Benzodiazepine Drug Class – Safety update

- On September 23, 2020, the FDA announced that the *Boxed Warning* will be updated for all benzodiazepine medicines to address the serious risks of abuse, addiction, physical dependence, and withdrawal reactions.

- The current prescribing information for benzodiazepines does not provide adequate warnings about these serious risks and harms associated with these medicines so they may be prescribed and used inappropriately. This increases these serious risks, especially when benzodiazepines are used with some other medicines and substances.

- Benzodiazepines are a class of medicines approved to treat generalized anxiety disorder, insomnia, seizures, social phobia, and panic disorder. They may also be used as premedication before some medical procedures.

- The dose, frequency and duration of treatment vary depending on the patient, the particular benzodiazepine being prescribed and the medical condition that the drug is being used to treat.

- Benzodiazepines can be an important treatment option for treating disorders for which these drugs are indicated. However, even when taken at recommended dosages, their use can lead to misuse, abuse, and addiction. Abuse and misuse can result in overdose or death, especially when benzodiazepines are combined with other medicines, such as opioid pain relievers, alcohol, or illicit drugs.

- Physical dependence can occur when benzodiazepines are taken steadily for several days to weeks, even as prescribed. Stopping them abruptly or reducing the dosage too quickly can result in withdrawal reactions, including seizures, which can be life-threatening.

- The FDA is also requiring updates to the existing patient Medication Guides to help educate patients and caregivers about these risks.

- Changes are also being made to several sections of the prescribing information, including to the *Warnings and Precautions*, *Drug Abuse and Dependence*, and *Patient Counseling Information* sections.

- Recommendations for health care providers:

    - Consider the patient's condition and the other medicines being taken, and assess the risk of abuse, misuse, and addiction when prescribing benzodiazepines.
    - Particular caution should be taken when prescribing benzodiazepines with opioids and other medicines that depress the central nervous system (CNS), which has resulted in serious side effects, including severe respiratory depression and death.
    - Advise patients to seek immediate medical attention if they experience symptoms, such as difficulty breathing.
    - Limit the dosage and duration of each medicine to the minimum needed to achieve the desired clinical effect when prescribing benzodiazepines, alone or in combination with other medicines.
    - Monitor for signs and symptoms of abuse, misuse, or addiction. If a substance use disorder is suspected, evaluate the patient and institute, or refer them for, early substance abuse treatment, as appropriate.
    - Use a gradual taper to reduce the dosage or to discontinue benzodiazepines and monitor for withdrawal symptoms or other worsening symptoms.

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- Recommendations for patients and caregivers:
    - Notify their health care provider about all the prescription and over-the-counter medicines they are taking or any other substances that are being used, including alcohol.
    - Benzodiazepines should be taken exactly as prescribed.
    - To avoid serious problems including withdrawal reactions, patients taking benzodiazepines should not suddenly stop taking them without first discussing with a health care provider.
    - Patients should contact their health care provider or immediate medical care if they experience withdrawal symptoms, worsening symptoms or other serious side effects.

- The FDA previously communicated about the serious risks of combining benzodiazepines with opioid pain or cough medicines in August 2016, and cautioned about withholding medication for opioid use disorder from patients taking benzodiazepines or CNS depressants in September 2017.