GOVERNMENT ACCOUNTABILITY OFFICE

Request for Medicare Payment Advisory Commission (MedPAC) Nominations

AGENCY: U.S. Government Accountability Office (GAO).

ACTION: Request for letters of nomination and resumes.

SUMMARY: The Balanced Budget Act of 1997 established the Medicare Payment Advisory Commission (MedPAC) and gave the Comptroller General responsibility for appointing its members. GAO is now accepting nominations for MedPAC appointments that will be effective May 2020. Nominations should be sent to the email or mailing address listed below. Acknowledgement of submissions will be provided within a week of submission.

DATES: Letters of nomination and resumes should be submitted no later than February 14, 2020, to ensure adequate opportunity for review and consideration of nominees prior to appointment.

ADDRESSES: Submit letters of nomination and resumes by either of the following methods: Email: *MedPACappointments@gao.gov* or Mail: U.S. GAO, Attn: MedPAC Appointments, 441 G Street NW, Washington, DC 20548.

FOR FURTHER INFORMATION CONTACT: Gregory Giusto at (202) 512–8268 or *giustog@gao.gov* if you do not receive an acknowledgement or need additional information. For general information, contact GAO's Office of Public Affairs, (202) 512–4800.

Authority: 42 U.S.C. 1395b–6.

Gene L. Dodaro,

Comptroller General of the United States.

[FR Doc. 2020–00521 Filed 1–14–20; 8:45 am]

BILLING CODE 1610–02–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Supplemental Evidence and Data Request on Treatments for Acute Episodic Migraine

AGENCY: Agency for Healthcare Research and Quality (AHRQ), HHS.

ACTION: Request for supplemental evidence and data submissions.

SUMMARY: The Agency for Healthcare Research and Quality (AHRQ) is seeking scientific information submissions from the public. Scientific information is being solicited to inform our review on *Treatments for Acute Episodic Migraine,* which is currently being conducted by the AHRQ's Evidence-based Practice Centers (EPC) Program. Access to published and unpublished pertinent scientific information will improve the quality of this review.

DATES: *Submission Deadline* on or before 30 days after date of publication in **Federal Register**.

ADDRESSES:

Email submissions: epc@ahrq.hhs.gov.

Print submissions:

Mailing Address: Center for Evidence and Practice Improvement, Agency for Healthcare Research and Quality, ATTN: EPC SEADs Coordinator, 5600 Fishers Lane, Mail Stop 06E53A, Rockville, MD 20857.

Shipping Address (FedEx, UPS, etc.): Center for Evidence and Practice Improvement, Agency for Healthcare Research and Quality, ATTN: EPC SEADs Coordinator, 5600 Fishers Lane, Mail Stop 06E77D, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Jenae Benns, Telephone: 301–427–1496 or Email: *epc@ahrq.hhs.gov.*

SUPPLEMENTARY INFORMATION: The Agency for Healthcare Research and Quality has commissioned the Evidence-based Practice Centers (EPC) Program to complete a review of the evidence for Treatments for Acute Episodic Migraine. AHRQ is conducting this systematic review pursuant to Section 902(a) of the Public Health Service Act, 42 U.S.C. 299a(a).

The EPC Program is dedicated to identifying as many studies as possible that are relevant to the questions for each of its reviews. In order to do so, we are supplementing the usual manual and electronic database searches of the literature by requesting information from the public (*e.g.,* details of studies conducted). We are looking for studies that report on *Treatments for Acute Episodic Migraine,* including those that describe adverse events. The entire research protocol is available online at: *https://effectivehealthcare.ahrq.gov/products/migraine-treatments/protocol.*

This is to notify the public that the EPC Program would find the following information on *Treatments for Acute Episodic Migraine* helpful:

