Formulary Criteria for Use: Dexmedetomidine (Precedex®) in the *Peri-Procedural* and *Peri-Operative Setting*

VHA Pharmacy Benefits Management Services and the Medical Advisory Panel

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The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. The clinician should utilize this guidance and interpret it in the clinical context of the individual patient. Individual cases that are outside the recommendations should be adjudicated at the local facility according to the policy and procedures of its P&T Committee and Pharmacy Services.

Refer to the Dexmedetomidine Abbreviated Drug Monograph at http://vaww.pbm.va.gov.

EXCLUSION CRITERIA (If one is selected, patient is NOT eligible)

- ☐ Presence of advanced heart block
- ☐ Baseline bradycardia (e.g., <50 bpm)
- ☐ Presence of severe ventricular dysfunction (e.g., known or suspected ejection fraction <30%)
- ☐ Known hypersensitivity

In addition, efficacy and safety have not been evaluated in the following situations (excluded from clinical trials)

- ☐ Central nervous system disease with an anticipated potential for increased intracranial pressure, uncontrolled seizure disorder, or known psychiatric illness that could confound a normal response to sedative treatment
- ☐ Concurrent use of epidural or spinal anesthesia
- ☐ Active myocardial ischemia or recent myocardial infarction (past 6 weeks)
- ☐ Hepatic impairment (elevated liver function tests >2x upper limit of normal)
- ☐ Systolic blood pressure <90 mmHg
- ☐ Acute alcohol intoxication

INCLUSION CRITERIA (One must be selected for patient to be eligible)

Dexmedetomidine may be considered in patients undergoing procedures or surgery in the following situations:

- ☐ When the risk of respiratory depression would be especially detrimental (e.g., respiratory disease, obesity, awake fiberoptic intubation, etc.)
- ☐ When wakefulness and arousability are desired (e.g., awake craniotomy)

DOSAGE AND ADMINISTRATION

- Procedural sedation: loading dose of 0.5 mcg/kg (for elderly or patients undergoing less invasive procedures) to 1 mcg/kg over 10 min followed by a continuous infusion of 0.6-0.7 mcg/kg/hr, titrated to desired clinical effects (usual range 0.2-1 mcg/kg/hr)
- Special Populations: dose reductions should be considered in the elderly and in patients with renal or hepatic dysfunction; pregnancy category C – use in pregnancy only if benefits outweigh potential risks to fetus

RECOMMENDED MONITORING

- Dexmedetomidine should only be administered by persons privileged to provide care in the management of patients in the intensive care or operating room setting; continuous monitoring is recommended.
- Dexmedetomidine administration may be associated with significant hypotension and/or bradycardia requiring intervention which may include: dose reduction, discontinuation, administration of fluids, pressors, or anticholinergic agents (e.g., atropine, glycopyrrolate). Blood pressure and heart rate should be closely monitored.
- Patient's level of and need for sedation should be routinely evaluated using a validated assessment tool.
- Although dexmedetomidine possesses analgesic properties, patients should be routinely assessed for pain and treated when needed.

ISSUES FOR CONSIDERATION

- **Withdrawal:** Dexmedetomidine may potentially be associated with a withdrawal syndrome similar to that observed with clonidine (another alpha-2 adrenergic agent) if administered for greater than 24 hours followed by abrupt discontinuation. Symptoms observed with clonidine withdrawal include nervousness, agitation, headache, and rebound hypertension.
- **Loading dose:** Dexmedetomidine has been associated with transient hypertension and hypotension with loading doses. Omission of loading dose has been studied and observed in clinical practice.
- **Hypotension, Bradycardia, and Sinus Arrest:** Use caution in administering dexmedetomidine to patients with diabetes, chronic hypertension, hypovolemia, significant aortic stenosis or left ventricular outflow tract obstruction, as well as the elderly who may be at increased risk of developing significant bradycardia and/or hypotension with dexmedetomidine.
- **Drug Interactions:** Additive effects may occur with co-administration of anesthetics, sedatives, hypnotics, opioids, negative chronotropic agents, and vasodilators
- **Sympatholytic effects:** Alpha-2 agonists as a class may confer a cardioprotective effect in patients undergoing surgery with known or at high risk of coronary artery disease; however, evidence of benefit of dexmedetomidine for this indication has not yet been established.
- **Prolonged recovery:** Dexmedetomidine may be associated with a prolonged recovery time and delayed readiness for discharge when used for outpatient procedures compared to other agents.

Note: These criteria are not intended to address the use of dexmedetomidine in the intensive care unit (ICU) setting. See separate document at http://vaww.pbm.va.gov (Criteria for Use: Dexmedetomidine in the ICU Setting).