****Denotes a schedule II medication requiring a Tamper-Resistant Prescription Forms for outpatient prescribing. See last page for an exception to this law.
%black box warning - may increase risk of death (cardiac or respiratory); order a baseline ECG; order weekly ECG if patient receiving dose greater than 100mg/day

TABLE 4: NON-OPIOID ANALGESICS AVAILABLE AT CSMC

Drug	Dose Interval	Maximum Dose	Available Formulations
Acetaminophen (Tylenol®)	q4hrs or q6hrs	3gm/day	Tablets: 325mg, 500mg Chewable tablets: 80mg, 160mg Oral liquid: 650mg/20.3mL Suppository: 120mg, 325mg, 650mg
Salicylates			
Aspirin	q4hrs or q6hrs	4gm/day	Tablets: 81mg, 325mg Suppository: 300mg, 600mg
Salsalate (Disalcid®)	BID or TID	3gm/day	Tablets: 500mg, 750mg
Non-Salicylate NSAIDs			
Etodolac (Lodine® and Lodine XL®)	BID to QID	1000mg/day	Capsules: 200mg, 300mg Tablets: 400mg, 500mg Tablets XL: 400mg, 500mg, 600mg
Ibuprofen (Advil®)	q4hrs or q6hrs	2400mg/day	Tablets: 200mg, 400mg, 600mg, 800mg
Indomethacin (Indocin®)	BID or TID	200mg/day (immed release)	Capsules: 25mg, 50mg
Ketorolac# (Toradol®)	q6hrs	120mg/day	Injectable: 30mg/1mL
Naproxen (Naprosyn®) Naproxen Sodium (Anaprox®)	q6hrs or q8hrs or BID	1250mg/initial day 1000mg/day	Tablets: 250mg, 500mg (Naprosyn®) Tablets: 375mg (Anaprox®)
Nabumetone (Relafen®)	QD or BID	2gm/day	Tablets: 500mg, 750mg
Sulindac (Clinoril®)	BID	400mg/day	Tablets: 150mg, 200mg
Cox-2 Inhibitors			
Celecoxib* (Celebrex®)	QD or BID	400mg/day	Tablets: 100mg, 200mg

Automatically expires in 3 days per P&T policy (Max= 5 days duration). Increased risk of cardiovascular thrombotic events, MI, stroke, and GI bleeding. Use caution in patients with cardiovascular risk factors or GI bleeding risks, which may be fatal.
*Restricted to patients with chronic inflammatory disorders (eg, rheumatoid or osteoarthritis) at high risk for GI toxicity or bleeding (age >65 years; active PUD on anticoagulants or with bleeding diathesis)

TABLE 4: COMMON NEUROPATHIC PAIN MEDICATIONS

Drug	Oral Tablet	Oral Solution
Calcium Channel Alpha 2 Delta Ligands		
Gabapentin (Neurontin®)	100mg, 300mg, 400mg	
Pregabalin (Lyrica®)	25 mg, 50 mg, 75 mg	
Serotonin and Norepinephrine Reuptake Inhibitors (SNRIs)		
Duloxetine (Cymbalta®)	20mg, 30mg, 60mg	
Venlafaxine (Effexor®)	IR 25 mg, 37.5 mg, 50 mg ER 37.5 mg, 75 mg, 150 mg	
Tricyclic Antidepressants (TCAs)		
Amitriptyline (Elavil®)	10 mg, 25 mg, 50 mg, 75 mg, 100 mg	
Nortriptyline (Pamelor®)	10 mg, 25 mg	10mg/5mL
Desipramine (Norpramin®)	10 mg, 25 mg, 50 mg, 75 mg, 100 mg,	

PAIN SCALE INTENSITY: PATIENT RATED 0 - 10 PAIN SCORE SCALE

SCALE	0	1-3	4-6	7-10
PAIN LEVEL	No pain	mild pain	moderate pain	severe pain

ORDERING PRN PAIN MEDICATIONS BASED ON PAIN SCALE

- If no PRN pain indication is ordered, the physician needs to be contacted to clarify the order.
- Avoid writing ranges for dose or frequency.
- Use oral pain medications as first line if the patient is able to tolerate PO medications; reserve SQ/IV pain medication routes for breakthrough pain.

- 1 PRN pain medication: write PRN pain (1-10) or based on above pain scale ranges
- 2 PRN pain medications: write PRN pain (1-4) and PRN pain (5-10)
- 3 PRN pain medications: write PRN mild pain (1-3), PRN moderate pain (4-6), PRN severe pain (7-10)
- Combinations: Do not write two or more PRN pain medications with the same PRN indication. Each pain medication order must be written with a specific PRN indication (e.g. mild, moderate, severe pain).
  - Ex: orders written for Tylenol 650mg PO q6h PRN mild pain, *Norco 5mg/325mg PO q4h PRN moderate pain, Oxycodone IR 5mg PO q4h PRN moderate pain,* Dilaudid 1mg IVP q3h PRN severe pain.
  - The above example with 2 medications PRN for moderate pain will require a clarification.