- A list of completed studies that your organization has sponsored for this indication. In the list, please *indicate whether results are available on ClinicalTrials.gov along with the ClinicalTrials.gov trial number.*
- *For completed studies that do not have results on ClinicalTrials.gov,* a summary, including the following elements: Study number, study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, primary and secondary outcomes, baseline characteristics, number of patients screened/eligible/enrolled/lost to follow-up/withdrawn/analyzed, effectiveness/efficacy, and safety results.
- *A list of ongoing studies that your organization has sponsored for this indication.* In the list, please provide the *ClinicalTrials.gov* trial number or, if the trial is not registered, the protocol for the study including a study number, the study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, and primary and secondary outcomes.
- Description of whether the above studies constitute *ALL Phase II and above clinical trials* sponsored by your organization for this indication and an index outlining the relevant information in each submitted file.

Your contribution is very beneficial to the Program. Materials submitted must be publicly available or able to be made public. Materials that are considered confidential; marketing materials; study types not included in the review; or information on indications not included in the review cannot be used by the EPC Program. This is a voluntary request for information, and all costs for complying with this request must be borne by the submitter.

The draft of this review will be posted on AHRQ's EPC Program website and available for public comment for a period of 4 weeks. If you would like to be notified when the draft is posted, please sign up for the email list at: *https://www.effectivehealthcare.ahrq.gov/email-updates.*

The systematic review will answer the following questions. This information is provided as background. AHRQ is not requesting that the public provide answers to these questions.

Key Questions (KQ)

For patients with acute episodic migraine.

KQ 1. Opioid Therapy

KQ1a. What is the comparative effectiveness of opioid therapy versus: (1) Nonopioid pharmacologic therapy (*e.g.,* acetaminophen, nonsteroidal anti-inflammatory drugs [NSAIDs], triptans, ergots alkaloids, combination

analgesics, muscle relaxants, anti-nausea medications, and marijuana/cannabis) or (2) nonpharmacologic therapy (*e.g.,* exercise, cognitive behavioral therapy, acupuncture, biofeedback, neuromodulatory devices) for outcomes related to pain, function, pain relief satisfaction, and quality of life and after follow-up at the following intervals: <1 Day; 1 day to <1 week; 1 week to <2 weeks; 2 weeks to 4 weeks?

KQ1b. How does effectiveness of opioid therapy vary depending on: (1) Patient demographics (*e.g.* age, race, ethnicity, gender, socioeconomic status (SES)); (2) patient medical comorbidities (previous opioid use, body mass index (BMI)); (3) dose of opioids; (4) duration of opioid therapy, including number of opioid prescription refills and quantity of pills used?

KQ1c. What are the harms of opioid therapy versus nonopioid pharmacologic therapy, or nonpharmacologic therapy with respect to: (1) Misuse, opioid use disorder, and related outcomes; (2) overdose; (3) medication overuse headache (MOH), (4) other harms including gastrointestinal-related harms, falls, fractures, motor vehicle accidents, endocrinological harms, infections, cardiovascular events, cognitive harms, and psychological harms (*e.g.,* depression)?

KQ1d. How do harms vary depending on: (1) Patient demographics (*e.g.,* age, gender); (2) patient medical comorbidities; (3) the dose of opioid used; (4) the duration of opioid therapy?

KQ1e. What are the effects of prescribing opioid therapy versus not prescribing opioid therapy for acute episodic migraine pain on (1) short-term (<3 months) continued need for prescription pain relief, such as need for opioid refills, and (2) long-term opioid use (3 months or greater)?

KQ1f. For patients with acute episodic migraine being considered for opioid therapy, what is the accuracy of instruments for predicting risk of opioid misuse, opioid use disorder, or overdose?

KQ1g. For patients with acute episodic migraine being considered for opioid therapy, what is the effectiveness of instruments for predicting risk of opioid misuse, opioid use disorder, or overdose?

