

DRAFT key questions and background

Treatment of chronic migraine and chronic tension-type headache

Public comments on the draft key questions will be accepted until 5 p.m. November 4, 2016.

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. The two major subtypes are common migraine (without aura) and classic migraine (with aura or neurological symptoms). Chronic tension-type headache and chronic migraine will be evaluated in this report. 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. 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. A variety of interventions may be used to treat or prevent 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.

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 insertion of a small needle 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. Usually local anesthetic is injected into the painful muscle and soft tissues. 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 placement of thin needles (with or without manual or electrical stimulation) along specific pathways, meridians, trigger points or pain points based on the condition being treated.

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.

Draft 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, 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, 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, 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, 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 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.

Analytic Framework