DEMEROL® USE AT CSMC IS RESTRICTED FOR THE FOLLOWING INDICATIONS:

- **Short-term** (< 48 hours) acute pain management of moderate to severe pain episodes **when morphine or HYDROmorphone (Dilaudid®) are contraindicated** due to allergy or documented intolerance.
- Treatment of **drug-induced rigors** (e.g. amphotericin B, interferon, infliximab, platelets, or PRBC).
- Treatment or prevention of **post-anesthesia shivering**.
- **Pre-procedure analgesia** prior to adult procedures (conscious sedation).
- Neuraxial analgesia administered by the Department of Anesthesiology when other agents **cannot** be used.

ALL ORDERS FOR INJECTABLE DEMEROL® FOR ANY OTHER INDICATION WILL BE AUTOMATICALLY SUBSTITUTED VIA THE CSMC AUTOMATIC SUBSTITUTION POLICY:

Demerol Dose	**First Drug of Choice** **HYDROmorphone** (Dilaudid) Dose	Second Drug of Choice Morphine Dose
25mg	0.4mg	2.5mg
50mg	0.8mg	5mg
75mg	1.2mg	7.5mg
100mg	1.5mg	10mg

Frequency conversion: at same frequency

Route conversion: **IM** Demerol will be converted to **SQ** Dilaudid or Morphine
IVP Demerol will be converted to **IVP** Dilaudid or Morphine

COMMON ADVERSE EFFECTS OF OPIOID THERAPY

Respiratory depression, CNS effects (sedation, dizziness, confusion), gastrointestinal effects (nausea, vomiting, constipation), hypotension, and pruritis.

***** Maximum dose of acetaminophen should not exceed 3gm/day *****

PRINCIPLES OF PAIN MANAGEMENT

DO'S	DON'TS
DO assess pain systematically. Ask the patient about his: • pain intensity (0-10 numerical scale) • quality of pain (in pt's own words) • previous therapy experiences • aggravating/relieving factors	**DON'T** assume opioid addiction is a prevalent phenomenon for all patients. A survey of more than 11,000 opioid-using patients with chronic malignant pain, taken over several years, found only 4 cases of documented addiction.
DO believe the patient's report of pain. Establish pain relief goals for patients at levels that they can tolerate.	**DON'T** use placebos to determine if the patient's pain is "real." Ordering placebos is against CSMC policy.
DO use subcutaneous (SQ) or intravenous (IV) route when administering pain medications parenterally.	**DON'T** use the intramuscular (IM) route when administering parenteral analgesics; it is more painful and absorption is erratic.
DO use morphine, HYDROmorphone (Dilaudid®) or oxycodone when choosing an opioid analgesic.	**AVOID** meperidine (Demerol®), especially in elderly and renally compromised patients, due to its neurotoxic metabolite normeperidine and shorter duration of action.
DO use around-the-clock (ATC) while awake dosing of analgesics, including withholding parameters (e.g. hold for respiratory rate <14 or sedation).	**DON'T** use analgesic adjuvants such as hydroxyzine (Vistaril®) and promethazine (Phenergan®), as they provide sedation without additional analgesia.
DO base the initial choice of analgesic on the severity and type of pain: • non-opioids for mild pain (rating 1-3) • opioids, in combination with a non-opioid for moderate pain (rating 4-6) to severe pain (rating 7-10)	**DON'T** forget to prescribe a PRN regimen for breakthrough pain concurrently with an around-the-clock regimen – use immediate-release formulations dosed at 10-20% of the total daily dose Q1hr or Q2hr PRN. Be specific and do not order using a dosing or time range (Q4-6hr).
DO provide comfort measures and emotional support such as repositioning, distraction, quiet environment, establishing trust, empathy, and education.	**DON'T** assume that what has worked for one patient will work for another patient for both pharmacological and non-pharmacological interventions. Take into account a patient's age and cultural, spiritual, and/or ethnic beliefs.
DO be aware of the acetaminophen content of combination oral products such as Percocet® and Norco®. Watch out for potential liver toxicity with cumulative daily doses of > 3gm of acetaminophen.	**DON'T** wait for constipation to occur before starting patients on bowel management therapy. Start a laxative or stool softener early in therapy for patients on around-the-clock opioids.

PAIN MANAGEMENT FOR THE TERMINALLY ILL "11159.2 EXEMPTION"

- Applicable only to terminally ill patients with a life expectancy of 12 months or less, if the illness is to follow its natural course.
- A Tamper-Resistant Prescription Forms is not required for a Scheduled Class II medication prescription. The CII medication can be written on an ordinary physician prescription blank if the physician writes **"11159.2 Exemption"** directly on the prescription. Schedule Class II medications, as defined by the Department of Justice, consist of most, but are not limited to opioids. (*See table 1 for a list of opioid medications that requires a Tamper-Resistant Prescription Forms.)*
- The prescription needs to be filled in 14 days.

REFERENCES: Available from the Department of Pharmacy Services upon request