

Final key questions and background

Treatment of chronic migraine and chronic tension-type headache

Background

Headaches are among the most common reasons for patient visits in primary care and neurology settings. Headache is considered primary when a disease or other medical condition does not cause the headache. Tension-type headache is the most common primary headache and accounts for 90% of all headaches; it is characterized by a dull, non-pulsatile, diffuse, band-like (or vice-like) pain of mild to moderate intensity in the head, scalp or neck. There is no clear cause of tension-type headaches even though it has been associated with muscle contraction and stress. Migraines are the second most frequently occurring primary headaches. Migraine headache is characterized by recurrent unilateral pulsatile headaches lasting 4- 72 hours; nausea, vomiting and sensitivity to light and sound are frequent co-existent symptoms. The two major subtypes are common migraine (without aura) and classic migraine (with aura or neurological symptoms). Migraine and tension headache attacks are classified as episodic if they occur less than 15 days per month. Headaches are considered chronic if they occur 15 or more days each month for at least 3 months or more than 180 days a year. Episodic migraine and tension-type headache may evolve to become chronic. Chronic tension-type headache (CTTH) and chronic migraine (CM) features differ but the two may coexist. CCTH and CM will be evaluated in this report. Both chronic tension-type headache and chronic migraine are associated with substantial impact on the physical, psychological and social well-being of patients as well as healthcare costs. They are a leading cause of disability and diminished quality of life.

Usual management of tension-type headache includes pharmacotherapy, psychological therapy and physical therapy. Migraine management generally focuses on pharmacological therapy. While abortive therapy for acute episodes is necessary for both CTTH and CM, the focus of management for CCTH and CM is on preventive treatments. Primary goals of preventive therapy are to reduce the number, severity and/or duration of acute episodes and reduce disability. Some of the treatments that are used in the acute setting are also employed for prevention/long term treatment. A variety of interventions may be used to manage chronic migraine and chronic tension-type headache. Interventions to be evaluated in this report include botulinum toxin injections, trigger point injections, transcranial magnetic stimulations, manipulation/manual therapy, acupuncture and massage. This report will focus on use of such interventions for the prevention of CTTH and CM.

OnabotulinumtoxinA (onaBoNT-A, Botox) is a type of botulinum toxin that is FDA approved for the prophylaxis of headaches in adults with chronic migraine (≥ 15 days per months with headache lasting ≥ 4 hours a day). It has been associated with reduction in the number chronic migraine headaches attacks.

Trigger point injections involve injection of local anesthetic or other injectate into trigger points which are muscle areas that are very irritable, show a band of tightness in the area of muscle itself, and, when pressed, produce a twitch within the affected muscle. Pain may not be confined to the affected muscle and may affect distant areas such as the head and neck, which is called referred pain. Trigger point injections may be done in conjunction with peripheral nerve blocks which involves injection of medication on or near nerves. Peripheral nerve blocks are not included in this review.

Transcranial magnetic stimulation involves use of a portable device that is held to the scalp and sends a series of brief magnetic pulses through the skin. FDA approval has been received for the Cerena Transcranial Magnetic Stimulator (TMS).

Manual therapies, including manipulation, involve passive movement of joints and soft tissues by hands or equipment to treat musculoskeletal and disability including headache and may be used by physiotherapists, chiropractors, osteopaths and others. Massage is often classified as a manual therapy and involves systematic and methodical manipulation of body tissues, including trigger points, usually with the hands.

Acupuncture involves the insertion of solid, filiform needles into the body (with or without manual or electrical stimulation) to directly or indirectly stimulate acupuncture points, including trigger points, and other tissues to promote health and treat organic or functional disorders.

Policy context:

Interventions for treatment of headaches include botulinum toxin injections, trigger point injections, transcranial magnetic stimulations, acupuncture, manipulation, manual therapy and massage. The topic is proposed to determine the safety, efficacy and value of interventions for treatment of migraines and other headache types. The topic was selected based on medium/high concerns for safety, efficacy and cost.

Key questions:

In adults with chronic migraine or chronic tension-type headache,

1. What is the evidence of the short- and long-term efficacy and effectiveness of botulinum toxin injection, trigger point injection, acupuncture, transcranial magnetic stimulation, manipulation/manual therapy and massage compared with standard alternative treatment options, placebo, sham, waitlist or no treatment?
2. What is the evidence regarding short- and long-term harms and complications of botulinum toxin injection, trigger point injection, acupuncture, transcranial magnetic stimulation, manipulation/manual therapy and massage compared with standard alternative treatment options, placebo, sham, waitlist or no treatment?
3. Is there evidence of differential efficacy, effectiveness, or safety of botulinum toxin injection, trigger point injection, acupuncture, transcranial magnetic stimulation, manipulation/manual therapy and massage compared with standard alternative treatment options, placebo sham,

waitlist or no treatment? Include consideration of age, sex, race, ethnicity, socioeconomic status, payer, and worker's compensation.