KQ1h. For patients with acute episodic migraine being considered for opioid therapy, what is the effect of the following risk mitigation strategies on the decision to prescribe opioids: (1) Existing opioid management plans; (2) patient education; (3) clinician and patient values and preferences related to opioids; (4) urine drug screening; (5) use of prescription drug monitoring program data; (6) availability of close follow-up?

KQ 2. Nonopioid Pharmacologic Therapy

KQ2a. What is the comparative effectiveness of nonopioid pharmacologic therapy (*e.g.,* acetaminophen, nonsteroidal anti-inflammatory drugs [NSAIDs], triptans, ergots alkaloids, combination analgesics, muscle relaxants, anti-nausea medications, and marijuana/cannabis) versus: (1) Other nonopioid pharmacologic treatments, such as those in a different medication class; or (2) nonpharmacologic therapy for outcomes related to pain, function, pain relief satisfaction, and quality of life after follow-up at the following intervals: <1 Day; 1 day to <1 week; 1 week to <2 weeks; 2 weeks to 4 weeks?

KQ2b. How does effectiveness of nonopioid pharmacologic therapy vary depending on: (1) Patient demographics (*e.g.* age, race, ethnicity, gender); (2) patient medical comorbidities; (3) the type of nonopioid medication; (4) dose of medication; (5) duration of treatment?

KQ2c. What are the harms of nonopioid pharmacologic therapy versus other nonopioid pharmacologic therapy, or nonpharmacologic therapy with respect to: (1) Misuse, (2) overdose; (3) medication overuse headache (MOH), (4) other harms including gastrointestinal-related harms, cardiovascular-related harms, kidney-related harms, falls, fractures, motor vehicle accidents, endocrinological harms, infections, cognitive harms, and psychological harms (*e.g.,* depression)?

KQ2d. How do harms vary depending on: (1) Patient demographics (*e.g.* age, gender); (2) patient medical comorbidities; (3) the type of nonopioid medication; (4) dose of medication; (5) the duration of therapy?

KQ 3. Nonpharmacologic Therapy

KQ3a. What is the comparative effectiveness of nonpharmacologic therapy versus sham treatment, waitlist, usual care, attention control, and no treatment after follow-up at the following intervals: <1 Day; 1 day to <1 week; 1 week to <2 weeks; 2 weeks to 4 weeks?

KQ3b. What is the comparative effectiveness of nonpharmacologic treatments (*e.g.* exercise, cognitive behavioral therapy, acupuncture, biofeedback, neuromodulatory devices) for outcomes related to pain, function, pain relief satisfaction, and quality of life?

KQ3c. How does effectiveness of nonpharmacologic therapy vary depending on: (1) Patient demographics (*e.g.* age, gender); (2) patient medical comorbidities?

KQ3d. How do harms vary depending on: (1) Patient demographics (*e.g.,* age, gender); (2) patient medical comorbidities; (3) the type of treatment used; (4) the frequency of therapy; (5) the duration of therapy?

PICOTS (POPULATIONS, INTERVENTIONS, COMPARATORS, OUTCOMES, TIMING, SETTINGS)

PICOTS elements	Inclusion criteria	Exclusion criteria
Population	• Patients with acute episodic migraine seeking abortive treatment. • Adults 18 years and older ..... * Special populations: ○ General adult. ○ Older populations >65 years. ○ Patients with history of substance use disorder. ○ Patients currently under treatment for opioid use disorder with opioid agonist therapy or naltrexone. ○ Patients with a history of mental illness. ○ Patients with history of overdose. ○ Pregnant/breastfeeding women. ○ Patients with comorbidities (*e.g.,* kidney disease, sleep disordered breathing).	• Animals. • Children (age <18 years).

