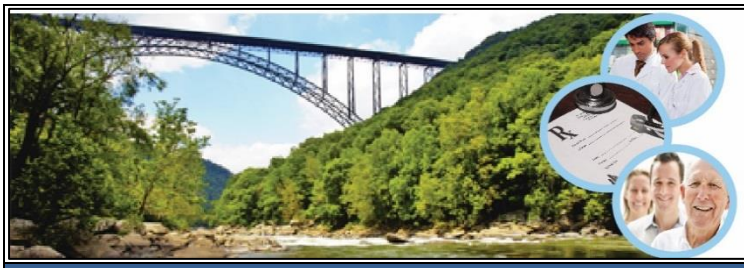

West Virginia Medicaid
Pharmacy Solutions

March 2019

West Virginia Medicaid Pharmacy Department

http://www.dhhr.wv.gov/bms/Pharmacy

Provider Services

888-483-0793
888-483-0801 (Pharmacy)
304-348-3360
Monday – Friday
8:00 am until 5:00 pm

Pharmacy Help Desk& Pharmacy Prior Authorization (Rational Drug Therapy Program)

800-847-3859 (Phone)
800-531-7787 (Fax)
Monday – Saturday
8:30 am until 9:00 pm
Sunday 12:00 pm until 6:00 pm

Member Services

888-483-0797
304-348-3365
Monday – Friday
8:00 am until 5:00 pm

Preferred Drug List

For a copy of the most recent preferred drug list, visit:
http://www.dhhr.wv.gov/bms/Pharmacy/Pages/pdl.aspx

State Maximum Allowable Cost (SMAC)

SMAC Review Form:
http://www.dhhr.wv.gov/bms/Pharmacy/Pages/smac.aspx
Please refer questions to Magellan at 1-800-763-7382 or e-mail to StateSMACProgram@magellanhealth.com

Migraine Prevention: Old and New Options

As the old saying goes, “an ounce of prevention is worth a pound of cure”. This holds true for some migraine sufferers as well. Some migraine triggers that can be controlled and possibly even avoided are: stress/anxiety, foods and food additives, alcohol consumption, caffeine consumption and changes in sleep patterns. For some migraine sufferers, the migraine may be due to uncontrollable factors such as: family history, aging, environmental factors, hormonal changes, etc. Patients with frequent or severe migraine headaches and those who cannot take or do not have an adequate response to acute treatment options are candidates for preventive treatment.

Some products have been used for migraine prevention for years. Beta blockers (metoprolol, propranolol, timolol, atenolol, etc.) have been commonly used for migraine prevention. Note that propranolol and timolol are the only beta blockers approved by the FDA for migraine prevention. The antiepileptic drugs, valproate and topiramate, are also approved for migraine prevention. Based on clinical evidence, 40 – 50% of patients receiving either valproate or topiramate achieve a ≥50% reduction in migraine frequency. For some patients, the side effects of these treatment options cannot be tolerated. Some antidepressants such as amitriptyline, venlafaxine and duloxetine have shown efficacy in preventing migraines but are not FDA approved.

Botox

Onabotulinumtoxin A (Botox), an acetylcholine release inhibitor and a neuromuscular blocking agent, is another FDA approved option for prevention of chronic migraine in adults. Botox is indicated for the prophylaxis of headaches in adult patients with chronic migraine of ≥15 days per month with headache lasting 4 hours a day or longer. The usual adult dosage of Botox is 155 units injected IM every 12 weeks. Botox was found to be statistically, significantly better than placebo in 2 multi-center, 24-week, 2 injection cycle, placebo-controlled double-blind clinical trials. The mean change from baseline in frequency of headache days per 28 days was -7.8 and -9.2 for Botox vs 6.4 and -6.9 for placebo. Botox has a boxed warning on the distant spread of toxin effect. More common adverse reactions include: overactive bladder, detrusor overactivity, chronic migraine, spasticity, dysphagia, neck pain, rhinitis and others.

CGRP Antagonists

CGRP is a potent vasodilator and pain-signaling neurotransmitter. It is widely distributed throughout the central and peripheral nervous systems. It is especially prevalent in the trigeminal ganglia. During a migraine attack, patients have elevated serum CGRP inhibitors. The FDA recently approved three calcitonin gene-related peptide (CGRP) antagonists (Aimovig, Ajovy and Emgality) for the prevention of migraine in adult patients. The mechanism of action of these CGRP antagonists is to bind to CGRP, preventing it from binding to its receptor.

