firstscript

Clinical Bulletin

October 26, 2020

Subject: Janssen Discontinues Duragesic® (Fentanyl Transdermal System) Patches

The U.S. Food and Drug Administration (FDA) has reported that Janssen Pharmaceuticals, Inc. has made the business decision to discontinue production of Duragesic patches (all available strengths) and withdraw them from the U.S. marketplace.[1] No additional information related to this change was reported on the Janssen website. However, the FDA announcement indicates the expiration date on the last production run of Duragesic will be July 31, 2021 and advised that it should be maintained on formularies until then to support continued reimbursement.

Duragesic brand transdermal patches were first approved in August 1990, and in passing years have seen the arrival of numerous generic equivalents of all available strengths.

Fentanyl transdermal patches are indicated for the management of persistent, moderate to severe chronic pain in **opioid tolerant** patients that require continuous, around-the-clock, chronic opioid treatment and cannot be managed by other means such as non-steroidal anti-inflammatory drugs (NSAIDs) or short-acting opioid medications.[2]

The Impact

Duragesic patches are expected to remain available in retail pharmacies until existing inventories have been exhausted or they expire in July 2021. A significant majority of current prescriptions for fentanyl transdermal patches at First Script® are filled generically and are subject to Smart PA criteria that help validate safe and sound prescribing of this potent medication. We do not anticipate changing the standard First Script formulary placement or Smart PA management approach to Duragesic or generic fentanyl patches until July 2021; however, clients with custom formularies wishing to make updates should contact their Account Manager. We do anticipate some continuing declines in utilization for branded fentanyl patches between now and then, as well as those prescriptions moving to generic equivalents and alternative medications. The Official Disability Guidelines (ODG) lists Duragesic as a "not recommended" medication for first-line treatment of chronic non-malignant pain and puts patients at high risk for misuse, diversion, or substance abuse disorder.[3]

Should specific questions or concerns arise, or for more information, please contact your Account Manager, Account Pharmacist or email us at: askthepharmacist@coventry.com

1. U.S. Food and Drug Administration (FDA). FDA Drug Shortages. Current and Resolved Drug Shortages and Discontinuations Reported to FDA. Fentanyl (Duragesic 100, 12, 25, 37, 50, 75) Extended-Release Film. April 1, 2020. Accessed at: https://www.accessdata.fda.gov/DURAGESIC
2. Janssenlabels.com. Package Insert. Duragesic-pi.pdf. Accessed at: http://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/DURAGESIC-pi.pdf
3. The Official Disability Guidelines. Accessed at https://www.odgbymcg.com