PICOTS (POPULATIONS, INTERVENTIONS, COMPARATORS, OUTCOMES, TIMING, SETTINGS)—Continued

PICOTS elements	Inclusion criteria	Exclusion criteria
Interventions	KQ 1 a–e: Any systemic opioid abortive therapy, include: • Codeine. • Fentanyl (Actiq, Duragesic, Fentora, Abstral, Onsolis). • Hydrocodone (Hysingla, Zohydro ER). • Hydrocodone/acetaminophen (Lorcet, Lortab, Norco, Vicodin). • Hydromorphone (Dilaudid, Exalgo). • Meperidine (Demerol). • Methadone (Dolophine, Methadose). • Morphine (Kadian, MS Contin, Morphabond). • Oxycodone (OxyContin, Oxaydo). • Oxycodone and acetaminophen (Percocet, Roxicet). • Oxycodone and naloxone. • And other agonists, partial agonists and mixed mechanism opioids. KQ 1 f–g: Instruments and genetic/metabolic tests for predicting risk of misuse, opioid use disorder, and overdose. KQ 1 h: Risk mitigation strategies, including: • Existing opioid management plans. • Patient education. • Clinician and patient values and preferences related to opioids. • Urine drug screening. • Use of prescription drug monitoring program data. • Availability of close follow-up. • And others. KQ 2: Any oral, injection, infusion, topical nonopioid abortive drug, including: • Acetaminophen. • Nonsteroidal anti-inflammatory drugs [NSAIDs] (if compared against active treatment). • Triptans (if compared against active treatment). • Ergots alkaloids. • Combination analgesics. • Muscle relaxants. • Anti-nausea medications. • Marijuana/cannabis. • And others. KQ 3: Any non-invasive nonpharmacologic abortive therapy, including: • Exercise. • Cognitive behavioral therapy. • Acupuncture. • And others.	For all KQs, exclude Invasive treatments, and preventive (prophylactic) treatment. For KQ2, exclude NSAIDs vs placebo and triptans vs placebo.
Comparators	KQ 1: a–e. Usual care, another opioid therapy, nonopioid pharmacologic therapy, nonpharmacologic therapy. KQ 1 f. Reference standard for misuse, opioid use disorder, or overdose; or other benchmarks. KQ g–h. Usual care. KQ 2: Another nonopioid pharmacologic therapy, nonpharmacologic therapy. KQ3: Sham treatment, waitlist, usual care, attention control, and no treatment, another non-invasive nonpharmacologic therapy.	None.
Outcomes	KQ 1. Opioid Therapy: KQ 1a–e. Pain, function, pain relief satisfaction and quality of life, harms/adverse events (including withdrawal, risk of misuse, opioid, OUD, overdose, MOH). KQ 1f. Measures of diagnostic accuracy. KQ 1g–h. Misuse, opioid use disorder, overdose and other harms. KQ 2. Non-Opioid Therapy: Pain, function, pain relief satisfaction, quality of life, and quality of life, harms/adverse events. KQ 3: Non-invasive non-pharm Therapy: Pain, function, pain relief satisfaction, quality of life and quality of life, harms, adverse events.	None.

PICOTS (POPULATIONS, INTERVENTIONS, COMPARATORS, OUTCOMES, TIMING, SETTINGS)—Continued

PICOTS elements	Inclusion criteria	Exclusion criteria
Timing	At the following intervals: <1 Day; 1 day to <1 week; 1 week to <2 weeks; 2 weeks to 4 weeks.	None.
Settings	ER, physician's office, hospital	None.
Study design	• Original studies: ○ RCTs. ○ Comparative observational studies. • Any sample size. • Relevant systematic reviews, or meta-analyses (used for identifying additional studies)	In vitro studies, non-original data (*e.g.,* narrative reviews, editorials, letters, or erratum), single-arm observational studies, case series, qualitative studies, cost-benefit analysis, cross-sectional (*i.e.,* non-longitudinal) studies, before-after studies, survey.
Publications	Studies published in English only	Foreign language studies.

Abbreviations: RCT = randomized controlled trial.

Dated: January 9, 2020.

Virginia L. Mackay-Smith,

Associate Director, Office of the Director, AHRQ.

