MC-Rx

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Current News: https://www.cdc.gov/coronavirus/2019-ncov/index.html

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Drug Information Updates

New Meningitis Vaccine MenQuadfi Approved **04/24/2020**

Sanofi's MenQuadfi™ (meningococcal [groups A, C, Y, W] conjugate vaccine), approved by the FDA helps to prevent meningococcal diseases caused by four specific serogroups (subtypes) of *Neisseria meningitidis*, which can infect the lining of the brain and spinal cord (meningitis) and/or the blood (bacteremia or septicemia). It does not prevent against meningococcal diseases caused by other kinds of bacteria. It also is not effective for *N. meningitidis* subgroup B, but other vaccines do target the B serotype, exclusively. Although meningococcal diseases are rare, they cause death some people who recover have serious complications such as amputations, brain damage, loss of hearing or seizures. The diseases are especially prevalent for children under one year old and for young adults between the ages of 16 and 23. MenQuadfi is expected to be introduced on the U.S. market in 2021.

Formulary Status: MenQuadfi will be reviewed at the next P&T Committee meeting in June.

FDA Expands Indications for Imbruvica **04/21/2020**

Imbruvica® (ibrutinib – AbbVie/Pharmacyclics) received approval from the FDA for a new indication of first-line treatment of patients who have chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL). Imbruvica, an oral Bruton's tyrosine kinase inhibitor (BTK), blocks a specific enzyme needed by the cancer to multiply and spread. It already has several other indications for various cancers, including as monotherapy or in combination with other drugs for later stages of CLL. For the new indication, it will be used with rituximab, an intravenously (IV) administered monoclonal antibody that causes B cells to disintegrate by binding to CD20 proteins on their cell surfaces.

Formulary Status: Imbruvica is a preferred brand specialty drug on MC-Rx's National Formulary.

Generic Butrans® Transdermal Launched **04/24/2020**

The FDA approved Amneal's generic version of Butrans® (buprenorphine) Transdermal system in dosages of 5mcg/hr, 7.5mcg/hr, 10mcg/hr, 15mcg/hr and 20mcg/hr. The generic patch will launch immediately in all strengths. While generics are available for most of the strengths, Amneal is the first company to received approval for a generic to the 7.5mcg/hr patch, being granted 180-days of generic exclusivity for this strength. Buprenorphine patches are partial opioid agonists approved for management of daily, around the clock pain and for opioid treatment for which alternative treatment options are inadequate. It is DEA schedule III control substance, bears a black box warning for risks of addiction, abuse, and misuse, and has a REMS for life-threatening breathing problems, accidental exposure, neonatal opioid withdrawal syndrome and risks from concomitant use with benzodiazepines and other central nervous system depressants.

Formulary Status: Butrans is a preferred brand drug on MC-Rx's National Formulary.

Warning Issued on COVID-19 Drugs **04/24/2020**

The FDA issued a warning against the use of hydroxychloroquine and chloroquine for COVID-19 outside a hospital or clinical trial setting due to the increased risk for heart rhythm issues. These medications have not been shown to be safe and effective for treating or preventing COVID-19.

Upon review of case reports and published literature of hydroxychloroquine and chloroquine, either alone or with azithromycin or other medications, the FDA was concerned about serious heart related side effects including rare electrical conditions that can cause dangerous heart complications. The FDA is recommending that patients who are prescribed these medications for FDA-approved uses, such as treating malaria or an autoimmune disease, continue to take the medication as prescribed and to speak with a health care professional if they have questions or concerns. The FDA is also cautioning patients to not buy supplies from illegal online pharmacies or consuming any form of chloroquine not prescribed by a healthcare professional. Patients and health care professionals are encouraged to report any medication side effects to the FDA at this web link, while the FDA caution can be found by clicking here.

GENERAL INFORMATION:

For more information, please either visit FDA.gov or contact your account manager.