XYREM
(sodium oxybate)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background
Xyrem is used to treat patients with narcolepsy. Narcolepsy is a disease where people have problems with falling asleep during the day at unexpected times. Xyrem differs from other treatments for narcolepsy in that it significantly decreases cataplexy episodes in addition to excessive daytime sleepiness (EDS). Cataplexy is characterized by loss of muscle control in response to strong emotions (1).

Regulatory Status
FDA labeled indication: Xyrem is a central nervous system depressant indicated for the treatment of cataplexy in narcolepsy and excessive daytime sleepiness (EDS) in narcolepsy (1).

Xyrem includes a boxed warning of central nervous system depression and misuse and abuse. Because of the risks of CNS depression, abuse, and misuse, Xyrem is available only through a restricted distribution program called the Xyrem REMS Program, using a centralized pharmacy. Prescribers and patients must enroll in the program (1).

Xyrem is contraindicated in patients with succinic semialdehyde dehydrogenase deficiency and in combination with sedative hypnotics or alcohol (1).

Safety and effectiveness of Xyrem in pediatric patients have not been established (1).

Summary
Xyrem is a central nervous system depressant indicated for the treatment of cataplexy in narcolepsy and excessive daytime sleepiness (EDS) in narcolepsy. Xyrem differs from other stimulant treatments for narcolepsy in that it significantly decreases cataplexy episodes in addition to excessive daytime sleepiness (EDS). Safety and effectiveness of Xyrem in patients under the 18 years of age have not been established (1).

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

References