[FR Doc. 2020–00488 Filed 1–14–20; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Docket No. HHS–OS–2019–0015]

Solicitation for Public Comments on Questions From the National Clinical Care Commission

AGENCY: Office of Disease Prevention and Health Promotion, Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Request for public comment.

SUMMARY: The National Clinical Care Commission (the Commission) solicits public comments on a set of questions concerning the context, policies, effectiveness, promising practices, and limitations and gaps related to prevention and treatment of diabetes and its complications. The Commission is charged to evaluate and make recommendations to the Secretary of Health and Human Services (HHS) and Congress regarding improvements to the coordination and leveraging of federal programs related to awareness and clinical care for diabetes and its complications. The set of questions is available in the **SUPPLEMENTARY INFORMATION** section, below.

DATES: Electronic or written/paper comments will be accepted through midnight Eastern Standard Time (EST) February 3, 2020.

ADDRESSES: Public comments can be submitted in the following ways:

• Electronic submissions can be filed on the online docket at *http://www.regulations.gov* by following the ''*Instructions for Public Comments*'' section, below. Evidence and information supporting your comments can be submitted as attachments. Comments submitted electronically, including supporting attachments, will be posted to the docket unchanged. Please provide your contact information or organization name on the web-based form for potential follow up by the Commission.

• If you prefer to comment on paper, mail your comments to the following address: *Public Commentary, National Clinical Care Commission,* 1101 Wootton Parkway, Suite 420, Rockville, MD 20852. For mailed submissions, the Office of Disease Prevention and Health Promotion will post your comments, as well as any attachments, to *http://www.regulations.gov.*

Instructions for Public Comments: All electronic submissions must be submitted in the Docket ID HHS–OS–2019–0015 for ''Solicitation for Public Comments on Questions from the National Clinical Care Commission.'' For access to the docket to provide and/or read all comments received, go to *https://www.regulations.gov* and insert the docket ID HHS–OS–2019–0015 into the search box and follow the prompts.

Comments are encouraged from the public and will be accepted through February 3, 2020. The *https://www.regulations.gov* electronic filing system will accept electronic comments until midnight Eastern Standard Time at the end of February 3, 2020. Comments received by mail/courier will be considered if they are postmarked or the delivery service acceptance receipt date is on or before that date. Written comments via mail will be uploaded into *https://www.regulations.gov* and are under the same limitations as for those directly submitted electronically into *https://www.regulations.gov:* 5,000-character limit for text box, and maximum number (10) of attached files and maximum size (10 MB) of each attached file.

FOR FURTHER INFORMATION CONTACT: Linda Harris, Designated Federal Officer, National Clinical Care Commission, U.S. Department of Health and Human Services, Office of the Assistant Secretary for Health, Office of Disease Prevention and Health Promotion, 1101 Wootton Parkway, Suite 420, Rockville, MD 20852. Email: *linda.harris@hhs.gov.*

SUPPLEMENTARY INFORMATION: The National Clinical Care Commission Act (Pub. L. 115–80) requires the HHS Secretary to establish the National Clinical Care Commission. The Commission consists of representatives of specific federal agencies and non-federal individuals and entities who represent diverse disciplines and views. The Commission will evaluate and make recommendations to the HHS Secretary and Congress regarding improvements to the coordination and leveraging of federal programs related to awareness and clinical care for diabetes and its complications.

The Commission invites members of the public to comment on any issues or concerns they believe are relevant or appropriate to the Commission's evaluation of federal programs. Specifically, the Commission requests public comment on the following questions:

1. *Context:* What social, economic, and/or environmental factors have the greatest impact on health care in general—and also on prevention (Type 2) and/or management of diabetes (both Type 1 and Type 2)? What can be done by the federal government to address those social/economic/environmental factors?

2. *Policies:* What policies should the federal government implement to improve diabetes prevention and/or management? What is the evidence to support those?