4. What is the evidence of cost-effectiveness of botulinum toxin injection, trigger point injection, acupuncture, transcranial magnetic stimulation, manipulation/manual therapy and massage compared with standard alternative treatment options, placebo, sham, waitlist or no treatment?

Proposed scope:

Population: Adults with chronic migraine (with or without aura) or chronic tension-type headache. Chronic headache is defined as 15 or more days each month for at least 3 months or more than 180 days a year.

Interventions: Botulinum toxin injection, trigger point injection, acupuncture, transcranial magnetic stimulation (TMS), manipulation/manual therapy, massage

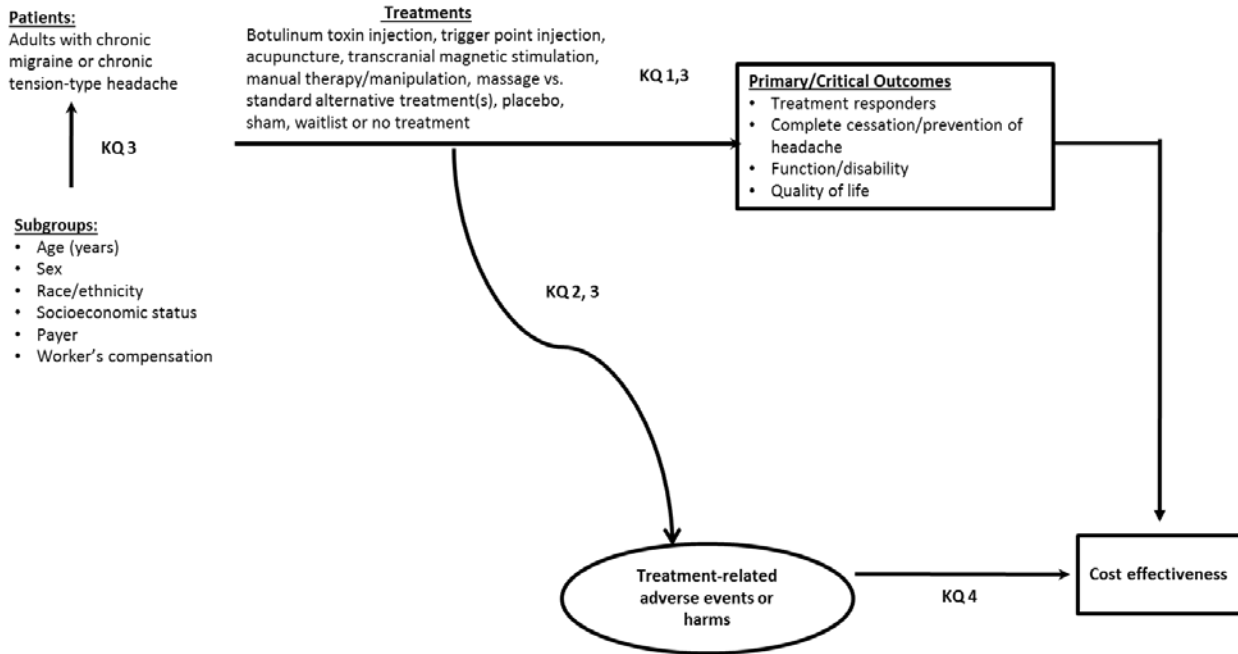
Comparators: Standard alternative treatment(s), sham, placebo, waitlist or no treatment

Outcomes: Primary/critical outcomes are 1) the proportion of treatment responders, 2) complete cessation/prevention of headache, 3) function/disability (based on validated outcomes measures), 4) treatment related adverse events/harms 5) quality of life. Economic outcomes are cost-effectiveness (e.g., cost per improved outcome), cost-utility (e.g., cost per quality adjusted life year (QALY), incremental cost effectiveness ratio (ICER) outcomes.

Studies: Studies must report at least one of the primary outcomes. Focus will be on studies with the least potential for bias such as high quality systematic reviews of randomized controlled trials and randomized controlled trials and full economic studies.

Timing: Focus will be on intermediate (>6 months) and long term (> 12months) for efficacy outcomes, particularly cessation/prevention; any time frame for harms.

Analytic Framework



Public comment and response

See **Draft key questions: Comment and response** published separately.