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Botulinum neurotoxin for the treatment of migraine and other primary headache disorders

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Migraine is a chronic neurovascular disorder that afflicts 2% to 15% of the world's population. In the United States there are an estimated 28 million migraine sufferers, with women being affected three times as often as men [1]. It is characterized by severe headaches and is often associated with nausea, vomiting, and heightened sensitivity to sound and light at the peak of the attack. Migraine is considered to cause more disability than epilepsy, and severe migraine has been judged by the World Health Organization to be as disabling as quadriplegia, psychosis, and dementia [2].

Most sufferers are in their most socially active and productive years (25 to 55) [1]. Not only is migraine painful and disabling for the sufferer, but it exerts a significant economic burden on society. It causes 112 million bedridden days each year and costs $14 billion in reduced productivity and missed workdays [3]. The economic burden of migraine is comparable with that of diabetes [4] and higher than that of asthma [5].

Even among migraineurs who consult a physician, many are not satisfied with their therapy and report that prescribed medications are not always optimal. Triptan medications, the most effective therapy for acute migraine attacks, are only effective in improving the pain and associated migraine symptoms, such as photophobia and nausea, in up to two thirds of patients [6]. There is a significant need to develop more effective therapies for migraine prevention because 35% of migraineurs suffer from two to three severe attacks per month, whereas 25% suffer from more than four attacks per month [6]. Furthermore, more than 4% of the United States population suffers from chronic daily headache [7].

Patients with frequent, disabling, or refractory migraine should be considered for prophylactic treatment. Current United States guidelines recommend preventive therapy in one or more of the following situations: (1) frequent headaches; (2) recurring migraines that significantly interfere with daily routine; (3) failure of, a contraindication to, overuse of, or adverse events (AEs) with acute migraine therapies; (4) cost of acute and preventive therapies; (5) patient preference; and (6) the presence of uncommon migraine conditions, including hemiplegic migraine, basilar migraine, migraine with prolonged aura, or migrainous infraction [8]. Although numerous therapies are currently available for the prevention and treatment of migraine, most of these agents have significant side effects.

Commonly used agents for migraine prophylaxis include β-adrenergic blockers, calcium channel blockers, tricyclic antidepressants, and anticonvulsants (Table 1). Moderate to severe AEs are not uncommon with all available prophylactic medications. β-Blockers are known to produce a wide array of AEs, including drowsiness, fatigue, lethargy, sleep disorders, and depression. AEs typically associated with the calcium channel blockers include constipa-

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