June Pharmacy Newsletter

EXXUA-NEW ANITIDEPRESSANT APPROVED BY THE FDA

The FDA has approved a new antidepressant medication. Under a new class of drugs to treat major depressive disorder. Gepirone, a 5-HT1A receptor agonist, has a different mechanism of action from that of SSRIs, which are currently considered the first-line treatment for depression.

Gepirone was rejected three times by the FDA in 2002, 2004, and 2007. The major concern was that the efficacy studies were too small. In 2015, an FDA advisory committee agreed that the evidence to date did not support approval of an extended-release form of the drug. But the agency decided to approve the medication in September 2023, based on the side effect profile is different from existing antidepressants.

Many patients may stop using SSRIs because of side effects such as insomnia and loss of libido. Gepirone has the potential to avoid activation of other 5-HT receptors that mediate side effects. Studies suggest that gepirone reduces both anxiety and depression scores on the Hamilton Depression Rating Scale in patients who have both conditions and decreases rates of depression relapse compared with placebo through at least 48 weeks. The drug also may be less likely than SSRIs to cause sexual dysfunction in men.

Dosing of Exxua (gepirone), an extended-release tablet is taken by mouth once daily with food. Starting dose is 18.2 mg once daily and maximum recommended dose is 72.6mg once daily.

Adverse effects of this medication:

Common

- Gastrointestinal: Abdominal pain (7%), Diarrhea (10%), Increased appetite (5%), Indigestion (6%), Nausea (35%), Vomiting (7%), Xerostomia (8%)
- Neurologic: Dizziness (49%), Headache (31%), Insomnia (14%), Somnolence, Tired
- Respiratory: Upper respiratory infection (8%)

Serious

- Cardiovascular: Prolonged QT interval
- Psychiatric: Suicidal behavior, Suicidal thoughts
- Other: Serotonin syndrome

Contraindications and Precautions:

The safety and efficacy of gepirone in pediatric patients have not been established for the treatment of major depressive disorder (MDD).

Gepirone prolongs the QTc interval; the use of gepirone is contraindicated in patients with congenital long QT syndrome or with a QTc interval greater than 450 msec at baseline (QT prolongation at baseline). Perform an electrocardiogram (ECG) prior to initiating gepirone, during dosage titration, and periodically during treatment. Do not initiate gepirone if QTc is greater than 450 msec at baseline. A recommendation of monitoring ECGs more frequently if gepirone is used concomitantly with medications known to prolong the QT interval, in patients who develop QTc of 450 msec or more during treatment, or in patients with significant risk of developing torsade de pointes.

Gepirone should not be used to treat bipolar depression. Antidepressant treatment can precipitate mania or a mixed or hypomanic episode. Prior to initiating treatment with gepirone, screen patients for a history of bipolar disorder and the presence of risk factors for bipolar disorder.

Gepirone is contraindicated in patients with severe (Child-Pugh C) hepatic disease due to the risk of increased gepirone plasma concentrations and subsequent risk of prolonged QTc interval.

Gepirone is contraindicated in patients taking monoamine oxidase inhibitors (MAOI therapy) due to the risk of serious and potentially fatal drug interactions, including hypertensive crisis and serotonin syndrome. At least 14 days must elapse between the discontinuation of an MAOI intended to treat depression and initiation of therapy with gepirone.

Gepirone is contraindicated with concomitant use of strong CYP34A inhibitors.

There is insufficient clinical data on the use of gepirone during pregnancy.

Gepirone should be available to prescribe to patients in fall 2024. Check the AHCCCS FFS Pharmacy Prior Authorization criteria for prior authorization (PA) requirements.

AHCCCS Medical Policy Manual (AMPM) 310-V Informed Consent

As a reminder that per AHCCCS AMPM 310-V, Informed consent shall be obtained from the member, or as applicable, the member's Health Care Decision Maker (HCDM) **for each psychotropic medication prescribed**. The comprehensive clinical record shall include documentation of the essential elements for obtaining informed consent. Essential elements for obtaining informed consent for medication are contained within Informed Consent Assent For Psychotropic Medication Treatment Attachment A (DOC). The use of Attachment A is recommended as a tool to document informed consent for psychotropic medications.

References:

1. https://reference.medscape.com/drug/exxua-gepirone-1000091
2. https://www.clinicalkey.com/pharmacology/monograph/728?sec=monadve
3. Product Information: EXXUA extended-release oral tablets, gepirone extended-release oral tablets. Mission Pharmaceutical Company (per FDA), San Antonio, TX, 2023.

REFERRED DRUG LIST UPDATES CAN BE FOUND HERE:

ACC-RBHA, DD, ALTCS and DCS CHP	Behavioral Health (Non-Title 19/21)

** Drugs that are not on the formulary will require a PA (prior authorization) request to be submitted**

Reminder for quicker determinations of a Prior Authorization use the ePA link for Our Providers: Please click here to initiate an electronic prior authorization (ePA) request.

This newsletter is brought to you by the Mercy Care Pharmacy Team. For questions, please email Fanny A Musto (MustoF@mercycareaz.org), Denise Volkov (VolkovD@mercycareaz.org) or Trennette Gilbert (gilbert@mercycareaz.org)