Pharmacy Benefit News

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Specialty Spotlight

Factor Xa Inhibitor Antidote?

Warfarin has been leading the anticoagulant market for some time now, and this may soon change as a reversal agent for the newer oral anticoagulants is expected to hit the market later this year. Portola Pharmaceuticals is currently awaiting FDA approval of Andexanet alfa, which binds to factor Xa inhibitors and rapidly reverses the anticoagulant effect of Xarelto (Rivaroxaban) and Eliquis (Apixaban). "We believe that a reversal agent could be an important consideration for physicians when initiating Eliquis and switching appropriate patients from Warfarin to Eliquis," says Bristol-Myers Squibb and Pfizer in a joint statement.

Berkrot B. New Blood Thinner 'Antidote' to Help Doctors Move Past Warfarin. Reuters. http://www.reuters.com/article/us-pharmaceuticals-bloodthinners-idUSKBN0U617320151223 (accessed 2016 Jan 31).

Commentary:
The potential for Andexanet alfa as an antidote for factor Xa inhibitors is an encouraging development for oral anticoagulation. Warfarin is slowly losing its popularity as the newer oral anticoagulants offer less monitoring and no diet restrictions. However, hesitation for prescribing a factor Xa inhibitor is often due to their costly price tags and the absence of an approved reversal agent. In clinical trials, Andexanet alfa has only demonstrated efficacy in rapidly restoring factor Xa activity and thrombin generation in healthy older adults. Typically, a rapid reversal agent is required to treat acute bleeding or for patients requiring emergency surgery. The study population also only included 145 participants and may not have been large enough to determine the true safety of the drug. With Andexanet alfa gaining momentum, physicians and patients must still be vigilant when choosing amongst the approved oral anticoagulants. Significant progress has been displayed by Andexanet alfa, but further investigation will be required to evaluate its effectiveness in real-life clinical settings.

Narcan Nasal Spray

The U.S. Food and Drug Administration (FDA) recently approved Narcan Nasal Spray by Adapt Pharma, which is the first FDA-approved nasal spray formulation for naloxone hydrochloride. Narcan is indicated for the reversal of overdose from opioids such as oxycodone, hydrocodone, morphine, and heroin. Typically, opioid overdose is treated using injectable formulations of Narcan.

With the newer nasal spray, Narcan administration should be easier as it does not require any medical training. Several states are now moving forward with making Narcan Nasal Spray easily accessible to the public by providing it over-the-counter (OTC) without the need for a prescription. Additionally, Adapt Pharma has collaborated with the Clinton Health Matters Initiative to offer free Narcan Nasal Spray to all U.S. high schools and provided a grant to the National Association of School Nurses (NASN) to aid their opioid overdose education efforts.

1. U.S. Food and Drug Administration. FDA News Release: FDA moves quickly to approve easy-to-use nasal spray to treat opioid overdose. http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm473505.htm (accessed 2016 Jan 25).

2. Adapt Pharma. Press Releases: Adapt Pharma to offer all U.S. high schools a free Narcan nasal spray and fund school-based opioid overdose education. http://www.adaptpharma.com/press-releases/ (accessed 2016 Jan 25).

Commentary:

Opioid addiction is a serious problem in the U.S. that has influenced the FDA to grant fast-track designation and priority review of Narcan Nasal Spray. Despite its ability to save lives, there are many concerns about the misuse of Narcan Nasal Spray and the possibility of increasing the frequency of opioid overdose. Preventing death is a promising step moving forward, but rather than focusing solely on the end result of an opioid overdose, there needs to be a similar emphasis on overall prevention.

As more and more pharmacies across the U.S. begin to make Narcan Nasal Spray readily available, pharmacists will have an increased opportunity to reach out and educate these patients as they visit to their stores. In addition to improved educational programs, more research and development of pharmacologic therapy to treat opioid addiction may be required to help these patients break free from their disease.

FDA Approves New Gout Medication

The FDA has recently approved Zurampic (Lesinurad), a URAT1 inhibitor indicated for gout, in combination with a xanthine oxidase inhibitor (e.g. Allopurinol or Febuxostat), to lower serum uric acid levels. Lesinurad works by inhibiting URAT1 and OAT4, two transporter proteins involved in uric acid reabsorption in the kidney. Traditionally, hyperuricemia is treated with a xanthine oxidase inhibitor to prevent the production of uric acid. With the new mechanism that Lesinurad offers, patients who have not achieved target serum uric acid levels with a xanthine oxidase inhibitor alone are provided an alternate method to treat their hyperuricemia and potentially decrease the development of gout.

1. U.S. Food and Drug Administration. FDA News Release: FDA approves Zurampic to treat high blood uric acid levels associated with gout. http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm478791.htm (accessed 2016 Jan 28).

Commentary:

Gout develops from the over production or under excretion of uric acid. Treating high serum uric acid levels is the route physicians take to prevent acute attacks. Patients are limited in options for hyperuricemia treatments, leaving Lesinurad as an appealing alternative with it being the first FDA-approved drug of its kind. However, FDA approval does not necessarily assume a drug will be effective when applied to real-life clinical practice.

Clinical trials associated with Lesinurad may have been able to suggest efficacy in decreasing serum uric acid levels, but questions about positive patient outcomes and safety concerns remain unanswered. Lesinurad has a boxed warning for risk of acute renal failure, more common when used without a xanthine oxidase inhibitor, and is only recommended for a specific patient population (i.e. in combination with a xanthine oxidase inhibitor and who have not achieved target serum levels with a xanthine oxidase inhibitor alone). Additional investigation is required to determine the true safety profile of Lesinurad and whether it has a significant impact on reducing the development of gout.

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