From: bdroese=amgen.com@medical.amgen.com on behalf of Benjamin Droese
To: Ellen Flowers
Subject: Nevada Medicaid June 24th SSSB Meeting
Date: Monday, June 21, 2021 7:55:23 AM

Hi Ellen,

I hope you are doing well!

Can you please include the document attached (via hyperlink below) for the SSSB committee's consideration at the upcoming Calcitonin Gene Related Peptide (CGRP) inhibitors Therapeutic Class Overview on June 24th?

For convenience, additional information related to the Aimovig® (erenumab-aooe) prescribing information is included below.

Thank you!

Ben

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INDICATION

Aimovig® (erenumab-aooe) is indicated for the preventive treatment of migraine in adults.

IMPORTANT SAFETY INFORMATION

Contraindication: Aimovig® is contraindicated in patients with serious hypersensitivity to erenumab-aooe or to any of the excipients. Reactions have included anaphylaxis and angioedema.

Hypersensitivity Reactions: Hypersensitivity reactions, including rash, angioedema, and anaphylaxis, have been reported with Aimovig® in post marketing experience. Most reactions were not serious and occurred within hours of administration, although some occurred more than one week after administration. If a serious or severe reaction occurs, discontinue Aimovig® and initiate appropriate therapy.

Constipation with Serious Complications: Constipation with serious complications has been reported following the use of Aimovig® in the postmarketing setting. There were cases that required hospitalization, including cases where surgery was necessary. The onset of constipation was reported after the first dose in a majority of these cases, but patients also reported later on in treatment. Aimovig® was discontinued in most reported cases. Constipation was one of the most common (up to 3%) adverse reactions reported in clinical studies.

Monitor patients treated with Aimovig® for severe constipation and manage as clinically appropriate. Concurrent use of medications associated with decreased gastrointestinal motility may increase the risk for more severe constipation and the potential for constipation-related complications.

Hypertension: Development of hypertension and worsening of pre-existing hypertension have been reported following the use of Aimovig® in the postmarketing setting. Many of the patients had pre-existing hypertension or risk factors for hypertension. There were cases requiring pharmacological treatment and, in some cases, hospitalization. Hypertension may occur at any time during treatment but was most frequently reported within seven days of dose administration. In the majority of the cases, the onset or worsening of hypertension was reported after the first dose. Aimovig® was discontinued in many of the reported cases.

Monitor patients treated with Aimovig® for new-onset hypertension, or worsening of pre-existing hypertension, and consider whether discontinuation of Aimovig® is warranted if evaluation fails to establish an alternative etiology.

Adverse Reactions: The most common adverse reactions in clinical studies (≥ 3% of Aimovig®-treated patients and more often than placebo) were injection site reactions and constipation.

Please click here for Aimovig® Full Prescribing Information

I hope you find this information useful. However, if you prefer to no longer receive these types of informational e-mails from me, please reply and let me know.

Erenumab- HOPE- Aimovig Clinical Fact Sheet 2 pager_LB