New Movantik (naloxegol) Approved for Use to Treat Opioid-Induced Constipation

Background:
AstraZeneca recently announced that they obtained approval from the US Food and Drug Administration (FDA) to market Movantik™ (naloxegol). Movantik™ is an opioid antagonist that acts in digestive tract for the once daily treatment of opioid-induced constipation in adult patients with chronic, non-cancer pain. [1] Prior to initiating Movantik™, AstraZeneca advises/recommends that all previous laxative therapy should be discontinued. The tablets should be taken whole on an empty stomach at least 60 minutes before the first meal of the day or 2 hours after the meal. The FDA has approved two different strengths of Movantik™: 12.5mg and 25mg. [2] Movantik™ is currently a schedule II controlled substance because it is structurally related to noroxymorphone, a metabolite of oxycodone. The current FDA approved label indicates no risk of abuse or dependency and AstraZeneca has submitted a petition to the US Drug Enforcement Administration (DEA) requesting de-scheduling of Movantik™. [1] The FDA is also requiring a post-marketing study to further evaluate the potential risk of cardiovascular adverse events in patients taking Movantik™. [3]

Impact to You
Opioid medications are among the most common medications prescribed in workers' compensation. Constipation is a common side effect of opioid medications and is typically treated with over-the-counter options, such as stool softeners and stimulant laxatives. Movantik™ is expected to be more costly than current treatment options for opioid-induced constipation; however, pricing information for this agent was not available at the time of publication. Movantik is expected to be released during the first part of 2015. [1] In an effort to control our clients' claim costs, Movantik™ will require a prior authorization on our formularies. Docusate with senna should be considered the first-line alternative to MOVANTIK for opioid-induced constipation. [4] Other currently available agents within the same drug class (peripherally-acting mu-opioid receptor antagonists) as Movantik™ include Relistor®[5] and Entereg®[6]

For questions regarding this eAlert or to learn more about our Clinical Rx Services please contact your dedicated Account Executive.

Sources