Formulary Criteria for Use: Dexmedetomidine (Precedex®) in the *Intensive Care Unit (ICU) 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)

Dexmedetomidine should not be used in the presence of the following:

- ☐ Advanced heart block
- ☐ Baseline bradycardia (e.g., <50 bpm)
- ☐ 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 ICU sedation clinical trials):

- ☐ Pregnancy or lactation
- ☐ Concurrent use of or anticipated need for neuromuscular blockade, epidural or spinal anesthesia
- ☐ Serious central nervous system pathology (e.g., trauma, acute stroke, active seizures, severe dementia, neurosurgical procedures)
- ☐ Acute hepatitis or hepatic impairment (Child-Pugh Class B or C)
- ☐ Active myocardial ischemia
- ☐ Dialysis
- ☐ Severe hypotension (e.g., systolic blood pressure <90 mmHg with the use of 2 or more vasopressors)
- ☐ Hypovolemic state (e.g., excessive bleeding, trauma, burns, etc.)
- ☐ Gross obesity defined as >50% over ideal body weight
- ☐ Drug overdose
- ☐ Alcohol or drug abuse or dependence
- ☐ Uncontrolled or unstable diabetes

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

Dexmedetomidine may be considered in mechanically ventilated patients in the following situations:

- ☐ When short term sedation is anticipated (<24 hrs) and propofol is contraindicated (e.g., allergy, pancreatitis, hyperlipidemia)
- ☐ For intermediate-term sedation as an alternative to continuous infusion of benzodiazepines where avoidance of other agents or treatment regimens (e.g., intermittent bolus dosing of benzodiazepines) is desired
- ☐ When transitioning from another sedative agent is desired to facilitate the process of ventilator weaning

DOSAGE AND ADMINISTRATION

- FDA approved dosing: loading dose of 1 mcg/kg over 10 min followed by a continuous infusion of 0.4 mcg/kg/hr, titrated to desired level of sedation (usual range 0.2-0.7 mcg/kg/hr), for up to 24 hours
- Additional dosing information: Omission, reduction, or slower infusions of the loading dose (which may be associated with transient hypertension or hypotension) have been studied and observed in clinical practice. Higher maintenance doses (up to 1.4 mcg/kg/hour, with most patients requiring ≤1 mcg/kg/hr), and longer infusion durations (approximately 3-5 days) have been used in recent, carefully performed clinical trials.
- Special Populations: dose reductions should be considered in the elderly and in patients with renal or hepatic dysfunction

RECOMMENDED MONITORING

- Dexmedetomidine should only be administered by persons privileged and able 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.
- **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.
- **Targeted Sedation Goals in ICU sedation:** Patients should have a targeted sedation goal measurable with the use of a validated assessment tool. Reassessment should occur regularly, with adjustments in therapy made as needed.

Note: These criteria are not intended to address the use of dexmedetomidine in the peri-operative/peri-procedural setting. See separate document at http://vaww.pbm.va.gov (Criteria for Use: Dexmedetomidine in the Peri-Operative and Peri-Procedural Setting).