THERAPEUTIC AREA BRIEFS

The brief summaries of unmet need and practice gaps provided herein were independently developed for informational purposes only and are not intended to be exhaustive or directive. The summaries should not be used as the primary resource for the development of a needs assessment, identification of practice gaps, or learning objectives for a proposed continuing medical education grant request.

Migraine (Neuroscience)

Migraine is a common disabling primary headache disorder. Many epidemiological studies have documented its high prevalence and socio-economic and personal impacts. In the Global Burden of Disease Study 2016, it was ranked as the sixth most prevalent disorder in the world. In the 2016 survey, migraine was ranked second globally in terms of years of life lived with disability, and was among the 10 most disabling disorders in each of 21 regions. In both males and females, migraine alone is third among people aged 15 to 49 years. [1, 2]

While preventive treatments are important in the management of migraine, no single treatment is effective for every patient, and often the improvement in frequency, severity, or duration of migraine attacks is minor. This is particularly problematic when accompanied with side effects which can lead to lack of adherence and discontinuation of treatment. Furthermore, vomiting and gastric stasis associated with migraine may interfere with treatment through delaying or reducing the absorption of medications. [3]

A high level of disability is associated with both episodic (patients < 15 monthly migraine days or monthly headache days) and chronic migraine (>15 monthly headache days where at least 8 are monthly migraine days), with disability increasing with increasing frequency of days with migraine. [4] Therefore, patients with chronic migraine have greater negative impact on daily activities, higher medical costs, greater healthcare resource utilization, reduced quality of life, and higher rates of comorbidities. In the 2016 GBD, medication overuse headache (MOH) was listed as a sequela of migraine and their burdens were added up resulting in higher ranking for migraine disability. [2,5,6] It is estimated that, in the U.S., insurance costs to treat migraine, including comorbid conditions, is $41 billion annually; 88% of chronic migraine patients have at least one comorbid condition. [7]

Calcitonin gene-related peptide (CGRP) is a vasodilator involved in the pathophysiology of migraine and is elevated during migraine attacks. Anti-CGRP monoclonal antibodies can target the CGRP ligand or the CGRP receptor, both leading to inhibition of downstream CGRP activity. [8]

A clinical difference between receptor vs ligand binding is not well established; however, complete elucidation of differences continues to be of scientific interest. Targeting the CGRP ligand appears to reduce levels of free CGRP, and is thought to prevent it from engaging with multiple CGRP receptors (including amylin and adrenomedullin), and further downstream signaling; targeting the CGRP receptor appears to prevent all peptides from binding to that one receptor, leaving free CGRP to engage other receptors. [9-11]

To reduce migraine disease burden, healthcare providers need to understand how to individualize existing approaches for the management of patients with migraine in order to maximize efficacy and minimize side effects. To keep pace with the rapid development of novel therapeutics, healthcare providers also require educational programs that present the rationale for their use, mechanisms of action, and emerging efficacy and safety profiles.

Unmet Needs and Practice Gaps

1. Healthcare providers may not be up to date on the latest approved preventive migraine pharmacological interventions and therefore may not be choosing the best therapy for their patients. HCPs could benefit from education that builds familiarity with newer medications and the proven efficacy, safety, and tolerability data of each in preventing migraines.

2. Healthcare providers can benefit from evidence-based education related to monoclonal antibody therapy and its relevance in the safe and effective use of new CGRP monoclonal antibodies (mAbs) for migraine prevention.

3. By increasing their understanding of the patient perspective and experience, Clinician competence can improve and HCPs may have greater confidence when providing individualized management to patients with migraine.

4. Healthcare providers can benefit from education that details the burden of migraine in patients from onset through recovery. Therefore, they may have a better understanding of patient's treatment goals and what they value in treatment.

5. Healthcare providers can benefit from education that highlights the barriers and challenges of currently available preventative migraine medications and therefore learn how to recognize a

variety of modifiable factors including medication overuse, lack of adherence and migraine chronification.

6. Healthcare providers can benefit from education emphasizing the risks, consequences, treatment and prevention of medication overuse headache.

7. Healthcare providers can benefit from understanding the array of symptoms associated with migraine and their impact on patient satisfaction with treatment.

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