RATIONAL FOR INCLUSION IN PA PROGRAM

Background
Ketamine is a rapid-acting anesthetic that can produce anesthesia while maintaining skeletal muscle tone, laryngeal-pharyngeal reflexes, and cardiovascular and respiratory stimulation (1).

Regulatory Status
FDA-approved indication: Ketamine is used as an adjunct in general anesthesia as well as a sedative in minor surgical or diagnostic procedures that do not require skeletal muscle relaxation (1).

There are several off-label uses that have been studied for ketamine including, but not limited to, chronic pain, including chronic neuropathic pain, restless legs syndrome and phantom limb syndrome. Alternative routes of administration, including oral, intranasal, transdermal, rectal and subcutaneous have been studied. However, these routes of administration and uses are investigational and are not supported by the FDA (2).

Common adverse effects of ketamine include hypertension, tachycardia and psychiatric signs and symptoms. Ketamine can also produce a transient respiratory depression therefore its use requires regular monitoring of vital signs (1).

Ketamine injection is commercially available in 10mg/ml, 50mg/ml and 100mg/ml vials (1-2).

Summary
Ketamine powder is a rapid-acting anesthetic that can produce anesthesia while maintaining skeletal muscle tone, laryngeal-pharyngeal reflexes, and cardiovascular and respiratory stimulation. Ketamine is used in patients 16 years of age or older for the induction of anesthesia or for conscious sedation for minor surgical procedures (1).

Prior approval is required to ensure the safe, clinically appropriate and cost effective use of Ketamine powder while maintaining optimal therapeutic outcomes.

References