The first CGRP antagonist to receive FDA approval was Aimovig (erenumab). The recommended dosage for Aimovig is 70 mg injected subcutaneously in the abdomen, thigh or upper arm once monthly. Some patients may benefit from a dosage of 140 mg once monthly. If a 140 mg dose is required, it is administered as two consecutive 70 mg injections.

The efficacy of Aimovig was evaluated in three randomized, double-blind, placebo-controlled studies. Study 1 and 2 included patients with episodic migraine (4 to 14 migraine days per month). Study 1 was a 6-month trial of 955 patients comparing Aimovig 70 mg, Aimovig 140 mg and placebo. The primary endpoint was the change from baseline in mean monthly migraine days (MMD) over months 4 to 6. MMD reduction was -3.2 for Aimovig 70 mg, -3.7 for Aimovig 140 mg and -1.8 for Placebo over months 4 to 6. A secondary endpoint was the percent of patients achieving a ≥ 50% reduction form baseline in MMDs. 43.3% of Aimovig 70 mg patients vs 50% of Aimovig 140 mg patients vs 26.6% of placebo patients achieved a ≥ 50% reduction in MMDs.

Study 2 was 3-month trial of 577 patients comparing only Aimovig 70 mg to placebo. At month 3, the change from baseline in MMD was -2.9 for Aimovig 70 mg and -1.8 for placebo. 39.7% of Aimovig 70 mg patients achieved a ≥ 50% reduction in MMDs compared to 29.5% for placebo.

Study 3 was a 3-month trial of 667 patients with chronic migraine, comparing Aimovig 70 mg, Aimovig 140 mg and placebo. The mean migraine frequency at baseline was 18 migraine days per month (MMD). At month 3, the change from baseline in MMD was -6.6 for Aimovig 70 mg, -6.6 for Aimovig 140 mg and -4.2 for placebo. Patients achieving ≥ 50% reduction in MMDs was 39.9% for Aimovig 70 mg, 41.2% for Aimovig 140 mg and 23.5% for placebo.

A second CGRP, Ajovy (fremanezumab), is administered as a 225 mg monthly SC injection or 675 mg (administered as 3 consecutive 225 mg injections) every 3 months. FDA approval was based on two 12-week, randomized, double-blind, placebo-controlled trials. Study 1 included 875 adults with a history < 15 days per month of episodic migraine. The primary endpoint of mean change in baseline of MMDs was -3.7 for Ajovy 225 mg, -3.4 for Ajovy 675 mg and -2.2 for placebo. The secondary endpoint of ≥ 50% MMD responders was 47.7% for Ajovy 225 mg, 44.4% for Ajovy 675 mg and 27.9% for placebo.

Study 2 was a 3-month trial in 1130 patients with chronic migraine, ≥ 15 headache days per month. The mean change from baseline in MMDs was -4.6 for Ajovy 225 mg, -4.3 for Ajovy 675 mg and -2.5 for placebo. 40.8% of Ajovy 225 mg patients achieved a ≥ 50% reduction in MMDs vs 37.6% for Ajovy 675 mg vs 18.1% for placebo.

The third CGRP, Emgality (galcanezumab), is administered as a loading dose of 240 mg (two consecutive 120 mg) SC injections followed by monthly doses of 120 mg. FDA approval of Emgality was based on three multicenter, randomized, double-blind, placebo-controlled studies comparing Emgality 120 mg vs placebo. Study 1 (858 patients) and Study 2 (915 patients) were 6-month studies in patients with episodic migraine while study 3 was a 3-month study in patients with chronic migraine. Change from baseline in MMD was -4.7 and -4.3 for Emgality Study 1 and 2 respectively vs -2.8 and -2.3 for placebo. Patients achieving ≥ 50% reduction in MMDs was 62% and 59% for Emgality Study 1 and 2 respectively vs 39% and 34% for placebo.

Study 3 included 1,113 patients with a history of chronic migraine defined as ≥ 15 headache days per month with 8 migraine days per month. Emgality 120 mg had mean change from baseline in MMDs of -4.8 vs -2.7 for placebo. Patients achieving > 50% reduction in MMD was 28% for Emgality vs for placebo 15%.

Adverse effects are similar for all three CGRP Antagonists. The most common adverse effects are: injection-site reactions such as pain and erythema and hypersensitivity reactions. At this time, there aren't any head-to-head studies comparing the efficacy of the CGRP Antagonists to each other or any other product used for the treatment of migraine prevention. The older products such as beta-blockers, anticonvulsants and antidepressants are generally the most cost-effective options for migraine prevention. While Botox and the CGRP Antagonists are more expensive options, they may be effective alternatives when other therapies have failed.

Upcoming PDL Changes

There are no PDL changes for this quarter.